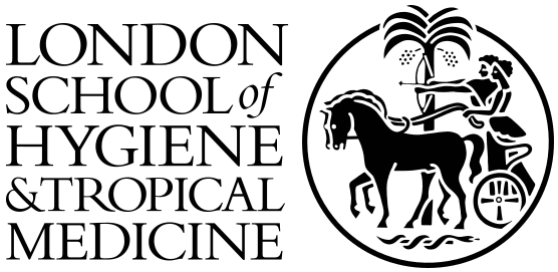

A Social Constructivist Analysis of China's Policy Responses to Substandard and Falsified Medicines (1978-2021)

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Declaration

I, Jingying Xu, confirm that the work presented in this thesis is my own.

Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed

31st March 2022

No problem can be solved from the same level of consciousness that created it.

—— Albert Einstein

Abstract

This thesis examines China's shifting policy responses to substandard and falsified (SF) medicines, since the economic reform in 1978. To date, most research on national and international policy responses to SF medicines have been concerned with generating scientific data, technological capabilities, regulatory structures and competencies, and coordination amongst bureaucratic agencies. While the importance of these material factors is firmly acknowledged, the social construction of the SF medicines issue also influences policy responses. Drawing on framing theory, this research therefore analyses the dual influence of both material and ideational factors shaping Chinese policy responses to SF medicines over time. Given China's ascendance in the global pharmaceutical sector during this period and increasing prominence in global health governance, a fuller understanding of the factors influencing how the country has responded to SF medicines has global relevance.

This research argues that SF medicines are not only a problem requiring technical solutions, but also an inherently political concern involving complex and contested policy ideas and objectives. It conceptualises China's policy responses to SF medicines as a contested and evolving landscape, defined by the interrelationships of ideas – embodied in dominant frames – of how the problem is perceived and should be responded to. Based on an extensive review of primary and secondary documentary sources, and seventy in-depth interviews with a wide array of key informants, this research reveals that China's policy responses to SF medicines have been shaped by three core policy frames over four decades: economism, health and well-being, and security.

This analysis highlights that framing of SF medicines can have multiple effects on policy responses, including changing regulatory frameworks, privileging certain interests over others, legitimising certain policy actions, and elevating the issue higher or lower on the policy agenda. Understanding the ascendance and descendance of policy frames advances our knowledge of the changing dynamics in issue perception, priority setting and policy action in Chinese responses to

SF medicines. Coexistence of frames can lead to competing policy objectives which undermine effective policy responses. However, cooperation of frames can help align policy objectives and elevate the priority level of the issue. Indeed, this occurred when the security frame acted as a "meta-frame" after 2012, and emerged as a potential bridge for enhancing synergies and coordinated policy response centred on improving medicine quality. These findings provide important insights to strengthen global policy responses to SF medicines, and China's expanding role in global health governance.

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My eleven-year journey to achieve my PhD, has been an outward journey of intellectual pursuit and an inward journey of mental and spiritual transformation. This journey would not have been accomplished without the love, encouragement, and generous support from many individuals.

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Lastly, I want to give special thanks to "me" – for my strength and persistence in going through challenges in both research and personal life over eleven years, but never stopping learning and growing. I am grateful for every past obstacle that has helped shape the person I am today.

I dedicate this PhD thesis to my parents and my unique path of growth in life.

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List of Abbreviations

AmCham	American Chamber of Commerce in China
AMR	Antimicrobial Resistance
APIs	Active Pharmaceutical Ingredients
CCCMHPIE	China Chamber of Commerce of Import & Export of Medicines and Health Products
CCP	Chinese Communist Party
CFDA	China Food and Drug Administration
CNKI	China National Knowledge Infrastructure
CNSC	Central National Security Commission
COVID-19	Coronavirus Disease
EU	European Union
EUCham	European Union Chamber of Commerce in China
FIP	International Pharmaceutical Federation
GATT	General Agreement on Tariffs and Trade
GHG	Global Health Governance
GMP	Good Manufacturing Practice
ICH	International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IMPACT	International Medical Products Anti-Counterfeiting Task Force
INTERPOL	International Criminal Police Organization
IPR	Intellectual Property Rights
JCCT	U.S.-China Joint Commission on Commerce and Trade
LMIC	Low- and Middle-Income Countries
LSG	Leading Small Group
MIIT	Ministry of Industry and Information Technology

MPCs	Multinational Pharmaceutical Companies
NDRC	National Development and Reform Commission
NGOs	Non-governmental Organisations
NMPA	National Medical Products Administration
NTS	Non-traditional Security
OECD	Organisation for Economic Co-operation and Development
PhRMA	Pharmaceutical Research and Manufacturers of America
QBPC	Quality Brands Protection Committee
QCE	Quality Consistency Evaluation for Generic Medicines
R&D	Research and Development
RDPAC	R&D-based Pharmaceutical Association Committee
SARS	Severe Acute Respiratory Syndrome
SMRA	State Administration of Market Regulation
SDA	State Drug Administration
SF	Substandard and Falsified
SFDA	State Food and Drug Administration
SGPA	State General Pharmaceutical Administration
SIPO	State Intellectual Property Office
SPA	State Pharmaceutical Administration
SSFFC	Substandard/spurious/falsely-labelled/falsified/counterfeit
UNDP	United Nations Development Programme
UNODC	United Nations Office on Drugs and Crime
USFDA	United States Food and Drug Administration
WHO	World Health Organisation
WHPA	World Health Professions Alliance
WTO	World Trade Organisation

Chapter 1 Introduction

1.1 Statement of the problem

Today, China is one of the world's largest suppliers of medical products including active pharmaceutical ingredients (APIs), medicines and vaccines. In their book *China Rx: Exposing the Risks of America's Dependence on China for Medicine,* Gibson and Singh (2018: 9) state that, "[w]ithout question, if China stopped exporting ingredients, within months the world's pharmacies would be pretty empty". During the COVID-19 pandemic, China provided free vaccines to more than 80 developing countries in urgent need and exported vaccines to 43 countries (Xi, 2021). In spite of China's growing importance in the global pharmaceutical supply chain, the quality and safety of China's medicines remains a global concern. The problem of substandard and falsified (SF) medicines has been a longstanding challenge for Chinese policy-makers and global health communities, but has received limited research attention to date.

In any health system, safe, effective, quality assured, and affordable medicines are essential for achieving positive and equitable health outcomes (WHO, 1988; US Pharmacopeia, 2020). SF medicines are a pressing global health problem affecting patients, health systems, the formal pharmaceutical industry, and can cause wider social, economic, environmental, and political consequences. Indeed, they remain a serious impediment to achieving global health goals such as Universal Health Coverage and the Sustainable Development Goals (Pisani, 2019; Pisani *et al*., 2019; Ravinetto & Dujardin, 2019; Schäfermann *et al*., 2020; Hasdina *et al*., 2021). SF medicines can be applied to APIs, branded and generic medicines. Substandard medicines result from errors, corruption, negligence or poor practice in manufacturing, procurement, regulation, transportation, and/or storage; whereas falsified medicines result from criminal fraud (Newton & Bond, 2019).

SF medicines are a multi-faceted problem that requires a coordinated response from a wide variety of actors on both the supply (manufacturers, distributors, wholesalers,

pharmacies/outlets, online businesses) and demand side (patients, health professionals, national government procurement agencies); as well as the regulatory and enforcement bodies (medicine approval agencies, law enforcement agencies such as the police and customs, and international organisations). With China's objective to become a leading global pharmaceutical manufacturing power and a responsible leader in global health governance, ensuring medicine quality and safety is critical.

Although we recognise the importance of scientific data, technological capability, regulatory competency, and legislation in informing policy responses to SF medicines, less is known about the complexity of policy arenas in shaping the response of national governments. In combating SF medicines, policy-makers often do not perceive material factors in isolation, but rather as interconnected elements in a larger social and political ecosystem. The fight against SF medicines cannot exist in isolation without an understanding of how the problem is perceived and its consequent effects. This research advances knowledge through developing a more comprehensive and systematic way to analyse the social construction of SF medicines shaping policy perception and responses, and thus increases our understanding of China's policy responses to SF medicines over the past four decades.

1.2 Research background

1.2.1 SF medicines as a global public health problem

Economic globalisation has influenced patterns of pharmaceutical production, supply, regulation and consumption worldwide. Alongside the fast-growing generic industry that emerged after the passage of the 1984 Hatch–Waxman Act, the problem of SF medicines has also grown rapidly in the past four decades. SF medicines may include products with the correct ingredients, wrong ingredients, without or insufficient active ingredients, and/or false packaging. They can enter into the pharmaceutical supply chain at several different stages and in various forms (Hopkins *et al*., 2003; Bate, 2008; Satchwell, 2004; Liang, 2006; Gautam *et al*., 2009; Morris & Stevens, 2006;

Harris *et al*., 2009; Bate, 2012). As the former United States Food and Drug Administration (USFDA) Commissioner Margaret Hamburg described, "globalisation has redefined the field of medical products regulation by adding layers of complexity to the supply chain and creating opportunities for the potential contamination and/or intentional adulteration of the raw ingredients and finished products that pass through its links" (Hamburg, 2015: 1).

Box 1- 1 Terminology

There are no agreed definitions on how the terms "medicine", "drug" and "pharmaceutical" should be used under what circumstances. For example, in Rägo and Santoso's seminal text, *Drug Regulation: History, Present and Future*, drug and medicine are used interchangeably (Rägo & Santoso, 2008). The USFDA uses the term "drug". In *Oxford Advanced Learner's Dictionary* (https://www.oxfordlearnersdictionaries.com), three terms are used interchangeably:

- Drug: a substance used as a medicine or used in a medicine
- Pharmaceutical (noun): a medical drug
- Pharmaceutical (adjective): connected with making and selling medical drugs
- Medicine: a substance that you take in order to cure an illness, especially a liquid that you drink or swallow

This research uses the term "medicine" wherever possible, because it encompasses both Western medicines (mostly chemical substances in nature) and Chinese herbal medicines – which are two major forms of treatment for health issues in China. However, this research is not restricted to using these terms. For example, although the term "drug" can be confused with illegal substance "drug", it is used in official contexts by institutions, policy documents or legislations . When referring to industry, the adjective "pharmaceutical" is used, as it refers to the acts of making and selling medicines.

It is worth noting that the term "medical products", as defined by the World Health Organisation (WHO), is a broad term that covers medicines, vaccines or in vitro diagnostic and medical devices (WHO, 2017b). This research focuses on medicines – while covering some major SF vaccine incidents, the analysis does not involve medical devices. APIs and excipients[1] are referred to separately as they are not strictly situated within the definition of "medical products".

[1] According to the US Pharmacopoeia's definition, pharmaceutical excipients are substances other than the APIs that are intentionally included in an approved drug delivery system or a finished drug product (US Pharmacopeia, 2016).

While the global medicines supply chain enables broader patient access to medicines, the system is increasingly threatened by vulnerabilities and disruptions (Satchwell, 2004; Finlay, 2011; El-Jardali *et al*., 2015). Evidence suggests that the impact on human health from falsified medicines is now similar in high, middle- and low-income countries (Rahman et al., 2018). All types of medications can be targeted for falsification, with anti-malarias and antibiotics among the most commonly reported SF products (Rahman *et al*., 2018; Ozawa *et al*., 2018; WHO, 2018). After China and India joined the global economy in the 1980s and became key players in the global pharmaceutical supply chain, several major studies have implicated China and India as major sources of SF medicines (UNODC, 2010; Attaran *et al*., 2012; Bate, 2012; Antignac *et al*., 2017; Zaman, 2018). High-income countries have increasingly imported APIs from countries such as China and India, where manufacturing standards and regulatory capacities are weaker (Morris & Stevens, 2006; Harris *et al*., 2009; Gren, 2009). In 2008, adulterated heparin, as an active ingredient sold by Chinese supplier Changzhou SPL to Baxter Healthcare Corporation in the US, caused 81 deaths (Zaman, 2018; Gibson & Singh, 2018). The heparin case reveals that even the best-regulated markets in the world can be penetrated with SF ingredients, able to pass sophisticated test (Bate, 2012). Eban's book *Bottle of Lies: The Inside Story of the Generic Drug Boom* investigated how the leading Indian generic medicine manufacturer Ranbaxy falsified data and deceived national regulators, including the USFDA, into approving substandard medicines, with "more than 200 products in more than 40 countries had elements of data that were fabricated to support business needs" (Eban, 2019: 116).

A globalised pharmaceutical supply chain has added complexity for medicine regulation, which over the past four decades has not been able to keep pace with the expansion of the global pharmaceutical supply chain. In particular, national medicine regulation has become increasingly challenging in this globalised environment. In many cases, it is difficult for patients, doctors and sometimes even regulators to determine the true origin of a medicine's production (Gibson & Singh, 2018; Eban, 2019). Variations in quality might be due to different business regulations rather than universal public health standards. For example, a Chinese API manufacturer could sell

different qualities of APIs (e.g., different levels of impurities) to different markets according to their regulatory requirements and medicine standards (Interview, 09HZ280218; Interview, 16TEL120318). The inspection of foreign manufacturing facilities might prioritise the risk of international conflict rather than the needs of public health. For instance, Eban documented how the USFDA inspection of Indian manufacturers were compromised by diplomatic considerations. Hence, inspections often could not be conducted unannounced, which prevented a candid assessment of a plant's true condition (Eban, 2019). With the exponential growth of on-line purchasing of medicines, those engaged in the manufacture, distribution and supply of SF medicines have gained easy access to a global market (Liu & Lundin, 2016).

The COVID-19 pandemic has further exacerbated the threat posed by SF medicines to the global pharmaceutical supply chain, because of the imbalance between high demand and supply shortages. The University of Oxford Medicine Quality Research Group has published monthly reports on the global impact of SF medical products since 2020. A report in November 2020 revealed that SF COVID-19 medical products had reached more than 60 countries (Van Assche *et al*., 2020), while a report in March 2021 stated that diverted and SF COVID-19 vaccines were already found in 32 countries (Van Assche *et al*., 2021). As such, the WHO and the International Criminal Police Organization (Interpol) have issued repeated warnings of increased selling of falsified COVID-19 vaccines by organised criminal groups on the dark web and other unregistered sources (Interpol, 2020, 2021a, 2021b; News China, 2021). As Newton and Bond (2020) commented, "The world risks a parallel pandemic of substandard and falsified products".

There have been several high-level calls for improving access to affordable and quality-assured medicines since the international consensus was made on definition in 2017 (more on definition in the next sub-section). During a side event of the World Health Assembly in May 2018, the US Pharmacopeia Convention (a non-profit organisation that produces an annual compendium of drug information for the US) and partners launched a campaign entitled *Access to Medicines We Can Trust*, which focused on access to quality medicines. While, at a side event of the 2018 United Nations General Assembly entitled *The fight for quality medicines in Africa* –

stopping falsified, substandard medicines, five African leaders spoke on SF medicines and the importance of medicine quality. In 2019, *The Oxford Statement* was published following the first international conference on *Medicine Quality and Public Health* in September 2018, and called for a shift in global attention, from "access to medicines", to "access to quality-assured medicines" (Newton & Bond, 2019). The 2019 UN General Assembly also made its first political declaration on universal health coverage, which highlighted the need for access to safe, quality, efficacious and affordable medicines and vaccines, without incurring financial hardship for all people (United Nations General Assembly, 2019).

1.2.2 Social construction of SF medicines

SF medicine is a socially constructed concept that was not developed through a straightforward technical discussion. Rather, definitions of SF medicines have been shaped by a variety of actors with different perceptions and value systems, since the issue was first discussed at the Rational Use of Drugs conference in 1985 (Gopakumar & Shashikant, 2010). The first international definition focused on "counterfeit medicines" was developed at a workshop co-organised by WHO and IFPMA[2] in 1992 (Appendix C provides a full list of WHO definitions between 1992 and 2017). Over the past two decades, the term "counterfeit" has been at the centre of global debate on definitions. It conflates the commercially motivated enforcement of intellectual property rights (IPR), with the critical issue of quality assurance of medicines from public health perspective ('t Hoen & Pascual, 2015). The term "counterfeit" is defined by the World Trade Organization (WTO) as "Unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods" (WTO, n.d.). Technically, a "counterfeit medicine" is one that is an unauthorised representation of a registered trademark, on a product identical or similar to one for which the trademark is registered (Buckley & Gostin, 2013). This

[2] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents the research-based pharmaceutical companies and associations across the globe.

led to a fundamental tension, which prevented consensus on a definition, between the public health community seeking to give priority to ensure quality and affordability of medicines, and the research and development (R&D)-based multinational pharmaceutical companies (MPCs) seeking to ensure economic return through IPR enforcement.

Controversy over the use of the term "counterfeit" came to a head when efforts to protect IPR began to impinge on the trade in legitimate generic medicines of assured quality. During 2008-2009, numerous seizures were made in the EU of shipments of generic versions of brand-name medicines, in transit from the source country (mostly from India) to destinations in Latin America and elsewhere (Clift, 2010; Brant & Malpani, 2011). These seizures by customs authorities were on the grounds that the generic medicines infringed European patents. The governments of India and Brazil, along with non-governmental organisations (NGOs) involved with access to medicines, expressed deep concern that the seizures threatened trade in legitimate generic products and, in particular, access to more affordable medicines in low- and middle-income countries (LMICs). The generic medicine producers, many of whom are based in India and Brazil, argued that the use of the term "counterfeit" provided an opportunity for MPCs, favouring a strong IPR regime, to use public health issues as a means to push forward strong patent protection of their products (Gopakumar & Shashikant, 2010). The generic industry, in turn, has its own commercial interests in promoting less stringent IPR protections to benefit the production and sales of generic medicines.

It was this complex web of public and private interests that makes an international consensus on the definition of counterfeit medicines an ongoing challenge. In 2010, WHO member states formed the substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) Medical Products Working Group. This new term SSFFC was a concession to member states wanting to abolish the use of "counterfeit", but to focus more on quality, safety and efficacy of medical products. The 65th World Health Assembly in 2012 established the Member State Mechanism on SSFFC medical products. After five more years discussion, the international

agreement on "substandard and falsified medical products" finally arrived in the 70th World Health Assembly in 2017. Box 1- 1 provides the 2017 definitions and categorisations by the WHO and Figure 1- 1 shows how these categories are related.

Box 1- 2 WHO 2017 categories and definitions

Substandard medical products:

Authorized medical products that fail to meet either their quality standards or their specifications, or both. Also called "out of specification".

Unregistered/unlicensed medical products:

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products:

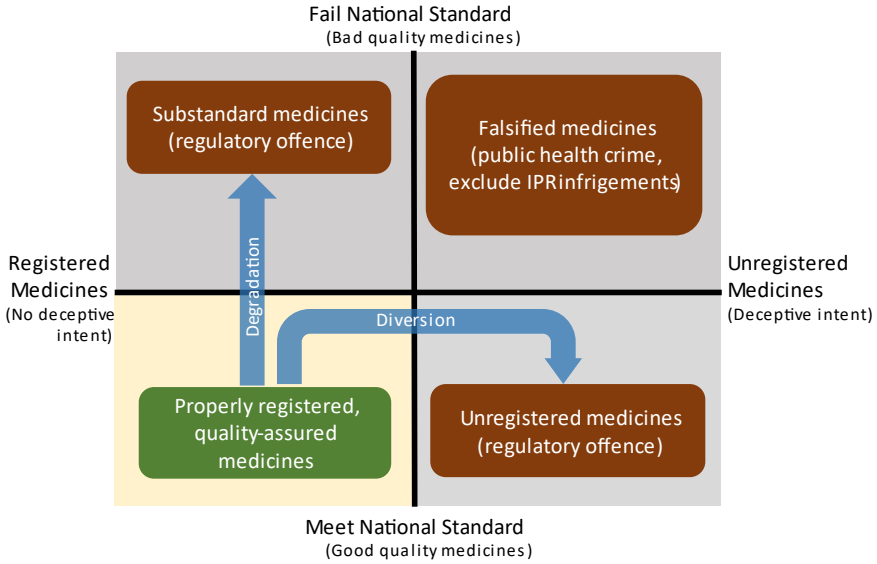
Medical products that have been deliberately/fraudulently misrepresented in their identity, composition or source. It is important to note that, as set out in the footnote of document A70/23: "When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered falsified". This means that intentionally making substandard medicines should be defined as falsified (with implication of more serious administrative or criminal penalties).

Source: Appendix 3 to Annex, World Health Assembly document A70/23 (2017)
https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

The 2017 definition made important steps to focus solely on public health. Since then, SF medicines (or medical products) began to replace "counterfeit medicines" and "SSFFC medicines" in the WHO's documents, scholarly literature, policy documents of international organisations and industry associations such as IFPMA. As sub-section 1.2.1 demonstrated, definitional agreement paved the way for enhanced international collaboration and high-level policy talks. More importantly, SF medicines demonstrates an important example of social construction. How the issue is defined and what constitutes SF medicines can have serious impact on priority setting and policy responses. It is important to note that the distinctive nature of SF medicines requires

different policy responses. Substandard medicines thrive on negligence and cost reduction, policy responses should thus focus on improving the competence of the manufacturers, distributors and the regulatory regime to close the quality gap (Ravinetto *et al.*, 2012; Pisani *et al.*, 2019). Falsified medicines, on the other hand, thrive on shortages, particularly when buyers depart from regulated supply chains (Pisani *et al.*, 2019). Deliberate falsifications often involves criminal activities operating outside regulatory oversight. Policy responses should thus focus on law enforcement, coordination between manufacturers, medicine regulators, customs and postal services.

Figure 1- 1 Typologies of substandard, falsified and unregistered medicines



Despite their differences in definition, drivers, and legal consequences, both types of SF medicines pose significant risks to global public health. This research hence focuses on SF medicines in China, encompassing both substandard and falsified medicines and their public health implications. However, it is important to note that although the WHO removed the use of "counterfeit" in 2017, "counterfeit medicines" and "anti-counterfeiting" may still be used in a country context and by particular interest groups, such as MPCs. Therefore, this research takes

into account varying perceptions by different interest groups and their influence in priority setting and policy responses.

1.2.3 The problem of SF medicines amid China's growing importance in the global pharmaceutical supply chain

China has become an increasingly prominent presence within the global pharmaceutical supply chain over the past four decades. On the demand side, in 2017 China became the world's second largest market for pharmaceutical consumption (www.gov.cn, 2017). On the supply side, today China is the biggest producer and supplier of APIs globally and has a global monopoly over many ingredients for essential medicines such as vitamins, antibiotics and hormones (China Daily, 2015). It controls about 80 percent of global penicillin production (Mukherjeel, 2017). Furthermore, the European Union (EU) uses more than 900 varieties of Chinese APIs and India imports 80-85 percent of APIs or raw materials from China for medicinal uses (Xueqiu, 2017; Mukherjeel, 2017). Under President Xi Jinping's flagship *One Belt and One Road* foreign policy initiative, in 2013 China boosted exports of traditional Chinese medicines to more than 160 countries (China Daily, 2015). As of March 2021, Chinese COVID-19 vaccines have been approved and used in 43 countries. With China's growing dominance in the pharmaceutical supply chain, Gibson and Singh (2018) suggested in *China Rx* that America's new reliance on China for essential medicines poses health, economic and national security threats. Indeed, the USFDA and EU authorities have warned about reliance on imported medical products from China (USFDA, 2019; Brunsden & Peel, 2020). While *The Times of India* reported that Indian national security advisors raised India's overdependence on China for the supply of APIs such as penicillin as a national security concern (Dey, 2014; Mukherjeel, 2017).

With the growth of China's stature in the global pharmaceutical market, safety and quality issue around Chinese-manufactured medicines has become a significant global public health concern. Research has identified China as one of the main sources of SF medicines since the late 1990s (Satchwell, 2004; Obi-Eyisi & Wertheimer, 2012; Bate, 2012). Several seizures were made

of large volumes of falsified cancer medications in Africa, originating from China (Newton *et al*., 2014; WHO 2017b). While WHO-prequalification programme helped improve quality-assurance ('t Hoen *et al*., 2014; El-Jardali *et al*., 2015), Bate and Hess (2012) found that China had the highest number of medicines produced by WHO-approved manufacturers that failed quality control testing. The first independent study on the pharmacopeial quality of antimicrobials in China, found 15 percent of poor-quality in the southern city of Shantou – a figure much higher than previously reported by the Chinese national medicines authority (1.9 percent in 2007) (Pan *et al*., 2016). In 2018, Changsheng Bio-Technology, the country's second-largest vaccine producer, was fined US$1.3 billion for falsifying data and selling ineffective vaccines, which affected hundreds of thousands of babies (Ng, 2018). In 2018, US and EU inspectors detected impurities in valsartan (a medication to treat high blood pressure, heart failure, and diabetic kidney disease) supplied by Zhejiang Huahai Pharmaceuticals, a leading Chinese API manufacturer, which posed cancer risk to patients. As a result of the US and EU authorities' banning of APIs and finished products from Huahai (Christensen, 2018), this quality issue has the potential to cause medicine shortages in the global supply chain.

Online sales of SF medicines have been another rapidly growing global problem, with significant supplies shipped from China. In 2013 alone, 12,320 cases of falsified medicines and medical devices were reported to the Chinese national medicines authority's hotline (China Daily, 2014). News reports from the Medicine Quality Monitoring Globe revealed many incidents of selling SF medical products via WeChat (largest messaging and social media app in China), including SF face masks and vaccines during the COVID-19 pandemic (https://www.iddo.org/mqmglobe/).

Despite the Chinese government and industry's continuous efforts to improve regulation and medicine quality, the problem of SF medicines remains a serious issue. Parallel to the complexity of issues of SF medicines at the global level, SF medicines remains a complex and multi-faceted problem in China. The scale of this problem, the far-reaching public health impacts

that it has, and the diverse configuration of institutions and interests involved, pose major challenges for policy-makers in China. In this context, this research aims to increase our understanding of China's policy responses to SF medicines over the past four decades. While acknowledging the importance of material factors such as scientific evidence (scarce in reality), technological capability, regulatory structure and competency, this research draws on framing theory to analyse the combined influence of material and ideational factors shaping Chinese policy responses to SF medicines. In doing so, it helps advance our knowledge of the changing dynamics in issue perception, priority setting and policy action in Chinese responses to SF medicines.

1.3 Purpose and objectives

The purpose of this research is to develop a more comprehensive and systematic way to analyse issue perception, priority setting and policy action in Chinese responses to SF medicines. This research adopts a social constructivist approach, which is centred on understanding the role of framing in shaping China's policy response to SF medicines, the interaction between ideational (framing) and material factors, and the implications for strengthening domestic and global policy responses to SF medicines.

1.3.1 Research question

To achieve the above purpose, this research addresses the following research question:

How has China's policy responses to substandard and falsified medicines over the past four decades been shaped by ideational and material factors, and how can this inform policy priority setting and action?

1.3.2 Research objectives

To answer the research question, this research sets out to:

a) Identify core policy frames through understanding how the SF medicines problem has been socially constructed (framed) by key policy actors and interest groups in China;

b) Analyse the effect of framing, in combination with material factors, on China's policy responses to SF medicines;

c) Explain the rise and fall of frames, the interaction among frames and the implications of framing on priority setting; and

d) Discuss wider policy implications for China's efforts to strengthen policy response to SF medicines, global policy responses to SF medicines, and China's expanding role in global health governance.

1.4 Organisation of the thesis

This thesis consists of 9 chapters. Chapters 2 begins with the literature review section on global and Chinese responses to SF medicines, and identifies the gap in understanding the ideational aspect of policy responses. Chapter 2 then addresses the philosophical underpinnings which this research is built upon: ontology, epistemology, and theoretical perspectives. Based on my ontological stance that social reality does not exist objectively, this research takes the epistemological approach centred on the social construction of social phenomena. This epistemological stance leads to adoption of the theoretical perspective of framing analysis. Chapter 2 explains the use of framing theory in public policy and reviews the key frames shaping policy responses in the study of global health governance (GHG). These identified frames serve as a starting point which inform the empirical research; while frames in this research will be identified through empirical data within the distinct social, political and cultural context of a changing Chinese policy environment over time.

Chapter 3 sets out the methodology for data collection and analysis. Given the research purpose, I adopt an inductive approach to understand the social construction of SF medicines and policy responses in China. Building upon the proposed epistemological stance and theoretical

perspective, this research undertakes a qualitative investigation and employs two methods for data collection: primary and secondary documentary sources from 1978 to 2021, and semi-structured interviews with key informants. Chapter 3 also explains the data analysis procedure for identifying core policy frames, including how to recognise a frame, its features, and the extent to which it is held by actors.

Chapters 4-7 consist of the core empirical analysis of this thesis, addressing research objectives a) and b). Every chapter is guided by two key purposes: 1) identification of core policy frames, i.e. what are the key policy frames taking place? How have they emerged?; and 2) analysis of policy effect, i.e. how have policy frame(s), in combination with material factors, affected China's policy response to SF medicines? Chapters 4-6 focus on understanding the internal or domestic policy dynamics involving the Chinese government and institutions; while Chapter 7 focuses on how external actors of MPCs and their industrial associations shaping China's perception and policy responses to SF medicines. The analyses of Chapters 4-7 are organised chronologically from the late 1970s to understand major domestic reforms to China's economic policy, social policy, and legal system over time. This period also marks China's reopening through a process of integration into the world economy and involvement in selected global governance institutions.

Chapter 4 analyses China's policy responses to SF medicines, from the initiation of Deng Xiaoping's market reform policy in 1978, to just before the establishment of China's first national medicine regulatory authority in 1998. This chapter highlights China's shifting perception on medicines from a social welfare perspective to a commercial-oriented perspective. It identifies the first core policy frame: the economism frame, as the dominant frame affecting China's policy responses to tackle the rising phenomenon of SF medicines. Much policy priority was given to commercialisation of medicines, development of the pharmaceutical industry, hence limited attention and resources were given to medicine safety and quality regulation at both central and local levels.

Chapter 5 focuses on the period from 1998, when China established the first independent national medicine regulatory authority, to when Xi Jinping became China's president in 2012. This chapter explains the beginning of a transformation of China's policy responses to SF medicines, from one shaped by the economism frame, to prioritising public health interests. Chapter 5 sets out the second core policy frame: the health and well-being frame which became accepted by the medicine regulatory authorities when catastrophic public health events such as the Severe Acute Respiratory Syndrome (SARS) epidemic, H1N1, a series of detrimental SF medicines and food safety incidents, and corruption scandals of senior regulatory officials, all served as catalysts to promote this new framing. The Chinese government realised the pressing need to address the quality issue seriously, as the industry could not achieve sustainable development without sufficient recognition of quality and regulation. Hence, prioritising health and well-being led to a new wave of policies to strengthen medicine quality and re-balance the relationship between public health and economic development.

Chapter 6 presents further analysis of the advancement of the health and well-being frame after Xi Jinping and Li Keqiang came to power in 2012, in combination with the rise of a security frame. It was during this period that the Chinese government adopted more stringent measures to promote medicine quality and regulation. Chapter 6 identifies the emergence of the security frame which was socially constructed by senior policy-makers seeking to link SF medicines (and medicine safety in general) to threats to both the society and the state. Chapter 6 argues that the main effect of security framing, through various ways of securitising the issue, has been to help elevate SF medicines higher on the policy agenda.

Bringing together the literature review and the empirical data and analysis, this research finds that any study on SF medicines, medicine quality and pharmaceutical policy in China, should not neglect the power and influence of major MPCs on both the pharmaceutical industry and public policy process since the 1990s. Hence, Chapter 7 examines how MPCs and industry associations have also contributed to the social construction of the SF medicines issue and

influenced policy responses in China. Analysis of foreign business actors are addressed in a separate chapter, rather than integrated into chapters addressing the domestic context, to enable more in-depth analysis of their importance. Chapter 7 argues that MPCs influence China's policy responses to SF medicines mainly through three economic-related arguments. First is MPCs' focus on IPR, as MPCs attempt to frame SF medicines from an IPR perspective including conflating patent infringements with medicine quality. Second is MPCs' creation of the concept "innovative medicines" to distinguish medicine quality from domestic produced generics. Third is MPC's consistent use of the key term "innovation" in advancing their policy pursuits on IPR and pricing. Through analysing MPCs' framing and policy influence, this chapter also broadens our understanding of the economism frame.

Chapter 8 constitutes a discussion chapter which addresses objective c) *explain the rise and fall of frames, the interaction among frames and the implications of framing on priority setting of this thesis*. It brings together how each frame fared over time with their rise and fall, influenced by four key factors: the role of powerful policy actors; the broader political context; the influence of focusing events; and the use of language in policy making. It then discusses the interrelationship of frames, and explains how the extent to which they compete or cooperate can shape policy perception and priority setting.

The concluding Chapter 9 is divided into two parts. The first three sections address research objective d) *discuss wider policy implications for China's efforts to strengthen policy response to SF medicines, global policy responses to SF medicines, and China's expanding role in global health governance*. The final two sections then present research implications, including limitations and future research directions.

Chapter 2 Literature Review and Theoretical Framework: Constructivism and Framing Analysis

2.1 Introduction

This chapter begins by reviewing the extent of research on global and Chinese responses to SF medicines, to identify progress to date and the reasons for continuing gaps in our knowledge. It reveals a lack of understanding in the ideational aspect of policy responses. This chapter then sets out the ontology, epistemology, and theoretical perspective adopted in this research. These three elements and the methodology (Chapter 3) constitute the philosophical underpinnings upon which this research is built, and are fundamentally interconnected. The epistemological stance taken on social constructivism leads to the adoption of the theoretical perspective of framing analysis, and the methodology connects framing analysis with the use of methods of qualitative investigation (interpretivism in nature) focusing on documents and semi-structured interviews. Framing in this research offers both a theoretical perspective and a method of data analysis, as framing analysis is fundamentally a type of discourse analysis. Section 2.3 reviews the core concept of social constructivism within which framing theory is located. While Section 2.4 explains the use of framing theory in public policy and reviews the key frames shaping policy in the study of GHG to date. These frames serve as a starting point to inform empirical analysis, and this research takes an inductive approach, identifying frames within the distinct social, political and cultural context of Chinese policy responses to SF medicines that change over time.

2.2 Literature review

This review of existing research on SF medicines is divided into two sub-sections, and was last updated in September 2021. The first sub-section reviews studies on SF medicines internationally (outside China) as well as global responses to SF medicines. A total of 432 articles and reports were consulted, including 421 English sources and 11 Chinese sources. The second sub-section reviews what is currently known about China's policy responses to SF medicines., in which a total

of 145 literature were consulted, including 12 English sources and 133 Chinese sources. Chapter 3 explains the methodological approach in searching and selecting literature (see Section 3.3 on "academic publications" for details). This review highlights that while there is a growing literature on SF medicines both in China and globally, much of it is oriented in a way that does not fully address the social construction of the issue and how perception shapes policy responses.

2.2.1 Global responses to SF medicines: Actors and policy dimensions

There were only 24 English academic papers on SF medicines (previously referred to as counterfeit or poor-quality medicines) prior to 2000. This number increased to 81 papers from 2000- 2009, and 316 from 2010 to September 2021. Research on SF medicines has grown significantly after 2010, covering topics on different therapeutic categories of SF medicines, different aspects of the problem (from production to sales), regulatory frameworks, definitional controversies, interest groups, and policy responses at national, regional, and global levels. Though quantifiable data on SF medicines prevalence remains limited and fragmented, analyses of different therapeutic categories including malaria, antibiotics, diethylene glycol, TB, HIV, cardiac medicines, and vaccines, provide important insights into the scale, magnitude and impact of SF medicines (Yeung *et al*., 2015; Lalani *et al*., 2015; Fadeyi *et al*., 2015; Yong *et al*., 2015; Renschler *et al*., 2015; Antignac *et al*., 2017; Kohler & Wright 2020; Do *et al*., 2021). Growing country and regional analysis in Africa and Asia, provide an understanding of how SF medicines are affecting human health in different political, economic and social contexts (Lon *et al*., 2006; Kaur *et al*., 2008; Newton *et al*., 2011; Binagwaho *et al*., 2013, Lamy & Liverani 2015; Lamy, 2017; Guo *et al*., 2017; Pisani *et al*., 2019; WHO, 2019; Hasdina *et al*., 2021; Sweileh 2021). Many studies have pointed out the complexity in international cooperation, given diverse stakeholders and differences in material interests spanning public health, industry, trade and customs, law enforcement, and patient groups (Clift 2010; Bate & Attaran 2010; Gopakumar & Shashikant 2010; Wertheimer & Wang, 2012; Attaran *et al*., 2012; Mackey 2013; Mackey & Liang 2013; Nayyar *et al*., 2015; Hamilton *et al*., 2016).

Some research has demonstrated an awareness of the ideational aspect of SF medicines and its impact on policy responses. One important example is the definitional contestation which many believed was one of the key drivers behind policy controversies and the ineffective global responses to SF medicines prior to 2017 (Anderson, 2009; Clift, 2010; Chatterjee, 2010; Mullard, 2010; Gopakumar & Shashikant, 2010, Attaran *et al*., 2012; Mackey & Liang, 2013), because the difficulty in achieving agreement on terminologies is rooted in different perceptions about how the problem should be defined. Researchers argued that the use of "counterfeit" suggested IPR oriented policy intervention, which was led by the OECD-based pharmaceutical companies keen to pursue their commercial interests (Cockburn *et al*., 2005; Lybecker, 2007; Lybecker, 2008; Anderson, 2009; Mullard, 2010; Chatterjee, 2010; Gopakumar & Shashikant, 2010), but irrelevant to public health concerns (Gopakumar & Shashikant, 2010; Brant & Malpani, 2011).

Literature further suggested that the definitional debate highlighted those responses to SF medicines are intertwined with other priorities, including IPR and trade agreements (Babyar, 2018) – and delayed more needful actions to address the issue from a public health perspective. For example, Bandiera and Marmo (2016) suggested re-framing from "counterfeit" to "fraudulent", because the latter emphasised the criminal angle of the issue and consumers are the true victims of misrepresentations of product quality and fraud, not pharmaceutical companies. Lamy's PhD research has provided important work in bringing framing analysis to contribute to an understanding of SF medicines, by exploring the role of ideas in policy processes and evaluating the variations in perceptions of the problem and the policy developments (Lamy, 2017). Her research identified six frames: security, health system, medical, economic, regulatory, and political frames used in defining and responding to poor-quality anti-malaria medicines in Cambodia, Laos and Thailand, the Greater Mekong Subregion (Lamy, 2017).

Given the increased magnitude and global scale of the SF medicines problem, there have been efforts to strengthen collective action across countries in the form of global leadership and coordinated policy responses (Newton *et al.*, 2014; Nayyar *et al*., 2015; Babyar, 2018). Research

has analysed policy responses and governance mechanisms to SF medicines from a variety of perspectives, including regulatory needs, supply chain analysis, and legal frameworks; while mostly focusing in on the material factors shaping policy responses. It is widely recognised that contestation exists about which aspects of the issue should take priority in policy action, such as criminal prosecution, supply chain management, consumer safety or IPR protection (Bate & Attaran, 2010; Bonino, 2014, New, 2014; 't Hoen & Pascal, 2015). Some suggest that the priority should be to improve policies on manufacturing practice, supply chain management, surveillance, and regulatory capacity (Gostin *et al.*, 2013; Ozawa *et al.*, 2018). Others suggest emphasis should be placed on better manufacturing practice and more stringent compliance with quality standards, as pivotal to ensure good quality medicines (Gostin *et al.*, 2013). Still others propose that addressing regulatory challenges and developing a robust national medicine regulatory authority should be the core considerations, and are essential for pharmacovigilance, quality testing, supply chain management, national reporting system, medicine certification requirements, and field testing (Hamilton *et al.*, 2016). Indeed, some have called for harmonisation of medicine regulation and implementing track-and-trace system to ensure supply chain integrity (Babyar, 2018; Parmaksiz *et al.*, 2020; Kootstra & Kleinhout-Vliek, 2021).

The transnational and criminal aspect of the problem has attracted research on legal approaches to falsified medicines. With different proposals and approaches put forward, no consensus has yet been reached within this community on which approach is the most appropriate, and which institution should take the lead. Some have proposed a strict legal approach to develop an international treaty with transnational jurisdiction to thwart international crimes of SF medicines (Attaran *et al*., 2012; Newton *et al*., 2014; Cannon, 2015). Attaran proposed a *Model Law on Medicine Crime* for countries to incorporate into their national legislations, providing stricter criminalisation against manufacturing, trafficking or selling of SF medicines (Attaran, 2015). The Council of Europe developed the first international criminal law

instrument on SF medical products – the *MEDICRIME Convention*[3] in 2011 – but faced criticism for heavily emphasising IPR issues rather than addressing public health concerns (Bate & Attaran, 2010; Hamilton *et al*., 2016). Some proposed that the WHO should take the lead in drafting an international treaty because of its mandate to protect public health (Bate & Attaran 2010; Binagwaho *et al*. 2013). While others have suggested a soft legal approach, calling for shared leadership. The US Institute of Medicine has called for the WHO, in partnership with the World Customs Organisation, United Nations Offices on Drugs and Crime (UNODC), to promote an international code of practice – a voluntary soft law to curtail SF medicines (Gostin *et al.*, 2013). Mackey and Liang (2013) suggested a GHG trilateral mechanism between WHO, UNODC, and Interpol to coordinate their respective actions on transnational crime prevention, public health, and law enforcement field operations. On issue framing, 't Hoen and Pascual (2015: 4) suggested that an international convention should focus on ensuring the availability of affordable medicines, because "framing the falsified and substandard medicines issues in the context of 'medicine crime' overlooks the best approach to counter the supply of illegal and dangerous medicines: ensuring the availability of affordable, quality assured essential medicines".

Overall, existing literature has revealed the complexity of SF medicines, spanning diverse sectors, policy arenas, and a blend of material and ideational factors. It has also revealed that SF medicines historically largely impacted populations in LMICs, but are now affecting all countries. However, for countries like China and India, where many problems of SF medicines originate from, studies of the problem and policy responses are especially inadequate. What remains lacking, however, is analysis of the underlying factors contributing to different perceptions of the issue which could lead to different policy pathways. Intrigued by the complex and multi-faceted issue of SF medicines, this research seeks to address the knowledge gap in understanding social

[3] Bate and Attaran (2010) suggested European officials lacked credibility to pursue the *MEDICRIME Convention* globally because it may criminalise legitimate generic medicine manufacturers. Research has also revealed examples of the EU providing funds to support the Uganda's Ministry of Tourism, Trade and Industry on a counterfeiting bill that could potentially make generic medicines illegal (Anderson, 2009; Mullard, 2010).

construction of SF medicines in China's context, as well as the role of policy ideas in shaping China's policy responses. It also aims to illuminate how framing can help achieve higher policy priority and strengthen global responses to SF medicines.

2.2.2 China's policy on SF medicines

To date, SF medicines in China, as a multi-faceted problem, cut across multiple policy arenas and actors, and has received limited research attention. Most of the literature on SF medicines in China, describes China's policy responses to SF medicines as inadequate and ineffective (Liu, 2010; Yang *et al*., 2005; Zhao & Shao, 2004; Liu & Meng, 2005; Yu, 2008; Wong, 2004; Bronshtein, 2008; Willson, 2010; Tan & Willson, 2009; Ding & Liu, 2009; Shao *et al*. 2010; Yan, 2010). Early research focused on medicine regulation and institutional analysis of the national medicine regulatory agency (Liu, 2011; Hu, 2012b). Institutional dysfunction, poor governance, including corruption and weak legislations, were identified as the main factors contributing to the ineffectiveness of policy responses to SF medicines in China (Yu, 1997a, 1997b; Song, 2009; Liu 2010, 2011; Hu 2012b; Huang 2013). Since 2010, research has drawn greater attention to the complexity of the issue, and called for more holistic and systematic analysis on improving medicine safety within a broader context of domestic governance structures (Hu *et al*., 2009; Kang 2012; Hu, 2013b; Liu, 2017; Hu, 2017; Zhou et al., 2019; Gao & Chen, 2020; Bing *et al*., 2021; Wang et al., 2021). There has been an increase in studies of the supply chain (Zhang, 2019), online pharmacy and internet regulation (Ran, 2019; Wang & Zhang, 2021), vaccine safety and quality (Bao *et al.*, 2018; Li *et al.*, 2019; Wang, 2020). Overall, however, there remains no systematic research on SF medicines in China which explain definitions, diverse actors, and policy-making.

Although SF medicines go beyond regulation, a functioning national medicine regulatory agency is pivotal to ensure access to safety and good quality medicines, as well as tackling SF medicines. Some important research has been done by Chinese scholars in examining institutional capacity and bureaucratic politics. Analysis has focused on the fragmented nature of the Chinese regulatory system, the so-called "bureaucratic fragmentation" (Yu, 1997a, 1997b;

Song, 2009; Liu, 2011; Hu, 2012b; Huang, 2013) and medicine safety concerns arising from this. Liu Peng (刘鹏)'s seminal book (2011) provided an important historical account of institutional analysis of the Chinese national medicine regulatory agency between 1949 and 2008, and discussed the challenges faced by Chinese medicine regulation. The fragmentation of the Chinese medicine regulatory system, including unclear division of labour, weak cross-ministerial and central-local government coordination, were ongoing issues shaping the effectiveness of policy responses (Song, 2008a; Liu, 2008; Song & Hu, 2008; Ding & Liu, 2009; Liu, 2011; Xu, *et al*., 2011; Hu, 2013a). In particular, under China's semi-centralised (半垂直) medicine regulation system (centralised at the provincial level, more details in Chapter 5), the national medicine regulatory agency didn't have much influence over localities, and policy implementation depended much on the political commitment of provincial governments (Song, 2008d; Liu, 2008; State Food & Drug Administration, 2009; Xu *et al*., 2011; Liu, 2011;). This research builds on existing literature to provide a fuller analysis of the challenges faced by the Chinese national medicine regulatory agency in addressing SF medicines. This will be achieved by enhancing understanding of how material and ideational factors, over the past four decades, have influenced perceptions and policy responses within the national medicine regulatory agency on SF medicines.

Regarding implications for definitions and policy, this review finds very few local studies and, unlike literature at the global level seeking to disentangle IPR and quality, much confusion and misunderstanding remains around quality and IPR in the Chinese context (Clark, 2003; Wong, 2004; Tan & Willson, 2009; Willson, 2010; Bronshtein, 2008; Cote, 2010). For example, Wong (2004) suggested that, to control SF medicines, China needs to resolve the dilemma of facilitating access and competition into the pharmaceutical market, and enforcing laws and regulations to ensure IPR protection (Wong, 2004). The study conflates IPR with quality issues, and lacked sufficient evidence to explain where this dilemma lay, what were the interest groups involved, and why it was important for the government to balance competing interests. Bronshtein (2008) similarly linked patent infringement with China's response to SF (referred to as "counterfeit")

medicines and mixed the issue of trademark with patent. These examples highlighted the need to clarify definitions, explain different perceptions of the problem, and how perceptions affect policy responses.

There is a growing recognition that business lobbying is an integral part of China's policy process at local and national levels. The discussion of interest groups (利益集团), including the role of MPCs in influencing the Chinese pharmaceutical industry and regulating policies, is ever more common (Yang *et al*., 2005; Yang, 2007; Sun, 2009; Song 2009; Yang & Liu, 2009; Yang, 2010; Sun, 2010; Xu 2010; Chen, 2012, 2013). Some scholars have suggested that MPCs and their industrial associations have been the most prominent actor (amongst interest groups) in influencing China's medicine regulatory policy (Song, 2008d; Zhu 2011; Liu, 2011; Hu, 2012a; Wang & Fan, 2013, Hu, 2017). Xu (2010) for instance, argued that MPCs have control over market share, equity, technology, and brand in the Chinese pharmaceutical market. Furthermore, Wang and Fan (2013) provided a detailed analysis of one major industrial association representing MPCs in China – RDPAC (see Chapter 7 for further details) – and its lobbying strategies in pursuing favourable policies in pricing and market share for MPCs. Given MPCs' growing dominance in China's pharmaceutical market structure and policy influence since 1990s, several studies have raised concerns for domestic industrial security (Hu, 2009; Xu, 2010; Hu, 2012a; Zhang, 2014; Qin, 2014). This part of the discussion will be expanded in Chapter 6 on securitisation.

Overall, MPCs' influence in Chinese pharmaceutical policy-making is a topic that has invited much speculation, but has generated only shallow analysis and limited concrete evidence. Given MPCs' concern about SF medicines in China (from the perspective of IPR and brand protection), no research has examined how MPCs and their industrial associations approached the issue of SF medicines in China and shaped policy-making. Hence, this research provides a fuller analysis of MPCs' perception on SF medicines and pursuit of a policy agenda, combining both material and ideational factors. In fact, how industry engages policy-makers and use their material and ideational power to shape every aspect of policy process, remains intriguing and

little known area of research (Deng & Kennedy, 2010). This research therefore devotes the entirety of Chapter 7 to examine MPCs' framing of SF medicines in the pursuit of shaping issue perception and policy. It then offers a new perspective on the pharmaceutical industry's role in policy process, how foreign and domestic companies lobby differently, and shape policy responses.

Recent scholarship has called for new thinking and stronger collective policy responses to SF medicines at the global level (Newton & Bond, 2019, 2020; The Inter Academy Partnership, 2020). And few studies to date have explored policy actors' perceptions of the problem across policy sectors in a national context. To this end, this research aims to contribute to new thinking by exploring policy ideas, issue framing, and understanding the blend of material (what we see and do) and ideational (what and how we think) realities affecting policy processes and responses. In doing so, it seeks to provide an in-depth and systematic investigation of the problem of SF medicines in China. It homes in on the perception and policy ideas (represented by framing) in policy-making, the interaction between ideational (framing) and material factors, and the resultant effect on policy making, including variations in policy pathways of response to resolve the issue. Thus, the remainder of this chapter consists of a full discussion of the conceptual framework used in my analysis, applying a social constructivist approach and framing theory.

2.3 Foundations of social constructivism

This research takes the ontological stance that social reality does not exist objectively. While we have established physical truths which are fact-based such as the laws of gravity and thermodynamics, as well as materials science, we also have the mental world of relative truth, comprising ideas, constructs, concepts, models, myths, patterns and rules developed and passed down from generation to generation (Lakhiani, 2016). As an individual, our mind constructs our reality, our thoughts and mental formations shape our reality. Social construction posits that a reality (a social issue or problem) can be constructed by collective minds or collective consciousness. This section briefly outlines three core concepts of social constructivism, which

constitutes the epistemological approach of this research and is central to framing analysis, the methodological approach adopted for this research: "reality" can be socially constructed and have different dimensions; the relationship between social and material realities; and the central role of language in understanding and interpreting social discourses.

2.2.1 The multiplicity of "reality"

Our thoughts shape how we experience and interact with our reality. We mentally construct reality all the time. Language, belief systems, worldviews, ideas, all shape how we understand, construct and interpret the world around us, which in turn shape our behaviours. A major focus of social constructivist analysis is uncovering the ways in which individuals and groups participate in the construction of perceived social reality. Social constructivism emerged during the 1980s as a theory of knowledge in sociology and communications. The theory holds that "our current accepted ways of understanding the world, is a product not of objective observation of the world, but of the social processes and interactions in which people are constantly engaged with each other" (Burr, 1995: 3). In Berger and Luckman's seminal book, *The Social Construction of Reality*, the authors argue that the development of human knowledge about an issue cannot be separated from the social context within which it arises (Berger & Luckman, 1967). What human beings call "reality" is not objectively "out there", waiting to be discovered, but constructed through human perceptions and social interactions. Human perception of reality is shaped by one's perspective, located within a particular space and time, and in the service of some interests rather than others; but over time, perceived reality can become embedded in the institutional fabric of society (Berger & Luckman, 1967, Burr, 1995). Social reality can be "multi-dimensional" particularly for political topics which depend on many circumstances leading to how an issue or problem is perceived, communicated and understood (Braun & Capano, 2010). This can result in different knowledge derived by different individuals looking at the same phenomenon.

Social constructivism does not deny the existence of material reality (the physical dimension), and social construction of a policy issue does not operate in isolation from the

material world. This research suggests that material reality alone does not provide sufficient explanation for why a certain policy issue is portrayed as a "problem" and is prioritised on the policy agenda, while others are not. Although material factors (such as technology, human and financial resources, institutional competencies) must be taken into account when explaining policy-making, how socially constructed realities interact with material reality provides fuller explanation. Often what matters more is policy-makers' perception of material factors such as scientific evidence, emergency events, and how they want to use these data to serve their wider policy agenda. For example, was the United Kingdom government's shift in position from resistance to face masks at the beginning of the COVID-19 pandemic to making it compulsory a few months later, really driven by a shift in scientific evidence? This thesis incorporates both material and ideational dimensions in policy process, hence, more it provides a more comprehensive understanding of the diversity in problem identification, agenda-setting, and rationales behind perceived legitimacy of different policy choices (Schneider & Ingram, 1993).

In the context of this research on policy responses to SF medicines in China, this research examines the dynamic process by which the material world and social phenomena interact, are perceived and defined as policy problems and solutions, become institutionalised in policy processes, and are acted upon by policy-makers. By focusing on national-level policy responses in China, alleged to be a major source of SF medicines worldwide, this research goes beyond explanations based on material factors notably institutional and technical shortcomings. Therefore, through adopting a social constructivist approach, it provides a fuller analysis of how ideational and material factors have been mutually constitutive in shaping Chinese policy responses to SF medicines.

2.2.2 The role of language

Language is defined as "a system of vocal signs" and "the most important sign system of human society" (Berger & Luckman, 1967: 36-37). The biggest benefit of language is that it allows us to create a whole new world within our heads which does not exist in the physical world, aside from

simply as "understandings" in our heads. It allows us to form cultures, mythologies, and religions (Lakhiani, 2016). Language shapes how we experience the world, and allows us to create and communicate complex information – and informs a society's representation of reality. This is because language, among social interaction of all kinds, is the basis of social relationships and the most essential system through which humans construct reality (Berger & Luckman, 1967; Gergen, 1999). In his book *Sapiens: A brief History of Humankind*, Harari calls this the "cognitive revolution" (Harari, 2015). He suggests that language is a unique means for us to share information about the world and enables social cooperation, which is key to survival and reproduction (Harari, 2015).

The Chinese language, building on more than 3,000 years of history, is fundamental to the Chinese belief systems, cultures, education, politics, and everyday learning and communication. As for policy-making, Campbell suggests that the use of language, including concepts, metaphors, linguistic codes, and rules of logic contain cognitive and normative elements that shape how policy ideas are articulated, understood, communicated and, as a result, more likely to be adopted (Campbell, 2002). Applied to Chinese policy-making, Bondes and Heep (2012)'s research of the authoritarian Chinese party-state, finds that the use of official language (what they call "official frames") and ideological innovation have reproduced beliefs among the populace concerning the ruling elites' leadership qualities and their determination to serve the common interest. They suggested that the Chinese Communist Party's (CCP) promotion of "official frames" has historically been effective at shaping people's perceptions of socio-political realities in China.

Hence, engaging language in analysing Chinese policy-making is central to our understanding of the social construction of realities. In the context of Chinese policy responses to SF medicines, this research analyses Chinese literature, including original Chinese-language "speech acts" such as official policy documents, public statements, and speeches. It also covers business publications and media reports. The empirical analysis presented in Chapters 4-7 is extensively based on Chinese language data sources, which help us understand the way Chinese policy actors construct and respond to the issue of SF medicines.

2.4 Framing theory and public policy

Based on the epistemological stance of this research, which emphasises the social construction of social phenomena, framing analysis has been adopted as the methodological approach to address the research question and objectives set out in Section 1.3. Situated within the broad approach of social constructivism, framing theory originates in communication studies and sociology, but has since been widely applied in other fields including psychology, economics and politics. Although the concept of frames has been defined and applied in different ways in these disparate fields, these varied applications share a basic premise, namely that "an issue can be viewed from a variety of perspectives and be construed as having implications for multiple values or considerations" (Chong & Druckman, 2007: 104). The following sections explain how framing theory is useful to understand the ideational process, an important component of public policy-making.

2.3.1 The essence of framing: Organisation, selection and salience

Framing analysis, the study of the organisation of social experience, was first proposed by sociologist Erving Goffman. In his book *Frame Analysis: An Essay on the Organization of Experience*, Goffman explains that a frame is a set of concepts and theoretical perspectives which structures an individual's perception of society and guides the actions of individuals, groups and societies (Goffman, 1974). Framing as a process of organisation, selection and salience has been widely applied in communication studies since the 1980s. Gitlin (1980: 7) defines frames as "persistent patterns of cognition, interpretation and presentation, of selection, emphasis and exclusion, by which symbol-handlers routinely organise discourse". Framing, as defined by Robert Entman (1993: 52), is to "select some aspects of a perceived reality and make them more salient in a communicating text, in such a way as to promote a particular problem definition, causal interpretation, moral evaluation, and/or treatment recommendation for the item described". A decade later Entman (2003: 417) revised his definition as: "framing entails selecting and highlighting some facets of events or issues, and making connections among them so as to

promote a particular interpretation, evaluation, and/or solution". All definitions highlight framing as a particular way to create or renew an understanding of reality which often leads to new solutions/treatments of an issue.

Research reveals, for example, that framing is a heuristic device to understand how the media curates and constructs information and, in turn, influences the perceived relative salience of issues in public discourse. Examples of comparative studies of media framing in the US and China found significant variation in how selected issues and events are presented (Luther & Zhou, 2005; Feng *et al*., 2012; Hong, 2013). Differences in social, cultural, political and economic contexts were used to explain the differences in the construction of meaning of selected issues. For example, the US media framed recalls of Chinese products as health and safety issues caused by deficiencies in China regulatory standards. By contrast, the Chinese media framed it as a trade issue (Hong, 2013). In reporting the SARS outbreak in the early 2000s, US newspapers emphasised the resultant economic impacts and blamed Chinese political leaders for seeking to hide the outbreak. Chinese newspapers focused on the positive initiatives that Chinese leaders were taking to curtail the economic and health impacts (Luther & Zhou, 2005). Framing also shows how some features of perceived reality are selected and highlighted, while others are omitted. Hong (2013) compared news coverage by the *New York Times* and *Associated Press* with *China Daily* and *Xinhua News Agency* of Chinese product recalls, and found differences in the sources used, nationality of the source, dominant frames employed, and attribution of responsibility for the problems. Similarly, a study of the baby formula and melamine scandal suggests that the US position, as a major importer of Chinese goods with feelings of concern about China's economic rise alongside their comparative position as a declining economic superpower, may have influenced the *Associated Press*'s framing of the issue as a problem with Chinese products (Feng *et al.*, 2012). These studies suggest that framing is influenced by the social context in which the media operates and not simply the events themselves. As Lippmann (1922: 216) stated, news media cannot mirror "reality", but can only provide "the report of an aspect that has obtruded itself".

2.3.2 Framing in public policy processes

The application of framing theory to the study of public policy-making offers to provide a deeper understanding of the role of ideational factors (Schön & Rein, 1994; Rein & Schön, 1996; Campbell, 2002; Fischer, 2003; Jerit, 2008; Surel, 2011). Public policy can be broadly defined as the centralised embodiment of the organisational, programmatic and purposive nature of social activities (Qian, 2007: 1). In the Chinese context, as defined by Qian (2007: 7), public policies are plans, courses of actions and behavioural rules, made by public authorities such as governments, to address particular social problems and agreed social goals. Such policies are often represented concretely as decrees, strategies, statutes or measures (Zhang, 1992; Hu, 1998; Zhu *et al*., 1999; Qian, 2007; Zhu, 2008). Social constructivist analysis suggested that ideational processes constitute a key aspect of public policy-making, emphasising how certain norms, ideas, values and shared beliefs shape the perceptions and behaviour of public officials. The ideational dimension in public policy process focuses on analysing the cognitive dimension of "what we know about the world and what we believe, and, given our assumptions about causality, how we can act in this world" (Hall, 1993; Braun & Capano, 2010).

At the individual level, our thoughts shape our reality. For policy-making, collective thoughts of policy actors shape their perceptions of policy issues and hence policy actions. Many scholars have analysed how ideational factors influence the construction of economic, welfare, environmental, security and public health issues, and the policy responses to them (Hall, 1993; Kingdon, 2003; Campbell, 2002; Béland, 2005; Gormley, 2007; Shiffman, 2009; Béland & Orenstein, 2010). The main types of ideas that could influence policy-making include beliefs, worldviews, world cultures, frames, ideas, and cognitive paradigms (Campbell, 2002; Braun & Capano, 2010). How is framing different to other ideational factors such as beliefs and worldviews? Clear's (2018) research suggests that behind every system of actions are a system of beliefs. Beliefs and worldviews influence the subconscious or unconscious level of the mind, indoctrinated during our formative years through parents, schools and the society where we

grow up, and can shape how we perceive reality and frame an issue. In policy-making, belief systems and worldviews are in the background of policy-making, determining how policy-makers formulate their thoughts and through which they perceive and construct their reality.

Framing, however, is at the forefront of policy-making and is more of a conscious act. Unlike beliefs, worldviews and paradigms, which connect to the deep core of embedded beliefs and are more difficult to change (Braun & Capano, 2010; Rushton & Williams, 2012), framing opens more possibilities for change in policy-making. This is because framing concerns the formation of collective thought development processes, and demonstrates a persistent embedding of certain ways of communicating about an issue. Framing suggests that an issue is presented in such a way as to tie into a broader set of ideas about the world, or "socially constructed reality", and through this gain influence and policy purchase (McInnes *et al.*, 2012). It promotes certain policy perspectives based on some shared beliefs, and is thus primarily concerned with explaining how policy-makers normatively present policies to give them greater political traction. A policy frame(s) represents the outcome of a "framing" process, which selects and calls attention to particular aspects of the reality presented, potentially directing attention away from other aspects (Gitlin, 1980, Entman, 1993). In policy debates, it is argued that frames are often purposefully and strategically used by actors to influence agenda setting, problem definition and policy response (McInnes *et al.*, 2012). Continuous reinforcement of a particular frame can generate new understandings and often lead to new recommendations or solutions to address the issue of concern.

As explained above, framing presents a more nuanced understanding of public policy-making compared to approaches that explain outcomes in terms of objective measures of a problem. Instead, framing helps reveal how the collective mind of policy actors works to achieve certain policy outcomes, and how the way public policy problems and solutions are framed stem from how individuals, groups, and societies organise, perceive, and communicate their perceived realities. Building on the above theories and concepts, this research seeks to more fully

understand how Chinese policy responses to SF Medicines form over time. It employs framing theory to analyse how SF medicines in China has been perceived, interpreted and presented by key policy actors. This research thus identifies which aspect(s) of the issue has been prioritised, and which actors have adopted and advanced which frames. In this way, framing theory is used to locate the SF medicines problem in China within changing social, political and economic contexts, and highlight how framing has interacted with material reality, to shape Chinese policy responses.

2.3.3 Key frames in global health governance

This section reviews key policy frames identified in GHG to date, and serves as a starting point for this research. In analysing policy responses to SF medicines in China, these frames may or may not be observed as shaping Chinese policy responses due to different social, political contexts, normative frameworks, and policy environments. Given the intertwined nature of national and global policy debates on public health and SF medicines, it is likely that there will be some common frames found. However, reviewing existing frames in GHG serves as a useful starting point for beginning to uncover and understand the role of frames in Chinese policy responses to SF medicines.

Framing theory has been used in a growing number of studies by GHG scholars to critically analyse why certain public health issues and responses to them, are prioritised over others in collective action by global health institutions (Shiffman & Smith, 2007; Labonté, 2008; Shiffman, 2009; Labonté & Gagnon, 2010; McInnes *et al.*, 2012; Reubi, 2012; Rushton, 2012; Woodling *et al.*, 2012; Kamradt-Scott & McInnes, 2012; Kamradt-Scott, 2012; Williams, 2012; Rushton & Williams, 2012; McInnes & Lee, 2012a; Labonté, 2014; McInnes & Roemer-Mahler, 2017). These studies focused on analysing how different individuals and organisations frame different global health issues in diverse ways, and hence promote differing pathways of response. Table 2- 1 presents five frames identified as dominant in GHG scholarship, the core ideas, causal explanations and the policy responses associated with each frame: *evidence-based medicine*, *human rights*, *economism*,

security, and *development*. Each frame is defined by a set of norms, and thus privileges particular ideas, interests and institutions (McInnes & Lee, 2012b). The same issue at different times or circumstances, or different aspects of the same issue, can invoke different frames. For example, HIV/AIDS has been framed alternatively as a public health problem, a development issue, a humanitarian crisis, a human rights issue, and a threat to security at different points in time, to maintain a position of policy priority among global health issues (Shiffman, 2009; Rushton, 2012). Similarly, global tobacco control has been alternatively framed by economism, evidence-based medicine and human rights with variable results.

In addition to the key frames outlined in Table 2- 1, Labonté and colleagues identified six dominant policy frames on how health is positioned in foreign policy: *security, development, global public good, trade, human rights,* and *ethical/moral reasoning* (Labonté, 2008; Labonté & Gagnon, 2010; Labonté, 2014). Each frame has implications for how health is conceptualised and each holds distinct rationales for the positioning health in foreign policy debates. The authors similarly describe how understanding different frames can help shed light on different strategic approaches to positioning an issue in the policy agenda (in their case health in foreign policy agenda), and hence help illuminate the different ways in which policy priority can be advanced. Wernli and colleagues emphasised that one issue can resonate with multiple policy frames through mapping out global policy discourse on antimicrobial resistance (AMR) (Wernli *et al.*, 2017). They suggest five policy frames associated with the rising importance of AMR on the global health agenda: *healthcare*, *development*, *innovation*, *security* and *One Health*. Each frame fosters distinct pathways for capturing the causes of AMR, setting priorities, promoting interventions, and measurements. McInnes and Roemer-Mahler (2017) find that framing global health issues as "risk" instead of "security", helps lower political sensitivity and promote inclusiveness in policy responses, such as strengthening pandemic preparedness.

Table 2- 1 Summary of dominant frames identified in the GHG literature

Frame	Core ideas	Causal explanations of global health problems	Proposed policy responses
Economism	Social phenomena are explained by economic causes and factors. Supply and demand are the most important factors in decision making. Public policy goals and outcomes should be measured in monetary terms, with priority given to fiscal measures such as taxation and subsidies.	Inadequate access to medicines is caused by insufficient market return for pharmaceutical companies in low-income countries.	Strengthen intellectual property rights protections as incentive to pharmaceutical companies to invest in R&D. Pool purchasing of medicines to negotiate lower price, increase economies of scale or create guaranteed demand.
		Illicit tobacco trade caused by tax differentials between jurisdictions.	Reduce differentials in rates of tobacco tax in nearby jurisdictions to reduce incentives to engage in illicit trade.
Biomedicalism	The world is knowable through positive knowledge based on natural phenomena and their properties and relations. Policy-making should be evidence-based or evidence informed, based on positive knowledge as the most legitimate and appropriate form of evidence.	HIV/AIDS pandemic is due to lack of available medicine treatment and effective vaccine.	Support R&D of medicines and vaccines. Improve treatment regimes for HIV infected patients.
Development	Societies have historically been shaped by unequal political and economic relationships that have led to parts of the world, and certain populations, being materially and structurally underdeveloped and disadvantaged. Public policies should redress the resulting inequities by supporting the development of these societies.	HIV/AIDS pandemic worsened by underdevelopment, lack of resources, and socioeconomic inequities.	Redistribution of resources, from developed to developing countries, to enhance the capacity of the latter to address global health challenges.

Human rights	All people hold basic rights and freedoms from birth to death based on universally shared values such as fairness, dignity, equality, respect and independence. Human rights are an entitlement to each individual and should underpin societies and their relationships with each other. Public policies should be based on the goals of ensuring the realisation of these basic rights.	Lack of access to medicines due to failure to realise the basic right to health	Adopt policies that provide universal access to essential medicines based on need as a human right
		High rates of unplanned pregnancies and maternal mortality due to lack of sexual and reproductive rights for girls and women.	Adopt legislation and provide education on sexual and reproductive rights. Improve access to health care for girls and women.
Security	There are major risks that pose a "clear and present" danger or existential threat to the functioning of a state and society, and the individuals living within them. These types of threats should be given the highest priority in public policy through exceptional programmes, actions and resources.	Population health risks from severe and acute infectious disease outbreaks.	National contingency plans to ensure continued societal functioning, focused on resilience and recovery of border integrity, governance, essential services, and economic interests.
		Risks from mobile populations with highly pathogenic infections (H1N1, Ebola).	Travel restrictions based on border or beyond border screening.

Sources: Compiled from Shiffman & Smith, 2007; Shiffman, 2009; Kamradt-Scott, 2012; Kamradt-Scott & McInnes, 2012; McInnes & Lee, 2012a; McInnes & Lee, 2012b; Rushton, 2012; Williams, 2012; Woodling *et al*. 2012.

2.3.4 Framing and policy effects

The above demonstrates how multiple frames can operate simultaneously in GHG, within and across issue areas. Studies suggest that key frames have played a critical role in certain global health policy responses being selected over others. For example, Shiffman (2009) argues that the framing of ideas played a critical role in the prioritising of issues such as HIV/AIDS and SARS over others such as pneumonia and malnutrition, despite epidemiological data that the latter causes higher rates of mortality and morbidity. Kamradt-Scott and McInnes (2012: S106) suggest that the reframing of pandemic influenza during the early twenty-first century, from a biomedical to a security issue, led to the adoption of exceptional measures (e.g., emergency plans) "which take responses to the disease outside the realm of 'normal politics'". Reubi (2012) identifies the use of human rights as a counter-frame to the previous security frame, for overturning travel restrictions imposed on HIV positive individuals. Reframing or counter-framing, which concerns the purposeful use of another frame to effectively respond to or oppose an existing frame, can be used to reshape the way an issue is understood – thus serving an integral role in policy change (Campbell, 2002; Rushton & Williams, 2012). In any given issue-area terrain, there are a variety of frames competing for meaning, policy space and material resources. Competition among frames is therefore indicative of differences in the ways in which actors view, interpret and respond to the material world around them. These perceptions, in turn, are socially constructed based on particular values, interests and knowledge. Social constructionism in GHG research, in short, seeks to understand how contestation and cooperation among different frames explains certain policy pathways and, ultimately, health outcomes.

In the analysis of framing, researchers have acknowledged the importance of understanding the connections among specific frames and policy/political actors in GHG, because actors (often referred to as policy entrepreneurs) can play a decisive role in a frame's success. Rushton and Williams (2012) argue that policy outcomes can be shaped, not only by the persuasiveness of a particular frame, but also by who is advancing that frame (Rushton &

Williams 2012). Similarly, McInnes and *et al*. (2012: S85) suggest that "actors often deliberately (and in many cases strategically) use frames as a tool of persuasion, deploying them to call attention to an issue, influence other actors' perceptions of their own interests and convince them of the legitimacy/appropriateness of the advocate's preferred policy response". Frames can be deployed and promoted by multiple stakeholders; for example, major GHG actors include transnational advocacy groups, international organisations and epistemic communities (Rushton, 2012; McInnes *et al.*, 2012). Depending on how the problem is perceived, different policy actors can come to put forth different recommendations about the same problem. Frames can thus sometimes overlap and compete with each other, with different actors promoting their own ways of understanding an issue and, in turn, their own preferred ways of addressing said issue. Moreover, different frames may resonate with different actors. For example, the economism frame in the access to medicines issue resonated with the R&D-based pharmaceutical companies and higher-income countries; whereas the human rights frame emphasising universal access to essential medicines resonated more with LMICs, public health professionals and health advocating NGOs.

The analysis of framing must also acknowledge the importance of material reality alongside ideational factors, as discussed in Section 2.3. Framing impacts on both social and material reality. Rather than seeking to understand whether one matters more than the other, Campbell (2002) suggested the need to better understand the blended relationship between ideational and material factors. The two interact in policy-making, with ideas held by actors affecting how they define their own material interests (Campbell, 2002). The existing GHG literature suggests that material realities, such as focusing events (e.g., major disease outbreaks), can gain the attention of policy-makers and generate new ideas within the political realm, or lead to the creation of new norms. Kingdon (2003: 98) similarly suggested that "crises, disasters, symbols, and other focusing events only rarely carry a subject to policy agenda prominence by themselves". These events need to be accompanied by something else, reinforcing some pre-existing perception of a problem or focusing attention on a problem that is already in place. In

their analysis of GHG, McInnes and Lee (2012a: S194-S195) stated that the world of ideas and material reality are mutually constitutive: "framings shape the social construction of key material events or data, while the material world provides the substance for framing"). While Campbell (2002) argued that frames could sometimes be constrained by institutional structures and mandates, Shiffman (2009) suggested that institutions could help to sustain frames. For the latter, Shiffman (2009: 608) noted that "those issues that attract attention may be ones in which policy community members have discovered frames – ways of positioning an issue – that resonate with global and national political elites, and then established institutions that can sustain these frames". This suggests that ideas can exert long-term effects on policy-making by becoming institutionally embedded in material reality in the form of laws, administrative procedures, programs, and bureaucratic practices.

On the policy responses to resolve SF medicines, as Section 2.2 has described, systematic analysis of framing in the global governance of SF medicines remains lacking, particularly on how this may be contributing to policy priority setting and action at the national and global levels. There has been limited application to date of framing theory to explain what, how and when frames are used, what they derive from, and what policy responses they lead to. This research addresses this knowledge gap by applying framing theory to explain policy responses in China over time. It identifies and analyses core policy frames, key policy actors, the blend of material and ideational reality, and will deepen our understanding of the relationship amongst frames, and the policy implications of when frames compete and/or cooperate.

2.5 Summary

This chapter identified the knowledge gap in understanding the ideational aspect of policy responses to SF medicines. It then set out the key concepts and analytical framework for analysing China's policy responses to SF medicines. Drawing on social constructivism and framing theory, this study seeks to analyse the transformation of China's perception on the issue of SF medicines since the late 1970s, the development of different policy frames, and how each frame could lead

to different policy pathways. It then explores the underlying causes of the complexity of policy responses, through analysing ideational factors and how they interact with material factors to shape policy responses. In this chapter, I introduced several core frames, including *economism*, *biomedicalism*, *development*, *human rights*, and *security*, that have been previously identified in the GHG literature as shaping selected global health issues – and serve as the starting point for understanding the framing of SF medicines in China.

Chapter 3 Methodology

3.1 Introduction

This chapter sets out the methodology used in this thesis for data collection and analysis. Building from the social constructivist perspective of reality and knowledge generation introduced in Chapter 2, this chapter explains how I have sought to address the research question and objectives in a reliable and valid manner, to more fully understand China's shifting policy responses to SF medicines over the past four decades.

Methodology concerns the procedure a researcher employs to acquire knowledge to address the research question and objectives. It constitutes the culmination of epistemological stance and methods of inquiry employed to produce results in keeping with the chosen epistemology. Based on the theoretical perspective I have selected, this chapter describes the main data sources drawn upon, and how I systematically searched for these sources and analysed them according to the research purpose and objectives set out in Section 1.3. It explains the procedure for identifying core policy frames, including how to recognise a frame, its features and the extent to which it is held by actors. While this chapter explains the effort to triangulate multiple sources of data wherever possible, it also highlights methodological limitations of methodology, including the issue of data access.

3.2 Qualitative investigation

Given the purpose of this research to understand the social construction of SF medicines and policy responses in China since the late 1970s, an inductive approach has been adopted. An inductive approach seeks to generate new theory or framework through observations and systematic analysis of empirical data. In this case, while previous research has identified key frames shaping a variety of specific issues in GHG (Section 2.4), this research does not assume that the same frames are at play in Chinese policy response to SF medicines. While these frames

are used as a potential starting point, this research is driven by observations and systematic analysis of empirical data, from which core policy frames will be identified and assessed.

Emerging from the epistemological stance and theoretical perspective, this research takes the form of a qualitative investigation. The emphasis is therefore about generating understanding through employing an interpretivism approach – as opposed to positivism which offers an explanation (Mash & Furlong, 2010). The investigation uses framing analysis, which is a particular causal-oriented and focused version of discourse analysis employed in qualitative studies (Lindekilde, 2014). Framing analysis can help us understand the construction of problems, the proposed solution (in the frame) and the effect of frames on policy responses. Analysis of framing thus requires careful attention to how policy discourses are purposefully crafted and mobilised in ways that shape how an issue is understood. To identify key frames at play in China's response to SF medicines over time, this research involved collecting data that describes a phenomenon of the social world and thereby helps construct explanations of said phenomenon. As such, two methods for data collection are employed: 1) a systematic literature search of published and unpublished grey literature on the development of the Chinese policy response to SF medicines; 2) a series of semi-structured (mostly face-to-face) interviews with key informants.

3.3 Data collection I: Documentary sources

The identification and analysis of framing of SF medicines in this research, require the issue to be located within Chinese history and culture and, in particular, within the context of shifting political economic structures, interests and processes in China. For this purpose, documentary sources are used to map key events, actors and policy decisions; as well as to understand the social construction of the SF medicines problem in China, through the identification of framing as expressed in "speech acts" or "utterances" by varied actors. To identify how the issue of SF medicines is framed in China by relevant actors over time, this research systematically reviews a large number of document material as primary and secondary sources from 1978 to 2021 (Table 3- 1), including: publicly available academic literature; government legislations and policies;

speeches and statements by public officials; reports by relevant business sector groups; consulting and legal firms; print and social media; conference records; and other grey literature. "Systematic" indicates that I have used an organised method for locating, assembling and reviewing the body of literature related to SF medicines.

Table 3- 1 Comprehensive review of documentary sources

	English sources	Chinese sources
Academic literature (on SF medicines outside China)	421	11
Academic literature (on SF medicines in China)	12	133
Official Chinese government policy documents	n/a	94
Yearbooks	n/a	35
Business publications including reports from pharmaceutical companies, pharmaceutical industrial associations, consulting firms	65	36
Other reports from international organisations, think tanks	36	8
Books on SF medicines and Chinese medicine regulation	6	25
Total	540	342

Academic publications

I conducted a review of secondary English and Chinese language sources from 1978 to 2021 using Google, Google Scholar and Baidu (the largest Chinese search engine). In addition, searches were conducted using the academic life sciences database PubMed, the social sciences databases Web of Science, IBSS, BASE, JSTOR, and the largest China-based academic database China National Knowledge Infrastructure (CNKI). The search used the keywords "counterfeit*", "fake", "falsified", "substandard" OR "pirate* AND "medicine*", "drug*" AND "China*".

This research begins by reviewing the existing English and Chinese-language literature to identify what is currently known about the history of Chinese policy responses to SF medicines from 1978 to June 2021. Databases searched for English literature included Google Scholars, PubMed, and social science databases including Web of Science, IBSS, BASE, JSTOR. To review and analyse SF medicines and policy response in China, more focus was placed on Chinese language data sources, including Baidu and CNKI using the keywords "counterfeit*", "fake", "falsified", OR "substandard" AND "medicine*", "drug*" AND "China*". For each database, the key terms "yao 药", "yaopin 药品" "yaowu 药物" – three different ways in Chinese meaning medicine/drug/pharmaceutical were searched. Additional searches were then conducted by combining the above searches with the keywords "medicine safety", "policy", ""law", "regulation" (监管), "supervision" (监督) and "administration" (管理). This literature provided an essential starting point for scoping out key issues, events, actors (individual and institutions) and policies concerned with Chinese policy responses to SF medicines. These key developments have been organised into an initial chronology. A total of 577 articles/reports were included in the comprehensive literature review: 433 English and 144 Chinese sources.

Official Chinese government publications

Extensive official Chinese language publications of the Chinese government since 1978 were consulted for this research, including: policy documents, legislations, speeches, statistics, mandates, and reports to compile a more detailed chronology of Chinese policy over time. A series of searches were conducted using internet search engines (mainly Google and Baidu). Critically, for policy documents such as national 5-year plans, decrees, opinions, circulars, and decisions, the research retrieved 93 number of available publications by authoritative bodies including the official websites of the State Council, the national medicine regulatory authority, National Reform and Development Commission (NRDC), Ministry of Health, Ministry of Industry and Information Technology, and Ministry of Commerce. Appendix B provide a comprehensive list of major legislation and official documents reviewed between 1978 and 2021 pertaining to SF medicines,

and more broadly on pharmaceutical regulatory policies. Another important official data source was the yearbooks (年鉴) published annually by the Ministry of Health and later the national medicine regulatory authority between 1983 and 2017 (details see Table 3- 2). These yearbooks were accessed by purchasing hard copies during fieldwork in China in 2012 and 2018 (no electronic copies were available). They document in detail the main activities, policies, and key speeches of the national medicine regulatory authority on issues pertaining to medicines, as well as statistical data on medicine registration, SF medicines, etc. Each yearbook was reviewed for speech acts and utterances that framed SF medicines in particular ways. Each book weighted about 2kg, so these speech acts along with other important information were photocopied in China and brought back to the UK for analysis. Other relevant information was manually compiled in OneNote yearly while in China, covering who applied these frames, how they were applied, and how they shaped policy responses in China over time.

Table 3- 2 Chinese national yearbooks consulted

1983-1990	China Health Yearbook (中国卫生年鉴) Before *China Pharmaceutical Yearbook* was first published in 1991, pharmaceutical affairs were presented in the *China Health Yearbook* with the inaugural yearbook published in 1983.
1991-1998	China Pharmaceutical Yearbook (中国医药年鉴)
1999-2003	State Drug Administration Yearbook (中国药品监督管理年鉴) This yearbook was first published in 1999 following the establishment of the SDA in 1998.
2004-2017	State Food and Drug Administration Yearbook (中国药品监督管理年鉴) Yearbooks were renamed the State Food and Drug Administration Yearbook in 2004 following the rename of the SDA to SFDA.

Official documents are critical for understanding how the issue of SF medicines is perceived and articulated in Chinese policy-making. According to Wu's research on Chinese documentary politics, "politically, *wenjian* (文件, its closest English counterpart is *document*)

covers all kinds of official paperwork produced by the government bodies. Such documents in China can be roughly divided into three categories: political, administrative, and information documents" (Wu, 1995: 25). A given document may perform all three functions of setting political principles, guiding daily administration, and offering information. The formulation of a document is a central part of the policy-making process and a document formulated or jointly drafted by multiple institutions is perceived as the final policy outcome, after settling conflicts among proponents of different policy preferences and disputes on issues across different governmental departments (Wu, 1995). Furthermore, Wu suggests that issues included in a document and the chosen wording, are usually carefully articulated (Wu, 1995) – which corresponds to the role of language in social construction of reality mentioned in Section 2.2.

Business publications

This study makes extensive use of business sector sources, including reports, statements, articles and information from the websites of pharmaceutical companies and industry associations. It consults official publications of major foreign policy actors including individual MPCs on SF (or counterfeit) medicines, such as Johnson & Johnson, Novartis and GSK, and major industrial associations representing MPCs (details of key actors in Chapter 6). It also reviews publications from major Chinese domestic pharmaceutical industry associations, but as most domestic industrial associations are affiliated with government departments, these are considered as quasi-business sources. Additional reports and articles published by consulting firms, such as McKinsey, BCG, PKMG, L.E.K., PricewaterhouseCoopers, on the Chinese healthcare and pharmaceutical industry, have been reviewed for background information on the changing nature of the Chinese pharmaceutical industry and healthcare sector. Finally, publicly available reports and articles from several law firms (mostly multinational law firms in China) on Chinese pharmaceutical regulatory and intellectual property systems were also consulted.

Other documents

This research consults other official sources, inducing relevant bilateral agreements, *Memorandum of Understandings*, publications of the US government, Council of Europe, etc. with some examples provided in Table 3- 3. It also includes documentary sources from international organisations such as WHO, International Pharmaceutical Federation (FIP), UNODC, and NGOs such as Oxfam, Médecins Sans Frontières, US Pharmacopeia; and consults relevant publications from both Western and Chinese think tanks, including Chatham House, RAND, Center for Strategic and International Studies, Sourthern Medicine Economic Research Institute (南方医药经济研究所) and ChangCe Thinktank (长策智库).

Table 3- 3 Other official publications consulted

Memorandum of Understanding between the Government of the United States of America and the Government of the People's Republic of China on the Protection of Intellectual Property (1992)
Agreement between the US Department of Human and Human Services and the China State Food and Drug Administration on *the Safety of Drugs and Medical Devices* (2007)
Transcripts and testimonies of the Congressional-Executive Commission on China on *Food and Drug Safety, Public Health, and Environment in China* (2013)
Transcripts and testimonies of the US-China Economic and Security Review Commission on *China's Healthcare Sector, Drug Safety, and the US-China Trade in Medical Products* (2014)
European Commission *Falsified Medicines Directive (FMD) 2011/62/EU* (2011)
Meeting reports and summary notes of *the US-China Joint Commission on Commerce and Trade (JCCT)*

Some major specialised Chinese language news sources on medicines have also been reviewed via their official websites or WeChat public accounts, including Pharmaceutical Economics News (医药经济报) (http://www.yyjjb.com.cn/, www.menet.com.cn), China Pharmaceutical News (中国医药报) (http://epaper.cnpharm.com/zgyyb/html/2019-02/01/node_21.htm), and PharmNet (http://www.pharmnet.com.cn/).

Finally, this research draws on grey literature including unpublished research reports, meeting notes, presentations (PowerPoint slides), internal reports and analysis by MPCs. These materials were largely collected through meetings with key informants during fieldwork. Indeed, grey literature was an important source of key insights which enriched the empirical analysis.

3.4 Data collection II: Semi-structured interviews

To understand more deeply about how SF medicines are framed by key policy actors, and the interaction between material and ideational factors, 70 semi-structured interviews were carried out in two stages in China, with the aid of interview guides. Appendixes E-G and H-J provide a full list of the semi-structured interviews (see Section 3.7 for anonymity and coding strategy) and samples of interview guide, in 2012 and 2018 respectively. The aim of the interviews was to elucidate and, to some extent, aid in understanding the key ideas and principles held by policy actors identified from the documentary sources described above. The format of the interviews was designed to allow key informants to tell their story of events, issues and debates as much as possible in their own words. Each key informant was given as much leeway as possible to express their own understanding and (retrospective) perception on SF medicines and policy responses in China.

Given the inductive approach taken in this research, a first set of interviews were conducted in 5 Chinese cities (Beijing, Shanghai, Hangzhou, Nanjing, and Tianjin) between March and July 2012 to scope out the parameters of this research, confirm key issues, actors and policy responses over time, identified through document analysis. This led to the initial identification of frames relevant to the Chinese context which, in turn, informed subsequent data collection. A second set of key informant interviews were conducted in Zhejiang Province between February and March 2018 as part of the Wellcome Trust project on medicine quality, to deepen understanding of the identified frames. Within this project, I led on a case study examining the interaction between international, national and state-level factors influencing Chinese API quality, production and regulation. These additional interviews were of great value to provide an update

on policy developments. A total of 70 face-to-face interviews were conducted during these two visits, with 51 and 19 interviews conducted in 2012 and 2018, respectively. Interviews typically lasted between 1 and 2 hours. Among the 70 interviews, the shortest lasted 45 minutes and the longest 220 minutes (if the interviewee did not have time constraint and was open to sharing insights, the researcher chose not to limit the time taken, but instead went with the flow). Table 3- 4 provides a list of interviews by the occupation type of key informants.

Table 3- 4 Categories of key informants

Occupation of Key Informants	**Total Number of Interviews**
Academics	21
Regulators (central and provincial medicine regulatory officials)	14
Officials from technical agencies (national and provincial institutes of drug control)	3
Other Chinese government officials (related to pharmaceutical economy and intellectual property protection)	2
Representatives from domestic and foreign pharmaceutical manufacturers	9
Representatives from domestic and foreign pharmaceutical associations	7
Chemical/pharmaceutical ingredients trading companies	5
Foreign chambers of commerce and embassy officials based in China	3
Consultancy and law firms	3
Journalists	2
International organisation (WHO China Country Office)	1
Total	**70**

Names of key informants were initially identified through literature and documentary sources. University academics were first approached via emails, due to their contact details being publicly available and ease of access. Key informants identified during a previous visit to the

Global Health Institute of Peking University on a medicine-related project in 2010, were also contacted in the first instance. In addition, personal contacts through families and friends in China (particularly for interviews in Hangzhou, Zhejiang Province) were also used to reach out to more key informants. Using personal contacts is a culturally common method of reaching out to people in China. The rest of key informants were identified and contacted mostly through snowball or chain sampling strategies, whereby initial key informants were invited to provide names of potential subjects for interview (Morgan, 2008). While it was more challenging gaining access to government officials given the potential political sensitivity related to the SF medicines issue in China, retired government officials who had taken up posts in pharmaceutical industry associations or government think tanks were interviewed wherever possible. In the business sector, most contacts were made through referrals from other interviewees. In general, representatives from foreign pharmaceutical companies and associations were easier to access than domestic Chinese companies.

Most interviews were conducted in person (except three telephone interviews) in Mandarin and, in a few cases, English. The adaptation of the interview guides was carried out to tailor them to the occupation and/or expertise of the subject (Appendixes F & I). A few informants were interviewed twice as they were deemed a rich source of information on the research questions posed, and were willing to be interviewed for the second round. During some interviews, I was also provided with some "internal circulation" (内部) materials which provided valuable understanding of the SF medicines problem in China. Each interview was audio recorded or through handwritten notes, depending on the permission provided by the subject. Sound recordings were then transcribed by the researcher. Only a fraction of interview data which was used in the thesis, was translated into English. Data were securely stored in Word documents and analysis was conducted via OneNote (this research did not use NVivo because the software did not code Chinese).

On the choice of locations, Beijing proved the main site for interviews conducted to access relevant policy-makers (incumbent and former) and policy advisory bodies, such as think tanks and university research institutes. It is also constituted the main location for the headquarters of key pharmaceutical companies and industry associations. Shanghai was an important site for meeting Chinese researchers and officials with interests in SF medicines. In addition, the medicine security branches of many MPCs are based in Shanghai. I took a day trip to Tianjin as one of the renowned scholars on pharmaceutical law-making was based in Nankai University in the city. I also spent 4 days at the China Pharmaceutical University (中国药科大学) in Nanjing, where the largest Chinese university specialising in research and teaching on pharmaceutical sciences and business is based. Hangzhou, the capital city of Zhejiang Province, was also a key site for interviews, particularly for the second round of interviews in 2018. Zhejiang Province is China's largest producer and exporter of APIs and home to four of the world's top ten producers (xueqiu.com, 2017). Hangzhou was also where my personal networks and connections through families and friends proved most useful.

This research also includes some important observation and meeting notes obtained from internal workshops and meetings. Attendance at these workshops were not known or planned before the fieldwork. I was invited by interviewees to attend eleven workshops related to medicine regulation and SF medicines. Examples of meetings included: *Forum on Health Legal System and Institution Building* organised by China Society of Economic Reform (a government think tank); *Pharmaceutical Working Group Meeting* at the European Union Chamber of Commerce; and the *Forum on Pharmaceutical Intellectual Property Protection* organised by the Center for Intellectual Property Study, Fudan University in Shanghai. I was given consent to draw upon some speeches and meeting notes recorded as data for this research. In addition, I also participated in the 3-day *WHPA/FIP Stakeholder Meetings on Quality and Safe Use of Medicines*[4]

[4] WHPA stands for the World Health Professions Alliance. FIP is a member of WHPA. WHPA started campaigns to raise awareness of health professions in the fight to combat SF medicines since 2010, by launching four regional-wide campaigns in Central America, the African continent, Asia and Central European in 2010 and 2011. In 2012, WHPA intended to conduct a campaign in China, the first campaign

with a colleague from International Pharmaceutical Federation (FIP). Stakeholder Meetings involved representatives from seven organisations including the US and UK Embassies, RDPAC, Pfizer, leading Chinese associations representing health professions such as the Chinese Pharmaceutical Association and Chinese Medical Association. I drafted the summary report after the trip, and upon consent from FIP, meeting notes of the report were available for analysis of this thesis. These events and meetings proved very helpful for generating valuable insights on how issues were discussed, with different perspectives emerging from the real life setting that often wouldn't otherwise develop from one-to-one interviews. Participation in these events helped data triangulation that supplemented the interviews. In addition, these events also opened doors for additional interviews, as I was able to establish new connections with potential key informants.

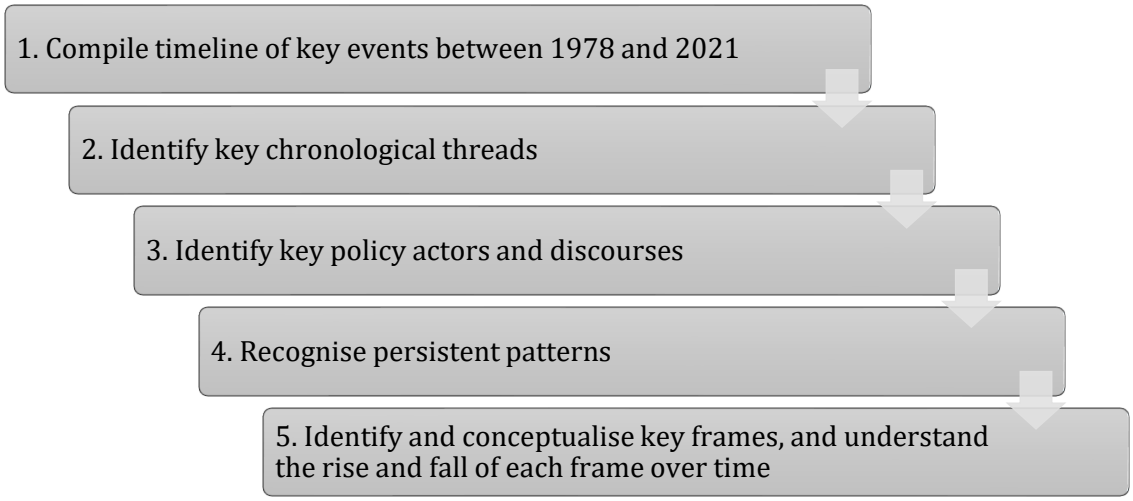
3.5 Data analysis

To contribute to a fuller understanding of China's shifting policy responses to SF medicines, this research goes beyond the existing scientific evidence on SF medicines, institutional competencies, through incorporating both material and ideational factors to analyse how social reality is constructed, perceived and responded to by policy-makers. By doing so, I argue that the multiplicity of policy responses adopted over four decades, can be more fully understood by shifting the analytical focus to policy framing and the "social construction" of SF medicines as a policy problem in China. Framing is used in this research as a hermeneutic tool to provide a deeper understanding of the effectiveness of policy actors, in terms of, how they portray and communicate issues in ways that gain political attention. This requires analysis of both material and ideational factors, and how they interact to produce policy responses over time. Moreover, is I hypothesise that how such factors play out differently across the experience of diverse policy actors, may better explain convergence or divergence of policy responses across different parts

focused on a single country. The campaign was led by Xuanhao Chan, the lead technical officer for FIP who was a PhD student at LSHTM, and a personal acquaintance of mine. These stakeholder meetings were initial scoping meetings conducted in Beijing with representatives from key organisations to understand activities and key players for combating SF medicines in China.

of the Chinese government. Like the Chinese expression "nine dragons trying to harness rivers" (九龙治水), framing analysis helps uncover the multiplicity of reality, the underlying causes of policy challenges, and how China has been trying to overcome these challenges by shifting policy framing and responses over the past four decades. Data analysis in this research thus follows the following five steps (Figure 3- 1).

Figure 3- 1 Process of data analysis



Step 1: Based on the literature review and documentary sources, a list of main chronological events between 1978 and 2021 were compiled on an Excel spreadsheet. These events included: changes in political leadership, structural and name changes to the national medicine regulatory authority, major incidents of SF medicines and public health crises, enactment of new laws, and issuing of major policy documents on SF medicines by the central government.

Step 2: This step involved identifying key chronological threads of events, such as the establishment of China's first national medicine regulatory authority in 1998, the 2002/3 SARS epidemic, the change of Chinese political leadership in 2003 and 2012. These threads informed the organisation and empirical analyses of Chapters 4 to 6 (as explained in Section 1.4). For Steps

1 and 2, documentary sources were more abundant, accessible and useful for compiling a chronology of key events and policy developments over time.

Step 3: This step involved the identification of key actors and the extent to which they held particular discourses on SF medicines and policy responses in China. This step helped to identify the main policy ideas through which SF medicines have been understood and interpreted. Documents and interviews were collected to help identify and understand what discourses were present among the key policy actors involved in SF medicines, as they either contain "speech acts" or "utterances" about the problem, or reflect actions that are framed within such discourses (for the process of recognising a specific discourse). In doing so, I did not privilege ideational variables, but rather suggests that the inclusion of ideational factors provides a fuller understanding of China's policy responses to SF medicines.

Step 4: The fourth step was to recognise persistent patterns. For example, political leaders carefully changed the wording to describe pharmaceutical industry from "social welfare industry" to "a big economic industry" beginning in the early 1980s and then consistently thereafter. This indicates the way they changed the frame of the issue, and when they persistently did so, they ultimately shaped issue perception and policy response.

Step 5: The final step of data analysis incorporated the conceptual framework and identified key frames which emerged from the general discourses and conceptualisation of each frame. Detecting the frames is part of discourse analysis. As this research takes an inductive approach, each frame organically grew from empirical observations, rather than being pre-determined. Some frames may be in line with GHG frames previously identified in the existing literature, while others are distinct to the Chinese context. Even when the same key frame has been identified, this research finds that there may be a distinctly Chinese understanding or interpretation of the frame and its policy effect. Each policy frame is introduced and conceptualised in the empirical chapters.

3.6 Caveats

Analysis of China's policy responses to SF medicines has required me to navigate a number of methodological challenges. The study of public policy-making in any context is challenged by the capacity of the researcher to access appropriate and sufficient data, as a policy "outsider", to reveal the inner workings of government. In a country ruled by a one-party system, governmental processes are particularly closed to external scrutiny (Hu, 1998). This poses additional difficulties for data collection and analysis. Understanding public policy-making in China over a long historical period, faces barriers to accessing documentary records and key informants, such as past and incumbent government officials.

Further methodological limitations are explained in more detail in Chapter 9. Briefly, this research reviewed whatever documents were available publicly, along with data collected from fieldwork, to enable the use of multiple sources of data to triangulate findings. I relied on analysis of speech acts and other utterances gleaned from available documents, key informants and participation in key stakeholder meetings.

Interviews were especially important sources for data verification and triangulation. The interviews specifically sought to focus on the way key informants used language directed towards SF medicines, where much of their beliefs, values and ideas tend to be expressed. Such use of language can hardly be captured simply by analysing the documentary sources, and thus interviews were useful in clarifying the ideas and values of the key informants who were identified during document analyses. One fruitful example was interviews with local government regulators and officials which proved an important source to understand their policy mindsets and responses at local levels (information is not available in Yearbooks or other forms of documentary sources). Interviews were also especially useful for discovering things usually unpublished. For example, interviews were great sources to understand MPCs versus domestic pharmaceutical companies' perceptions of, and responses to, SF (or counterfeit) medicines, and

helped generate more detailed insights into MPCs' lobbying activities and policy influence. This type of information is largely undocumented in China and can only be collected via interviews.

3.7 Research ethics

This research received approval from the Ethics Committee of the London School of Hygiene and Tropical Medicine in 2012 given the involvement of human subjects in key informant interviews. As well as receiving support from supervisors Professor Kelley Lee and Dr Anne Roemer-Mahler in submitting the ethics application, Dr Roemer-Mahler accompanied me on several interviews during her visit to Beijing, China in June 2012 to ensure compliance with recognised ethical principles.

The researcher followed the principle of informed consent to ensure subjects were provided with the information needed about the project to make an informed choice about whether or not to participate and how they agreed to be cited (Oliver, 2004; Green & Thorogood, 2005). Prior to each interview, key informants were provided with a consent form (Appendixes E & H), explanation about the aims of the study, the voluntary nature of participation, and the steps to be taken to protect confidentially (i.e. data storage strategy and anonymity of subjects). In addition, informants were asked to complete and sign the informed consent form at the beginning of interviews.

Regarding the use of data from interviews, all subjects were permitted several options to preserve confidentiality. Anonymity was especially important for Chinese government officials, who were cautious about disclosing their identities. Providing confidentiality arguably also encouraged more candid responses. In this research, individual names, formal positions and institutional affiliations are cited in full or partial depending on the preference of individual interviewee as given in the consent form. As shown in Appendixes G and J, most interviewees chose to remain anonymous. Interviews have been coded using a standardised format to optimize data organisation and protect anonymity. Coding for the five cities where interviews were conducted are:

BJ: Beijing

HZ: Hangzhou

NJ: Nanjing

SH: Shanghai

TJ: Tianjin

For example, "Interview 01BJ120312": "01" is the interview serial number (by chronological order), "BJ" represents the city where it was conducted, "120312" means the interview date was 12 March 2012 (ddmmyy). In a telephone interview, the code TEL is added, e.g., a telephone interview conducted in March 2018 was file coded as "Interview 14TEL050318". Coding of meetings and workshops have followed a similar format: short name of a meeting/workshop, following by a city, following by a date. Examples are: "Meeting IFBJ100312", "Meeting EUCBJ120312". Sound recordings and transcripts were stored electronically on the hard drive of my personal laptop.

3.8 Summary

This chapter presents the data collection and analysis procedure used in this research to address the research questions and objectives set out in Section 1.3. It employs two methods of data collection: documentary sources and semi-structured interviews. It then explained the procedure for identifying core policy frames, including how to recognise a frame, its features and the extent it is held by actors. The following four chapters present empirical analysis through applying the theoretical framework set out in Chapter 2 and data analysis procedure in Chapter 3, to identify and conceptualise core frames, as well as analyse the effect of frames on policy responses.

Chapter 4 Medicine Commercialisation and the Economism Frame (1978-1998)

4.1 Introduction

This chapter analyses China's policy responses to SF medicines, from the initiation of Premier Deng Xiaoping's market reform policy in 1978, to before the establishment of China's first national medicine regulatory authority in 1998. During these two decades, China experienced major domestic reforms, spanning economic policy, social policy, and the legal system. The pharmaceutical sector was among the earliest industries in China opened up for domestic market competition and foreign investment since the early 1980s (Wei, 2009; Liu, 2011). With China's integration into the world economy through globalisation, China re-joined selected global governance institutions like the Asian Development Bank in 1986, the World Intellectual Property Organisation in 1993, and was preparing to join the WTO, which it did in 2001.

In this context, this chapter analyses the shifting social construction of medicines, from a social welfare commodity to a commercial (or economic) commodity, as a top-down process in China amidst economic reforms. It identifies the first core policy frame – economism – and explains how the re-framing of medicines affected the way the problem of SF medicines was perceived and responded to. This analysis also takes into account material factors such as institutions, special events, and local human and financial resources. From this, it reveals that the strong influence of the economism frame, and consequent focus on the economic implications of SF medicines, limited attention and resources given to regulating safety and quality at both central and local government levels.

4.2 China's shifting perception on medicines amid economic reform

This section sets out the broader policy context in China after 1978, as Chinese policy-makers began to embrace a new reality that medicines are a highly profitable commodity and an important economic driver, replacing the traditional narrative of medicines as a social welfare

commodity during Mao's era. From this, I argue that the way the framing of medicines was re-constructed, directly affected how SF medicines were then perceived and thus, became the basis upon which China's policy responses to SF medicines were premised. The resultant impact on policy-making is then set out in the following sections.

4.2.1 Medicines as a "special" social welfare commodity under Mao

Prior to China's economic reforms in 1978, medicines were largely perceived as a "special commodity" (特殊商品)[5], with Chinese policy-makers placing strong emphasis on social welfare goals and attributes such as quality and universal access. Under the centrally planned economy during the Mao Zedong era (1949-1976), health and social welfare provision were shaped by Communist political ideology and a socialist economic (i.e., state planning) system which emphasised egalitarianism and universalism. The state thus played the central role in the health system (Guan, 2000; Duckett, 2011; Huang, 2013), while the pharmaceutical sector was structured to support this health system based on principles of equity and universal access (Duckett, 2013; Huang, 2013). Hence, medicines were considered essential public goods rather than a source of profit-making. Medicines production was centrally planned, using publicly funded capital, with production quotas set by a central ministry, such as the Ministry of Petroleum and Chemical Industries (Lampton, 1978). Research was conducted on products selected by these central planning processes and shared among all manufacturers. Products were then distributed via the state network of hospitals and retail pharmacies, and sold at set, government-subsidised prices. Even when relatively efficient pharmaceutical manufacturers were able to earn profits, these profits were not retained by the enterprise but remitted to the central treasury (Lampton, 1978). Available literature and policy documents from this period, identified that growth was not a policy goal for the pharmaceutical sector (Wei, 2009; Chen *et al*., 2010; Liu, 2011). In order

[5] In his book *History of the Chinese Medicinal Industry*, Tang (2007) states that since the Chinese ancient time, there has been discussion on special attribute vs. commercial attribute of medicines.

words, China under Mao had a pharmaceutical welfare system, not a pharmaceutical market system.

The political upheavals of the Great Leap Forward (1958-1962) and the Great Proletarian Cultural Revolution (1966-1976) adversely impacted many parts of the Chinese economy, including the pharmaceutical sector. Before China's major economic reforms in 1978, the pharmaceutical sector was left with major disruptions in production and supply shortages, alongside widespread problems with quality regulation. During this period, the government seemed to be intolerant of SF medicines. This perspective, based on Cultural Revolution ideology, was evident in the first national medicine regulation policy issued by the State Council, known as the 1978 *Drug Administration Regulations*. Article 7 of the *Drug Administration Regulations* stated that "all levels of health and medical bureaus should pay close attention to the class struggle on medicines, criticise capitalism, criticise revisionism, and strictly ban substandard and falsified medicines" [*translated from Chinese by the author*]. Paradoxically, medicine regulation prior to 1978 was deemed as politically incorrect and unnecessary. Medicine regulators were seen as "the bourgeoisie in the field of medicine taking the path of white expertise[6]" (资产阶级在医药领域的白专路线) (Liu, 2011), meaning medicine regulation served the interests of capitalism and the middle class rather than the masses, particularly those living in rural areas (the focus of Mao's public health policy). The previous medicine regulatory system of production and distribution, developed over time from the establishment of the People's Republic of China in 1949, was largely abolished due to its perceived political incorrectness (Liu, 2009). Many pharmaceutical factories became controlled by so-called revolutionary committees (consisting of representatives from the Communist Party, workers, and People's Liberation Army) whose members largely had limited knowledge about medicines, their manufacture or regulation. Instead, quality and safety largely relied on moral principles or ideology. The overall policy goal was to make medicines available

[6] The term "white expertise" was used to refer to individuals who performed well at academic studies but were considered to have a poor understanding of politics. This was a criticism used to attack individuals from families with scholarly backgrounds during the Cultural Revolution.

to the masses, with little attention paid to the need for regulation per se. Overall, the Chinese pharmaceutical industry in the pre-reform period was characterised by limited autonomy for company managers, strict control over labour mobility, and weak material incentives, where opportunities for improvements in quality and productivity were stifled (Brandt *et al*., 2008).

4.2.2 Re-framing medicines towards commercialisation: Context and actors

The death of Mao Zedong in 1976, and the ensuing internal battle for political leadership, eventually gave way to the historic emergence of Deng Xiaoping as Premier and his agenda for fundamental political and economic reform (Duckett, 2011). Deng introduced a gradual but steady period of change – tempering the central planning system of the previous era with selective adoption of market-based reforms. The reforms were declared by the Third Plenary Session of the 11th Central Committee of the Chinese Communist Party (CCP) in 1978 as "taking economic construction as the core" (以经济建设为中心). This pivotal meeting of the CCP marked the beginning of the reform and opening up policy under Deng's leadership. The aim was to enable Chinese people to generate wealth, based on the idea that "poverty is not socialism" and "to get rich is glorious". Deng set out achieving *Four Modernisations* (four areas of development including agriculture, industry, defence, and science and technology)[7] as key tasks, which would require hard work, enterprise and capital investment.

This significant change in CCP policy, in turn, shifted perceptions about how medicines should be produced and regulated. Chinese policy-makers in the post-Mao era began to realise that the older perception of medicines as a social welfare product with excessive state control, no longer served China's new strategic movement towards economic development. While maintaining medicines as a social welfare commodity, this research finds evidence for the re-framing of medicines as an economic product, prioritising its commercial potential. Qian

[7] *Four Modernisations* was first purposed in December 1964 by the Chinese Premier Zhou Enlai but was not prioritised by the government until Mao's death in 1976 (Mishra, 1988). With the emphasis on economic development, *Four Modernisations* became the core of CCP's policy contributed to China's economic growth during the 1980s and 1990s.

Xinzhong (钱信忠), the then Minister of Health and chairman of the National Family Planning Commission, was a key figure advocating policy reform and changes in thinking concerning medicines, during this early reform period. In 1978, speaking at the National Science Conference, Qian proclaimed that "Great progress must be made in modernising China's medical, pharmaceutical and public health work, and in raising the country's medical science to advanced levels by the end of this century" (quoted in Hillier, 1983: 124). In another speech given at the National Conference of Directors in Charge of Health Bureaus (全国卫生局长会议) in 1979, he called for a shift in understanding medicines among high-profile health officials, stating that "We need to shift the focus of health work to the modernisation of medicines and medical health. We are materialists." ("China Health Yearbook" Editorial Board, 1984: 22) [*translated from Chinese by the author*]. At the same national conference in 1981, Qian further criticised Chinese Leftists that supported social equity and egalitarianism, claiming they hindered the development of medicines and medical services more broadly: "For a long time, the 'leftist' thinking in our health work was serious. For a long time, due to the mistakes of 'leftism' in economic construction, health services have not been given their warranted place in the national economy." ("China Health Yearbook" Editorial Board, 1984: 47) [*translated from Chinese by the author*]. During that year, the State Council explicitly declared that "the medicine production and distribution is both our country's socialist economic work as well as the people's health welfare work" [*translated from Chinese by the author*] in its 1981 policy directive *Decision on Strengthen Pharmaceutical Administration*.

Following the political turmoil that arose in the wake of the pro-democracy demonstrations in Tiananmen Square in 1989, Deng made his famous "Southern Tour" in 1992, during which he reiterated the need to rebuild the country's confidence in CCP's leadership through more intensive reforms. With CCP declaring that building a socialist market economy was the ultimate direction of China's economic reform, rapid development of the stock market, flourishing of private enterprises and foreign investment were notable changes during the 1990s

(Guo, 2013). More senior policy-makers started to consciously re-frame medicines as an economic commodity vis-à-vis a social welfare commodity, in the pursuit of commercialisation of medicines as a target for reform. Chinese policy-makers began to emphasise that medicines, like other commercial products, should be produced and consumed according to market principles, and serve as a source for profit, employment and economic growth. The Deputy Secretary General of the State Council, Xu Zhijian (徐志坚), at a meeting with State Pharmaceuticals Administration (SPA) officials in December 1991, for example, stated that:

> The pharmaceutical industry is an important part of the country's entire industrial sector. The production and trade of medicines should be perceived with economic vision as a pivotal economic sector. The pharmaceutical industry is not only necessary for people's health care, but also an important source of finance for the country. This is not recognised by some people because in our history we often associate medicines with the old concept of "low-profit" "public welfare" work ("China Pharmaceutical Yearbook" Editorial Board, 1992: 39). [*translated from Chinese by the author*]

Similarly, Deputy Commissioner of the SPA Jin Tongzhen (金同珍), expressed disapproval at prioritising the social welfare attributes of medicines by publishing a keynote article in the 1992 *China Pharmaceutical Yearbook*, titled "The pharmaceutical sector is an important economic industry". He advocated for the commercial aspect of medicines to be prioritised in policy-making, and argued that the previous focus on the social benefits of medicines that ignored the economic benefits, was an obsolete thinking, because "it was wrong to perceive the pharmaceutical industry as part of social welfare" ("China Pharmaceutical Yearbook" Editorial Board, 1992: 64-68) [*translated from Chinese by the author*]. A 1996 speech by the Vice Premier Wu Bangguo (吴邦国) was also critical in promoting commercialisation of the pharmaceutical industry, where he stated:

> The pharmaceutical industry is not a welfare sector, it's a big industry. With the improvement in our country's living standards, people will consume less grains but more medicines. There will be an inevitable trend of increasing demand for medicines. The medicines sector is developing very fast. In spite of the international market, growth of domestic demand is also an important factor ("China Pharmaceutical Yearbook" Editorial Board, 1997: 3). [*translated from Chinese by the author*]

The SPA Commissioner Zheng Xiaoyu (郑筱萸) also urged expansion of medicine production and trade, establishment of export-oriented pharmaceutical companies, and increased foreign exchange income and earnings ("China Pharmaceutical Yearbook" Editorial Board, 1997: 45). The proposed reforms included decentralisation, privatisation and trade liberalisation from the mid-1980s, and the Chinese pharmaceutical sector experienced an unprecedented average annual growth rate of 17%, surpassing most other industrial sectors during this period (Shen & Xu, 2009). New policies mandating favourable treatment of foreign direct investment and a reduction in tariff barriers contributed to the rapid growth of the pharmaceutical sector (Chapter 7 has more on foreign investment). Total output tripled in value between 1980 and 1995 (Cooke, 2008). Between 1985 and 1997, the total number of Chinese pharmaceutical manufacturers increased from 2,731 to 5,100, and total number of distributors rose from 53,269 to 86,000 (Liu, 2010).

These types of statements by politicians, and the policy reforms accompanying them, shifted prioritisation the commercial attribute of medicines. This research argues that speech acts by senior Chinese policy-makers and CCP members, and the frequency with which they were deployed since 1978, had a considerable impact on constructing a new reality/understanding that medicines were foremost an economic commodity. Policy-makers began to call attention to the commercial aspects of medicines and to promote the legitimacy of presenting the importance of medicines to the national economy. Analysis of these speeches indicates a significant shift from previous narratives of medicines solely as serving social welfare. Changes in framing fit with the broader government strategy of promoting economic reform and growth; in other words, to transform a centrally-planned command economy into one in which market-oriented enterprises could flourish. As described below, however, the industry in the 1990s was largely filled with small-scale, inefficient manufacturers operating with obsolete manufacturing technology. The pharmaceutical sector shifted focus to price competition rather than equity and universal access. SF medicines soon became an overwhelming issue in China.

4.3 SF medicines: Issue framing and policy debates

The reframing of medicines as an economic commodity became central to policy responses to SF medicines. The first half of this section examines how SF medicines were viewed by Chinese policy-makers as a "market order" (市场秩序) problem, emphasising the goal of minimising disruptions to production and market competition. Amid the rapid increase in incidents of SF medicines during the 1990s, the second half of this section discusses a return of the social welfare perspective on medicines. There, I analyse the main policy debates in China on whether policy priority should be given to the social welfare or commercial attribute of medicines. This research argues that, despite some efforts to reconcile these two perspectives and attempts to modify the existing policy direction, overall policy thinking remained centred on expanding the commercial attribute of medicines.

4.3.1 Constructing SF medicines as a "market order" problem

Amid an increasingly liberalised national economy, medicine production in China was boosted enormously. While the production of medicines was positioned to increase commercialisation, issues concerning quality and safety were largely left on the side-lines. The Chinese pharmaceutical market began to be plagued by SF products almost immediately following the initiation of economic reforms. It was already an acute issue during the Cultural Revolution, but became more serious. A 1979 cross-departmental report (full name in Box 4- 1) revealed the scale of the SF medicines problem: "Surveys carried out in Jilin, Liaoning, Henan, Anhui and other provinces revealed that unauthorised medicine manufacturing factories accounted for about 70 per cent of the total pharmaceutical manufacturers." (Ministry of Health *et al*., 1979) [*translated from Chinese by the author*]. By the end of 1985, more than 11,300 cases of SF medicines were prosecuted, valued at 180.67 million yuan (US$61.45 million equivalent[8]) ("China Health Yearbook" Editorial Board, 1986: 176).

[8] Based on the 1985 exchange rate ¥2.94 = US$1.00.

The perception that SF medicines were a problem of market order was first suggested by the Ministry of Health, who was the main governmental agency responsible for addressing SF medicines before 1998 (as defined by Article 2 of the 1984 *Drug Administration Law*). Policy responses were conveyed mainly through administrative directives (see Box 4- 1) by the Ministry of Health, or in consultation with other government agencies. Administrative documents were key instruments in China for mobilising political campaigns to address specific issues, including SF medicines, through mass mobilisation and are often repeated periodically (Lieberthal, 2004). Between 1979 and 1982, the Ministry of Health led three political campaigns to combat SF medicines, which repeatedly emphasised the need for "rectifying the market" to eliminate unlicensed and illegal production and distribution. For example, the 1980 *Implementing Rules* (full name in Box 4- 1) stated the purpose of the campaign was "to rectify and change the chaotic situations in the pharmaceutical sector, whereby factories are set up against the regulations and medicine production is carried out unknowingly" (Ministry of Health, 1980) [*translated from Chinese by the author*].

According to official reports at that time, the problem of SF medicines was seen as caused by a "disorderly market" (不规范市场) which was flooded with unregulated, semi-regulated and/or criminal activities. Policy responses to SF medicines thus focused on investigating and revoking illegal business licenses, and shutting down unregulated trading markets in an effort to restore "order". Some scholars argue that linking SF medicines to "rectifying the market" further changed the way people perceived the issue (Song & Hu, 2008; Liu, 2011), with less emphasis on public health consequences.

Box 4- 1 Major administrative policies and legislations on SF medicines (1979-1998)

1978 *Drug Administration Regulations*
1979 *Report of the Ministry of Health, State Planning Commission, State Economic and Trade Commission, Ministry of Chemical Industry, Ministry of Agriculture, Ministry of Commerce, General Logistics Department of the People's Liberal Army, and State Pharmaceutical Administration on Carrying out a Nationwide Campaign to Rectify Pharmaceutical Manufacturers*

1980 *Detailed Implementation Rules of the Ministry of Health on Carrying out a Nationwide Campaign to Rectify Pharmaceutical Manufacturers*

1980 *Circular of the State Council for Approving and Forwarding the Report of the Ministry of Health and Other Agencies on Strengthening the Administration of Pharmaceutical Affairs and Prohibiting the Production and Sales of Falsified and Substandard Pharmaceuticals*

1981 *Decision of the State Council on Strengthening Pharmaceutical Administration*

1984 *Drug Administration Law*

1992 *Circular of the Ministry of Health on Further Carrying out the Investigation and Punishment of the Illegal and Criminal Activities of Manufacturing and Sales of Falsified and Substandard Drugs*

1994 *Urgent Circular of the State Council on Further Strengthening Drug Administration*

1996 *Circular of the General Office of the State Council on Continuing to Rectify and Standardise the Market Order in Pharmaceutical Manufacturing and Business Operation and Strengthening the Work of -Pharmaceutical Administration*

1997 *Criminal Law* (*Chapter III Crimes of Disrupting the Order of the Socialist Market Economy*)

The term "market order" did not simply arise, but appears to have been used by policy-makers to reframe the SF medicines issue. The official coining of the term "market order" occurred in a Communiqué issued by the CCP in 1993[9], after which it was used instead of "planned order" to describe decisions on production and investment by the central government (Fang 2004). As defined in the Communiqué, market order consists of three key components in China in this context: order for market entry and exit (市场进出, e.g. licensing policy); order for market competition (市场竞争); and order for market trading (市场交易)[10]. This term was developed to re-affirm that the party/government still played a central role in economic transformation, with maintaining market order "critical for improving and strengthening the management and supervision of the market."[11] In 1990, the then Deputy Minister of Health Hu Ximing (胡熙明), speaking at the opening ceremony of *the National Medicine Supervision and Administration*

[9] 1993 *Decision of the Central Committee of the Chinese Communist Party on Some Issues Concerning the Establishment of a Socialist Market Economic Structure*
[10] Ibid 9
[11] Ibid 9

Conference, stated that "Medicine supervision and management work, not only constitutes an important part of the entire health services, but is integral to the governance of the economic environment and rectification of the economic order" (Hu, 1991: 7) [*translated from Chinese by the author*]. This statement suggests that the economic impact of SF medicines on the market system, seemed to have become a more pressing concern for the Chinese government.

A 1996 *Circular* (full name in Box 4- 1) suggested that the problem of local protectionism and corruption (e.g., the activities of officials accepting kickbacks), facilitated the spread of "disorderly market" activities. Campaigns centred on "rectifying market order" to crack down on SF medicines, such as clearing up unlicensed and partially licensed manufacturers, and closing down illegal pharmaceutical markets distributing and selling Western and herbal medicines.

The classification of SF medicines under the Chinese *Criminal Law* reinforced this framing to prioritise market order. In the 1979 *Criminal Law*, criminal prosecution of falsified and substandard medicines (Article 164) was classified under *Chapter VI Crimes of Obstructing the Administration of Public Order*. In the revised 1997 *Criminal Law*, prosecution for SF medicines (Articles 141 and 142 respectively) was categorised under the more economic-oriented category of criminal sanctions – *Chapter III Crimes of Disrupting the Order of the Socialist Market Economy*. Notably, the 1997 *Criminal Law* developed a new *Section 5 Crimes of Impairing Public Health* under *Chapter VI Crimes of Obstructing the Administration of Public Order*. However, SF medicines was not put under this category. The health impacts of SF medicines did not seem to be prioritised in the legislation adopted during this period.

Chapter 5 further explains the concept of "market order" in China's responses to SF medicines in the 2000s. The term is later expanded to incorporate IPRs protection, along with selected social and political dimensions. Over time, the frame has evolved and remains an important ideational factor shaping China's responses to SF medicines.

4.3.2 On-going policy debate on medicines: Commercial attribute vs. special attribute

By 1990, total number of enterprises distributing medicines grew to 33,857, with 10,946 (32%) distributors without licenses and 7,658 (23%) with incomplete licenses (Wei, 2009). Detected cases of falsified medicines rose from 17,000 in 1992 to 24,500 in 1993, and 41,700 in 1994 (Yu, 2008). At this time, Chinese policy-makers began to reflect on how medicines should be perceived, and whether prioritising the commercialisation of medicines was the best way forward. This led, to some degree, to the return of the old narrative of medicines being a "special" and "social welfare" commodity. For example, at a December 1989 meeting with directors of provincial and municipal bureaus charged with regulating medicines, Li Tieying (李铁映, a member of the Political Bureau of the CCP Central Committee and State Councillor) stated:

> I am in favour of this claim, that medicines are a special commodity for disease prevention and treatment, family planning and emergency relief. It is directly related to people's health and safety of life. Its production, distribution, and administrative systems must respect the special nature of this commodity. We also need to acknowledge that we are a socialist country, medicines should directly alleviate people's suffering and support the interests of the populace. ("China Pharmaceutical Yearbook" Editorial Board, 1991: 42) [*translated from Chinese by the author*]

At the same meeting, Shi Huan (石岘), then Deputy Director of the SPA, also emphasised that the special attributes of medicines should not be neglected, amid local governments strongly focus on generating revenues. He provided the example of a county with a population of less than 500,000, with about 20,000 people (4% population) selling medicines and other products that were either falsified or substandard ("China Pharmaceutical Yearbook" Editorial Board, 1992: 78-81). Furthermore, those in support of prioritising the special social attributes of medicines proposed the establishment of a state monopoly (医药专营) over medicine distribution. Although this was not implemented, it marked an important policy shift. Li Tieying was the main political leader advocating for this scheme and emphasised that, due to the special nature of medicines in a society, a strict closed-loop system was needed so that all wholesale and retail production and distribution processes remained subject to centralised regulation ("China Pharmaceutical Yearbook" Editorial Board, 1993). Shi Huan also fully supported the scheme, arguing that "In the

current chaotic pharmaceutical market where people feel insecure about using medicines, a state monopoly could combine the special and commercial attributes of medicines in a positive way." ("China Pharmaceutical Yearbook" Editorial Board, 1992: 79) [*translated from Chinese by the author*].

In July 1991, China launched the first pilot scheme of centralised medicine production and distribution in Nanyang, Henan Province. Later that year, in October 1992, the policy proposal won the backing of then Deputy Prime Minister Zhu Rongji (朱镕基), who issued a statement supporting the pharmaceutical state monopoly and instructed relevant government agencies to draft regulations for implementation. By April 1994, this piece of regulation was incorporated into the *1994 Legislative Work Plan of the State Council* by the Legislative Affairs Bureau. However, there was limited further progress made after 1994 and the scheme was strangled for various reasons. It has been difficult for me to trace the details of these deliberations. However, as described below, overall the economism frame remained dominant within the central Chinese government. Commercialising the pharmaceutical sector was a key priority during a period when China was seeking further integration into the world economy, including membership of the WTO.

Although the proposal for a state monopoly failed, the Chinese government seemed to be more determined to tackle the rising problem of SF medicines. Major incidents including Bai Wusong (白武松) and the Zhoukou case (see Box 4- 2 in Section 4.6), served as catalysts for elevating quality and safety issues in high-level policy thinking. The Chinese government issued the first death sentence to Bai Wusong in 1993, for producing falsified medicines and causing the death of 7 children, 1 adult, and many injuries (Ren, 2007). Quality issues began to be frequently reported by the CCP's mainstream news media, including the *People's Daily*, *Chinese Youth Daily* and *CCTV* during the 1990s (Liu, 2010). During this time, the State Council issued a key policy document, an *Urgent Circular of the State Council on Further Strengthening Drug Administration* in 1994, the highest administrative measure on medicines since 1981, to address the SF medicines. Concurrently, the central Chinese government held three high-level meetings in 1994

exclusively on SF medicines ("China Pharmaceutical Yearbook" Editorial Board, 1995). At these high-level cross-departmental meetings, the State Councillor[12] Peng Peiyun (彭佩云), senior officials from the SPA, the Ministry of Health, the State Administration for Industry and Commerce, and the State Bureau of Quality and Technical Supervision, all spoke about the growing quality and safety issues in the pharmaceutical sector, with negative impacts for people's health, social stability, and the government's reputation ("China Pharmaceutical Yearbook" Editorial Board, 1995).

4.4 The economism frame: Core ideas and policy context

As discussed above, the first key policy frame identified in this research is the economism frame. Applied to SF medicines in the early reform period from the late 1970s, the economism frame suggests that the SF problem in China stems from the nascent pharmaceutical industry. This argument states that policy responses should give priority to development and promotion of the market economy (commercialisation of medicines), with development of the pharmaceutical industry helping to eliminate SF medicines. As shown in Chapters 5-7, this frame does not remain static and was later adapted and expanded). This section therefore introduces the fundamental core ideas of the economism frame.

Economism is the fundamental belief that economic-based forces can best allocate scarce resources in a society among competing and unlimited needs and wants, including issues concerning distribution and efficiency. Economism, in the context of public policy, concerns the portrayal of a policy issue (problematisation) and prioritisation of potential responses based on economically-defined values, goals and actions. In global health, as discussed in Chapter 2, economism values efficiency, consumer choice, and market-based competition in the distribution of scarce resources (McInnes & Lee, 2012b). Importantly, economism distinguishes the political power of economic ideas from the academic discipline of economics. As Kay (2008: 19) writes,

[12] State Councillor is a senior CCP position within the State Council, ranking below Vice-Premier but above all ministers of various government departments.

"the term 'economism' refers to governance structures where economic logic or economically inspired advice is institutionally embedded, normalised and held as necessary in the determination of policy choices". A policy informed by economic logic is the outcome of an explicitly political process which has both political intentions and political consequences. In other words, the economism frame identified in this research emerges from economic logic/ideas that interact with social and political ideas and contexts.

Economic ideas in China, of course, encompass a broad range of thinking. Chinese economic theory and policy thinking in the post-Mao era was dominated by Deng Xiaoping's pursuit of a modernised economy that would materially improve the life of Chinese citizens (Magnus, 2018). Since 1978, Deng and his allies believed that the key problem confronting China was not class struggle but economic growth (Shirk, 1993; Peerenboom, 2002). Driven by a desire to lift a vast population out of poverty, economic policy focused on developing a more efficient economy that could produce the highest possible rate of economic growth, advance technological change, raise living standards, and bolster China's participation in the world economy (Lieberthal, 2004; Chen, 2006; Russell, 2007; Chan *et al*., 2008; Saich, 2011). The key dimensions of China's economically defined values, goals and actions are:

- economic growth;
- industrial development, including extending industrial capability which is measured by the capacity to sell into overseas markets (Brandt *et al*., 2008): include closing the quality and innovation gaps between the domestic/local pharmaceutical firms in relation to the MPCs (Brandt *et al*., 2008; Sutton, 2012);
- earn foreign exchange through export;
- increase taxation; and
- enhance local economic development and employment.

Economic reforms in China since 1978 led to widespread and profound changes in health policy thinking. Social welfare before the reforms, based on socialist and egalitarianism ideology,

was seen as an impediment to achieving economic growth. A different view evolved from Beijing's health and finance departments, who advocated that the "social welfare" approach was misleading and created a "one-sided emphasis on welfare" (Du *et al*., 2010). Chinese health policy was hence reinterpreted, such that health care as solely public welfare was no longer tolerated by top political leaders. While national policy priority began shifting to embrace market mechanisms, market principles were widely introduced in the delivery of healthcare services, and public hospitals were transformed into profit-making institutions (Chan *et al*., 2008). It was believed that health and well-being could only be achieved through a strong emphasis on economic development. In other words, economic development was a precursor for higher living standards and, in turn, improved health and well-being (Duckett, 2013).

The effect of economism on health policy reform in China was further influenced by the rise and spread of the neoliberalism paradigm globally, shaping public policies worldwide from the 1980s. Economism thus gained significant purchase in health policy which, *inter alia*, privileges the commodification, privatisation, and liberalisation of health financing and service provision. The World Bank was among the most prominent international organisations supporting this profound ideational shift, via policy conditionalities linked to health development loans to low- and middle-income countries. The 1993 *World Development Report* set out the application of neoliberalism to health development (e.g., user fees, purchaser-provider split, contracting out, autonomous hospitals), which heralded a major shift towards the dominance of economic ideas and approaches (Walt, 1994; Borowy, 2013). Health policy in China was influenced by this global shift in ideas, including a reduced role for the state in providing health care services and financing, and increased individual responsibility for health and well-being (Guan, 2000). As analysed in the next section, health policy reform in China then had knock on effects on the issue of SF medicines. In particular, the retrenchment policies in the health sector from the mid-1980s, alongside top-down fiscal decentralisation, gave further impetus to the rise of economism at the local level. As described below, these two policies led to the emergence of

economic development-driven (some Chinese scholars refer to it as "developmental-oriented") local states, which posed enormous challenges for medicine safety and quality regulation.

4.5 Policy impact of economism I: Limited capacity of central government to promote medicine quality and safety regulation

Ideational and material factors interact to shape issue perception and policy responses, as described in Chapter 2. Shiffman (2009: 610) suggests that "ideational portrayals alone are insufficient for issue ascendance and sustainability; they must be accompanied by institutions that create, negotiate, promote and sustain these portrayals". This Section examines how the economism frame led to the creation of the State Pharmaceutical Administration which, in turn, reinforced core ideas underpinning economism. It reveals that the shift in framing of SF medicines to prioritise economic goals, cannot be separated from material factors that, in turn, sustain the economism frame.

4.5.1 Founding of the State Pharmaceutical Administration: Representing industry not public health

The Chinese State Pharmaceutical Administration (SPA), the precursor of the Chinese national medicine regulatory authority, established in 1978, was key to the ideational framing of the pharmaceutical sector outlined above. Briefly, the agency's set-up and focus on industrial policy re-enforced and sustained the economism frame. As Liu (2011: 152) puts it, the creation, institutional location and mandate of the SPA all "indicated the status of medicines in the national economy" [*translated from Chinese by the author*].

The creation of the SPA was supported by the Ministry of Health, who was the main government institution overseeing the regulation of medicine quality prior to 1998. However, the Ministry of Health did not seek to strengthen its regulatory capacity. Rather, it sought to extend its administrative powers from quality regulation to economic activities of medicine production and distribution. Before 1998, the Medicines Affairs Bureau (药政管理局) within the Ministry of Health, assumed the main responsibility for medicine regulation. This Bureau and its local

counterparts remained relatively small in size, with limited institutional capacity (Song, 2009; Liu, 2011). Professor Song Hualin (宋华琳), specialising in medicine administration law and regulation recalled:

> Prior to 1998, the division of the Medicines Affairs Bureau under the Ministry of Health, as well as local health bureaus, were supposed to regulate medicines. However, medicine regulation and law enforcement capacity were very weak because the overall function of medicine administration within the health bureaucratic system was very weak. The Ministry of Health was already overwhelmed by its responsibility for hospital supervision and dealing with infectious diseases. Medicine regulation was positioned very low. (Interview, 08TJ250312) [*translated from Chinese by the author*]

The Ministry of Health was actively involved in creating the State Pharmaceutical General Administration (SPGA, renamed the SPA in 1982), by putting forward a report to the State Council conveying its intention to first consolidate the administration of pharmaceutical manufacturers,[13] and then take over the leadership of the SPA (代管, see Table 4- 1). However, the Ministry of Health's political intention in gaining control over the SPA did not succeed. In proposing separation from the Ministry of Health, the SPA suggested that the administration of "health services and medicines required a separate division of speciality" (医药要专业分工) (Liu, 2011: 170). The SPA claimed that it was primarily positioned as an economic institution and hence should not be consolidated into the Ministry of Health – which had limited capacity to regulate the pharmaceutical industry from a "socialist economic work" perspective; in other words, limited capacity to sustain the economism frame.

The SPA was established as a designated "line department" for the pharmaceutical industry, a government body that would exercise exclusive authority over the industry with regard to ownership, business operations and industrial policy, along with regulatory enforcement. The SPA's primary mandate was to formulate policies to streamline pharmaceutical operations and centralise economic policy for the pharmaceutical industry (Liu, 2011; Hu, 2012b).

[13] The document Ministry of Health put forward approved by the State Council in 1978 was called the *Notification of the State Council for the Approval of the Ministry of Health's Report on the Recommendation of the Establishment of the State Pharmaceutical Administration*, which led to the formation of SPGA.

Notably, its role was not to strengthen regulation to improve quality and safety. Rather, where the SPA was located, and the boundaries set in its institutional mandate, indicate that its role was to support and sustain the economism frame.

With regards to institutional location, the SPA underwent several organisational changes between 1982 and 1998, under different departments but all oriented to economic policy goals (see Table 4- 1). For example, in 1982 the SPA became a vice-ministerial specialised bureau for the pharmaceutical sector under the State Economic Commission.[14] After a few years as an independent agency, it was integrated into the State Economic and Trade Commission in 1993.[15] Qi Moujia (齐谋甲), the Director General of the SPA, wrote a Special Discussion (专论) in 1993 centred on industrial administration (行业管理) as to the transformation of managing the pharmaceutical sector by various departments (prior to 1978), to a more centralised administration on medicines and industrial policy-making ("China Pharmaceutical Yearbook" Editorial Board, 1993: 53-62). There was no administrative mandate to regulate quality or enact regulatory reform to medicine administration. As Professor Song explained:

> Prior to 1998, the SPA was an agency with no separation between its administrative function and its role as an industrial enterprise. Its subsidiaries, local pharmaceutical corporations, oversaw medicine production and distribution. These corporations only cared about getting bigger and stronger. They didn't care whether the medicines were falsified or substandard. (Interview, 08TJ250312) [*translated from Chinese by the author*]

Table 4- 1 Institutional change of the State Pharmaceutical Administration (1978-1998)[16]

Date	**Name**	**Subordinate to (隶属)**

[14] The State Economic Commission (SEC) one was of the State Council's department existed between 1956-1970 and 1978-1988. Its initial responsibility covered comprehensive national macro-level economic management over the industry and transportation systems. SEC was officially closed in 1988 and replaced by the new State Economic and Trade Commission in 1993 which existed until 2003 before integrated into the Ministry of Commerce.

[15] In between in 1988, the SPA moved back to be directly under the State Council, but its authority on herbal medicines was separated and transferred to the Traditional Chinese Medication Administration Bureau (established in 1988).

[16] These changes were associated with the State Council's institutional reform, taking place every five years since 1982, to downsize and streamline the government organisational structures.

Jul 1978 – May 1982	State Pharmaceutical General Administration (国家医药管理总局)	The State Council (supervised by the Ministry of Health)
May 1982 – Feb 1988	State Pharmaceutical Administration (国家医药管理局)	The State Economic Commission (国家经济委员会)
Feb 1988 – Mar 1993	State Pharmaceutical Administration	The State Council
Mar 1993 – Apr 1998	State Pharmaceutical Administration	The State Economic and Trade Commission (国家经济贸易委员会)

This combining of regulator and regulated enterprises was further demonstrated by the SPA ownership of several manufacturers, including the China National Pharmaceutical Industry Corporation (中国医药工业公司), China Pharmaceutical Company (中国医药公司), China Medical Devices Manufacturing Company (中国医疗器械工业公司), and China Pharmaceutical Foreign Trade Corporation (中国医药对外贸易公司) ("China Pharmaceutical Yearbook" Editorial Board, 1991). SPA officials also held senior positions within some pharmaceutical firms. For example, Qi Moujia, the Director General of the SPA was the Managing Director for the China National Pharmaceutical Industry Corporation (中国医药工业公司). Jin Tongzhen, the Deputy Director of the SPA, served as CEO for China's first pharmaceutical joint venture with Sweden, the Sino-Swede Pharmaceutical Corporation ("China Pharmaceutical Yearbook" Editorial Board, 1994: advertisement page).

4.5.2 Implementing Good Manufacturing Practice: Economic and trade priorities

To ensure medicines are safe and work as designed, manufacturers must produce them according to a strict protocol known as Good Manufacturing Practice (GMP). According to Bate (2012: 36-37), "GMP is designed to ensure, among other things, that the medicine is appropriately soluble, any trace impurities are minimised, variations in the amount of API are small, API is sustained at

the requisite levels prior to expiration, and any degradation occurring prior to expiration is not dangerous." In addition, the protocol "regulates the condition of the building, qualification, and training of staff, cleanliness and sanitation, monitoring, supervision, and many other aspects of medicine production." (Bate, 2012: 37). Since the early 1990s, medicine quality standards such as GMP have been recognised by Chinese policy-makers as a critical means for improving product quality and thus promoting exports. Much emphasis was thus placed on how implementing GMP domestically served China's economic goals to increase international trade. With some progress made since economic reforms were initiated in the 1980s, deeper integration with the world economy required further action. Two major events gave important impetus to upgrading the domestic pharmaceutical sector, including acceleration of GMP implementation. One was China's preparation for resuming its status as a contracting party to the General Agreement on Tariffs and Trade[17] (GATT, the forerunner of the WTO in January 1995) since 1986. The second was the two memorandums of understanding reached between China and the United States on market access and IPRs in 1992.

Efforts to implement the GMP were viewed by various experts and senior government officials as a means to raise quality but, more importantly, to increase understanding of the economic importance of the GMP to China's pharmaceutical exports. Bo Qicheng (卜绮成), an expert on medical devices and an SPA senior official, wrote an article about the effect of GMP on China's GTTA membership and pharmaceutical trade:

> Whether pharmaceutical manufacturers meet GMP requirements or not is of major importance and will be examined in international pharmaceutical trade in recent years. For example, if China's pharmaceutical products were to export to the United States, they must first pass the GMP inspection of the US FDA ("China Pharmaceutical Yearbook" Editorial Board, 1993: p81). [*translated from Chinese by the author*]

[17] The Chinese government was a contracting party to GATT in 1948. After the Chinese Revolution and the founding of the People's Republic of China in 1949, the Taiwan authorities withdrew from GATT in 1965. The Government of the People's Republic of China officially applied for resumption of China's membership to GATT in 1986.

Bo also spoke repeatedly on how critical GMP compliance is to China's pharmaceutical export, stating that "[t]he government has been determined to embrace the market economy and participate in international competition. This requires China's economic structures and policies to move closer to the GATT system as soon as possible." He went on to assert, "the pharmaceutical industry's GMP and other quality assurance systems will also be forced to speed up implementation" because "manufacturers who do not meet GMP requirements, their products cannot enter the international market, and this will inevitably affect their domestic market sales." ("China Pharmaceutical Yearbook" Editorial Board, 1993: p. 74-85) [*translated from Chinese by the author*]. Other senior officials, including Qi Moujia, the Director General of the SPA, and Huang Dehui (黄得惠), the Director of Quality Management Department at the SPA, also gave speeches and published articles calling for the need to accelerate the implementation of GMP and the Good Supply Practice (GSP) from an economic and trade perspective. In Huang's Special Discussion in 1993 on implementation of GMP, he suggested that:

> Accelerating and strengthening the pace of GMP implementation is a major subject associated with the rise or fall of the pharmaceutical industry. It is a long-term task that the pharmaceutical industry must carry out under the socialist market economy regime. It is also in line with international standards and the needs of the international market. ("China Pharmaceutical Yearbook" Editorial Board, 1993: 67). [*translated from Chinese by the author*]

As GMP needs to be revised regularly in line with evolving science, Chinese regulatory authorities have frequently revised the domestic GMP guidelines since the early 1980s, known as the Chinese GMP (Table 4- 2). Despite policy-makers' emphasis on the pivotal role of GMP in achieving economic goals, evidence suggests GMP implementation was never satisfactory before 1998. Although Article 9 of the 1984 *Drug Administration Law* mandated that manufacturers adhere to GMP, GMP implementation was hindered by several factors, including institutional rivalries, voluntary rather than mandatory adherence, and inadequate expertise. Among these factors, the institutional rivalries between the Ministry of Health and the SPA were the most prominent.

There was an on-going battle between the Ministry of Health and the SPA over who held authority over GMP standard setting and implementation until 1998, as each maintained the other had inadequate expertise and lacked legitimacy. In the SPA's view, the Ministry of Health had insufficient expertise to formulate industry standards given its healthcare remit. More importantly, the SPA's overwhelming emphasis on industrial development was criticised by the Ministry of Health for not making medicine quality and safety the priority. The SPA emphasised the importance of the domestic market, encouraging more firms to compete but not enhancing capability to produce high quality and safe products. After the SPA revised the first Chinese GMP promulgated by the China National Pharmaceutical Industry Corporation in 1984, the Ministry of Health refused to recognise that the SPA had legitimate authority over GMP standard setting and enforcement, given its role in representing industry interests. In drafting the new *Drug Administration Law* during the early 1980s, the Ministry of Health intended to exclude the SPA's involvement in GMP, and argued that the SPA was the "mother for the pharmaceutical companies", who was inclined to adopt lower standards to reduce barriers for market access and generate income from licensing fees, by encouraging more firms to enter (Liu, 2011). However, even while the GMP was revised by the Ministry of Health in 1988, implementation was still voluntary (SFDA, 2009).

Table 4- 2 Chronology of Chinese GMP standards before 1998

Year	Chinese name	GMP formulation institution
1982	Drug Manufacturing Management Standards (药品生产管理规范) (Trial implementation within CNPIC) *First Chinese GMP*	China National Pharmaceutical Industry Corporation, the then largest state-owned pharmaceutical corporation
1984	Drug Manufacturing Management Standards (Revision of the 1982 GMP)	State Pharmaceutical Administration

1988	Drug Manufacturing Quality Management Standards (药品生产质量管理规范) *First Chinese GMP with statutory status*	Ministry of Health
1992	Drug Manufacturing Quality Management Standards (Chinese GMP Revision 1)	Ministry of Health
1998	Drug Manufacturing Quality Management Standards (Chinese GMP Revision 2)	State Drug Administration

4.6 Policy impact of economism II: Local governments[18] and the tight relationship between industrial and health policies

Since the 1980s, the central government began to implement a range of new policies to boost local development and economic growth. As local governments played an extremely important role in China's economic growth, as well as policy responses to addressing medicine quality, this section demonstrates how the framing of SF medicines described above resonates within the local context. Understanding the local policy environment helps us contextualise this shift in framing and reveals how economism has manifested locally. This section thus suggests that the decentralisation of medicine production, multi-tiered medicine standards, and the state's reduced role in the health sector since the 1980s, added further impetus to the economism frame at the local level. This, in turn, posed further challenges to strengthening medicine safety and quality regulation in China.

4.6.1 Decentralisation and the expansion of local medicine production

Since the 1980s, local governments were empowered to boost medicine production in order to address supply shortages and spur local economic growth. This decentralisation strategy was

[18] Local governments (地方政府) in China refer to provincial/municipal (省、直辖市、自治区), prefecture (地级市), county (县级) and town (乡镇) (Zhou 2008). Because medicine regulatory authorities only go down to the county level, this thesis only concerns itself with local governments of provincial/municipal, prefecture and county governments.

used by reformists in the post-Mao era, as a powerful incentive for mobilising local governments to adopt market principles and pursue economic efficiency (Lin *et al*., 2010; Lai, 2013). Under this shift, local governments were delegated increased power over economic policy, and fiscal incentives were created to encourage the growth of local markets. Decentralisation allowed local governments to keep a larger portion of revenues earned by local enterprises (mainly taxes) for their discretionary use (Li, 2013), and these retained tax revenues contributed to rapid local industrial growth across many sectors (Burns & Rosen, 1986; Zhang, 2006). Many provincial governments, including Sichuan, Shanghai, Heilongjiang, Zhejiang, Jilin, Jiangxi, and Hunan began to prioritise the commercial aspects of medicines by proclaiming that medicines were a "pillar industry", building many manufacturing plants and distribution enterprises (Liu, 2010).

As described by Liu (2011:179), "Since economic construction became the central task, the role of local governments went beyond overseeing planning and regulating the pharmaceutical industry. Many local officials, after decentralisation, became directly involved in promoting development of the pharmaceutical sector [*translated from Chinese by the author*]." Local governments sought to strengthen the economism frame by tying the political advancement of local officials to economic performance. In this context, local officials took senior posts in pharmaceutical companies as members of boards of directors, and sometimes as chief executive officers. The intertwined interests of the pharmaceutical industry and local government officials were captured in a popular saying in China during this time: "If you want to become a County Governor, you should build pharmaceutical plants (要想当县长，就要办药厂)" (Liu, 2011) [*translated from Chinese by the author*].

With provincial and local governments given increased control (and ownership) of the pharmaceutical sector, the functions of public administration and business enterprise became closely intertwined. This overlap of state and market is described by Jean Oi as "local state corporatism", by which "local governments treat enterprises within their own administrative purview as one component of a large corporate whole" (Oi, 1995: 1132). Local governments, in

turn, were motivated to become entrepreneurial, as if running a conglomerate or diversified corporation. The protection and promotion of economic activities within its jurisdiction thus became a predominant concern in policy-making (Oi, 1992; Zhang, 2006). Local governments' exercise of their administrative powers to protect these enterprises was commonly referred to as "local protectionism" (地方保护主义) in China.

Box 4- 2 Example of local protectionism of falsified pharmaceutical manufacturer

In Zhoukou, Hainan Province pharmaceutical manufacturer Wang Zhiqiang sold 23 types of falsified medicines (a mixture of veterinary and human medicines) in eight provinces between 1986 and 1992. Despite operating an illegal business worth ¥2.6 million (approximately US$473,000[19]) in 1992, he was lauded by the local government as a "hero for the economy" (Wang, 1997; Ren, 2007). His factory was honoured with 16 awards and protected by the local communist party, economic development agencies and law enforcement at the county, municipal and provincial levels for many years. In 1993, a central government inspection team uncovered the case and proceeded to prosecute many people. Wang was sentenced to life imprisonment, along with several county-level political officials who supported Wang who were sentenced to several years imprisonment.

Consequently, local protectionism led to the neglect of local responsibility and capacity for effective medicine quality and safety regulation, and local governments allocated limited resources to medicine regulation. While China had approximately 360,000 pharmaceutical manufacturers, distributors and health institutions by 1993, regulatory officials numbered less than one person per twenty enterprises (Xie & Wang, 1993). Thus, medicine regulation overall was considered a hindrance to the development of the local pharmaceutical industry (Liu, 2010).

4.6.2 Multi-tier medicine standards

The expansion of local medicine production was further spurred by the decentralisation of the process of medicine approvals on "new and generic medicines". As defined by Article 15 of the

[19] Based on the 1992 exchange rate ¥5.5 = US$1.00.

1978 *Drug Administration Regulations*, "new medicines refer to the Chinese indigenously formulated medicines and generic medicines [*translated from Chinese by the author*]." This vague definition could apply to almost all medicines and hence served the goal of boosting output and, in turn, economic growth by facilitating the approval and sales of new medicines. Legislation adopted during this period did not suggest the intention of strengthening medicine standards to enhance quality and safety. Rather, the reviewed evidence suggests multiple medicine standards were permitted to evolve in order to advance the commercial attribute of medicines and expand production. As set out in Article 19 of the *Drug Administration Regulations*, and later in Article 23 of the *Drug Administration Law*, Chinese medicine quality standards were classified into three categories (known as levels until 2001): a) national standards set by the *Chinese Pharmacopeia*; b) central Ministry of Health standards; and c) local (provincial) standards set by the health bureau of each province, municipality or autonomous region.

Multi-tier medicine standards allowed for substantial expansion of pharmaceutical manufacturing, but created increased challenges for quality assurance and regulation. As a result of the loose definition and multi-tier standards, as many as 363 "new medicines" were approved by the local health authorities in Shanghai alone between 1978 and 1983. In 1982, 172 approvals were granted by the Ministry of Health and provincial heath authorities across the country (Liu, 2011). While between January and October 1985, 27 provincial health authorities approved 679 new medicines, four times the total number of new medicines granted in 1982 (Liu, 2011)[20]. This occurred because many provincial health authorities sought to approve as many new medicines as possible before the *Drug Administration Law* came into force in 1985, after which provinces only had the power to approve generic medicines. Yet, even between 1985 and 1988, many provincial health authorities were still actively approving new medicines while bargaining and negotiating with the Ministry of Health (Liu, 2011). As a compromise, the Ministry of Health

[20] By comparison, the USFDA only approved 12 new medicines in 1980, 27 in 1981, 28 in 1982, 14 in 1983, 22 in 1984, and 30 in 1985 (Russell, 1986).

delayed centralisation of power for approving new medicines (which happened in 2001 as the revised *Drug Administration Law* came into force) for several years. As Liu described:

> The provincial health authorities were keen to put (new) medicines into production as quickly as possible and to make quick sales for the sake of generating profits and economic benefits. The processes of investigation and approval by provincial health authorities were driven by these powerful utilitarian considerations at the expense of medicine quality control, which was often neglected in the process. (Liu, 2011: 176) [*translated from Chinese by the author*]

A key informant interviewed for this research from a provincial Institute for Food and Drug Control (a technical agency responsible for medicine testing and inspection), confirmed this trade off:

> Medicine standard? Oh it was such a chaotic period of time. On the one hand, various standards were adopted to serve economic development, i.e., to encourage more the entry of more pharmaceutical manufacturers. On the other hand, because the level of our technology development was still very low, the main issue was to resolve the shortage of medicine supply after the reform, i.e., to produce more medicines needed by the people, that was the most critical issue. In theory, these technical standards are part of the legislation and should be reflected in law-making, but it didn't really happen. (Interview, 51HZ220712) [*translated from Chinese by the author*]

Under the system of multi-tier medicine standards, what constituted SF medicines, and particularly substandard medicines, became ambiguous. The detection and verification of SF medicines became more difficult across provinces, let alone the complexity involved in addressing the problem. Although the term SF medicines was used broadly to describe the issue, during the first 20 years the focus was on eliminating falsified medicines. It was difficult to detect and define "substandard" medicines under the multi-tier standards (existed until 2001).

4.6.3 Healthcare retrenchment's impact on SF medicines

As explained in Section 4.4, economism affected health policy throughout China, by shifting thinking towards increased market competition and reducing the role of the state in the provision of health services and financing. This was a major policy change which significantly increased demand for medicines (after health retrenchment), and affected how local governments perceived medicines and responded to SF medicines.

The effect of economism on health policy first began when the then Minister of Health Qian Xinzhong signalled the direction of planned healthcare reforms in 1979, by requesting government departments to "act according to economic rules" (quoted in Huang, 2013: 54). The first major policy document guiding these reforms was issued by the State Council in March 1985, entitled *Report on Several Policy Issues Concerning Reform of Health Work*, with the core message of "decentralisation of power and benefits" (Meng *et al*., 2015). Under this new policy, central government transferred primary responsibility for funding healthcare services to local authorities, and decentralised fiscal policy to fund healthcare through local taxation (Blumenthal & Hsiao, 2005; Duckett, 2012). The relative share of overall government spending for healthcare dropped, from 37 percent in 1981 to 18 percent in 1995. Out-of-pocket spending by patients correspondingly rose from 24 percent to 58 percent (Lin *et al.*, 2010). The central government's emphasis on more local financing, in turn, created new incentives for local governments to promote the commercialisation of medicines. This was led by public hospitals which were given greater financial autonomy to generate income from sales of services (e.g., increase user fees), medical technologies and medicines (Ramesh *et al*., 2014). According to Duckett, one major consequence of healthcare reforms was a significant increase in demand for medicines at urban healthcare institutions:

> The influence of pharmaceutical business, meanwhile, is difficult to pin down as they lobby individually and behind closed doors and are often influential in the localities rather than at the centre. They are benefitted from the rapidly rising medicines sales usually blamed on health service providers' reliance on medicines for income, but some also profit from having medicines listed as reimbursable on BHI [basic health insurance].[21] (Duckett, 2011: 18)

As Lin *et al.* (2010: 304) confirm, "most urban hospitals received less than 10 per cent of their total revenue from the government budgetary allocation, while generating 60 per cent of their revenue by selling medicines".

[21] BHI refers to the basic health insurance of urban workers (城镇职工基本医疗保险).

Supported by a follow-up *Opinions on Several Issues Related to Expanding Health Services* in 1989, healthcare services providers were encouraged to establish multiple channels and with diverse forms to generate income. This approach was defined by the *Opinions* as "using the sideline occupation to subsidise the regular occupation" (以辅补主) (State Council, 1989). This important *Opinions* was jointly formulated by the Ministry of Health and four other central government agencies: the Ministry of Finance, the Ministry of Human Resources, the State Price Bureau, and the State Administration of Taxation. In practice, hospital staff were encouraged to set up retail outlets and/or manufacturing plants to subsidise the financing of healthcare through the production and sales of pharmaceutical formulations, known as hospital-branded medicines (医院制剂).[22] Amid an absence of stringent quality standards and regulation, 7,205 cases of SF medicines (serious harm to patients) were reported across 27 provincial hospitals in 1996 (Liu, 2010). In 1996, the *Xinhua News Agency* reported that around 30-40 per cent of medicine consumption in the country was inappropriate or unnecessary, generating additional healthcare cost to the public around ¥30 billion (US$3.6 billion[23]) per annum (quoted in Lin *et al*., 2010: 304).

4.6.4 Development-oriented local states and adverse effects on medicine quality

This research argues that the above policies resulted in a rapid expansion of the pharmaceutical sector, without adequate regulation on quality. Evidence suggests that local health authorities began to favour economic goals over their regulatory responsibilities. Professor Song commented on the quality regulation from the perspective of local governments, stating:

> National regulatory authority on medicine regulation is not quite the same as local regulatory authorities. Local regulatory authorities are often hindered by local governments who are more development oriented. Medicine regulation for local governments is important by saying, secondary by doing, and neglected when busy promoting economic activities. (Interview, 08TJ250312) [*translated from Chinese by the author*]

[22] The so-called hospital-branded medicines are medicines developed, produced and used only within the specific hospital which developed the product. These medicines are not allowed to be sold on the market for wider sales or distribution (Song, 2008b).
[23] Based on the 1996 exchange rate ¥8.33 = US$1.00.

There is insufficient evidence to determine the causality as to whether the changing policy environment caused changes in framing or changes in framing led to changes in policy environment. However, these two developments are closely linked.

In summary, the evidence reviewed in this research demonstrates that economism dominated the framing of policy priorities from the 1980s. Promoting economic growth and development became dominant, while regulation on medicine quality and safety was largely neglected by local governments. This was linked to two major policies pursued by the CCP. On the supply side, the decentralisation of state production alongside multiple medicine standards encouraged expansion of medicine production as an engine of economic development. On the demand side, health retrenchment by the central government led to dramatic increase in medicine demand in health institutions, as pathways to pursue additional income streams. These three policies generated significant political commitment to prioritise the commercialisation of medicines, contributed to the growth of developmental-oriented local states, and in turn further reinforced the economism frame.

4.7 Conclusions

This chapter identified economism as the dominant frame shaping China's policy responses to SF medicines for the twenty years following the economic reforms in 1978. This was a period of profound change in thinking at central and local levels of the Chinese government, resulting in fundamental and far-reaching economic reforms and social transformation. Policies on medicines were subsumed under these changes in thinking and practice. China's re-framing of medicines from a social welfare to largely commercial product, was driven by the emergence of the economism frame.

The economic frame in this context acted as an effective re-framing, allowing policy-makers to overturn the old policy response based on the perception that medicines were not for profit but to serve social welfare, to support an opposing policy response oriented towards economic growth. From top Chinese political leadership, senior officials, to institutional agencies

such as the SPA, and local governments, all began to re-position medicines as a commercial product. This shaped the way SF medicines was perceived and responded to, leading to policies centred on promoting economic growth, international trade, and foreign exchange earnings through exports. As a result, insufficient policy attention and action were given to medicine quality and regulation. The dominant policy responses to SF medicines focused on treating the problem as one of "market order", hence prioritising the economic implications of SF medicines. Legislations and administrative policies, promoted the importance of tackling SF medicines to restore the "market order" of the pharmaceutical economy. Although the social welfare perspective on medicines returned after a series of SF medicines incidents, no formal regulatory agency was in place to ensure quality and safety. The decentralisation of medicine production, multi-tier medicine standards, and the state's withdrawal from health sector from the 1980s added further impetus to the rise of the economism frame at local levels. This set the scene for increased challenges to ensuring the safety and quality of medicines in China.

Chapter 5 The National Medicine Regulatory Authority: Reframing and Policy Change (1998-2012)

5.1 Introduction

This chapter analyses China's policy responses to SF medicines, from the founding of China's first national medicine regulatory authority in 1998 to Xi Jinping becoming president in 2012. During this period, China's economic power and global influence steadily grew, surpassing Japan in 2010 to become the world's second largest economy. By end 2011, China had 4,629 pharmaceutical manufacturers (including APIs) and 440,248 certified distribution enterprises (SFDA, 2012a). However, amid rapid economic growth, social issues such as health inequality, corruption, food and medicine safety, environmental degradation attracted increasingly attention from the media, academia, and the public. The SARS epidemic between 2002 and 2003, which induced extensive economic and societal disruptions, demanded that the Chinese central and local governments re-think the direction of economic and societal development. Internationally, China during the first decade of the new millennium, became more active within major multilateral institutions and global governance. China was granted membership to the WTO in December 2001, and by 2010 held the third largest voting share (based on relative size of economy) in the World Bank and International Monetary Fund. In addition, Chinese nationals ascended to senior positions in international organisations: for example, Margaret Chan, a Chinese national, was appointed the Director General of the WHO in 2006.

This chapter examines China's shifting responses to SF medicines from an economism to health and well-being frame in the mid-2000s. It argues that policy change with regards to SF medicines did not happen immediately after China established the national medicine regulatory authority, nor following the SARS outbreak. Driven by a mixture of material and ideational factors, I identify a major shift in China's responses to SF medicines around 2006, with the deployment of a heightened health and well-being frame. This chapter thus discusses why the economism frame

continued to dominate before 2006, how the health and well-being frame arose, and what subsequent policy effect it had.

5.2 China's first national medicine regulatory authority: The continued dominance of the economism frame

An effective national medicine regulatory authority is not only central to the delivery of quality medicines, but also to the entire health system and the healthy development of domestic pharmaceutical industry. The overall objective of a national medicine regulatory authority is to ensure that only safe, effective and quality-assured medicines are manufactured, traded, imported, and consumed. This is the most vital element for eliminating SF medicines, and is also the system the public would are most likely to question when incidents of SF medicines arise. This section examines why the economism frame continued to dominate policy responses after China's first centralised national medicine regulatory authority was founded in 1998, the interaction between framing and institutional change, and the overall effect on policy responses to SF medicines.

5.2.1 Building a national medicine regulatory system

Amid growing SF medicines incidents, establishing a national medicine regulatory system became a pressing issue in the Chinese government's policy agenda. China's first national medicine regulatory authority was established in April 1998, named the State Drug Administration (SDA). Although the SDA experienced several changes to its institutional structure, political status and affiliation in first 20 years since inception (see Table 5- 1), its initial iteration appears to have been driven by the goal of improving medicine quality and safeguarding health.

The 1997 *Decision on Health Reform and Development*, a key policy document that provided political guidance for Chinese health reforms over the next fifteen years, urged that the country should "actively explore the reform of the management system of medicine and gradually form a unified, authoritative and efficient management system" [*translated from Chinese by the author*] (Central Committee of the CCP & State Council., 1997). It was the first time that senior

policy-makers and political leaders recognised medicine regulation as part of broader health reforms. Pharmaceutical policy and industrial development were treated as equally important in the document, with the overall policy goal set to meet national health targets. Adding more public health elements into policy goals was endorsed by senior SDA officials, such as Shen Dengle (沈登乐), to support the founding of the SDA:

> Between 1996 and 2010, what basis should pharmaceutical development be based on? If in the past, we only considered the development of pharmaceutical industry per se, now we must adhere to the spirit of the *Decision*, transforming our strategic thinking into the direction and aim of health reform. That says that by 2000, the production and supply of medicine must meet everyone's primary health care needs. By 2010, China's pharmaceutical production and supply must reach the average level of the world's moderate developed countries; if not, the realisation of main National Health Targets will be affected. ("China Pharmaceutical Yearbook" Editorial Board, 1998: 24) [*translated from Chinese by the author*]

Table 5- 1 The national medicine regulatory authority (1998-2021)

Year	**Name**	**Political Ranking**
Apr 1998 – Apr 2003	State Drug Administration (SDA)	Vice-ministerial
Apr 2003 – Mar 2008	State Food and Drug Administration (SFDA)	
Mar 2008 – Mar 2013		Vice-ministerial (merged into *the Ministry of Health* in 2008)
Mar 2013 – Mar 2018	China Food and Drug Administration (CFDA)	Ministerial
Mar 2018 – 2021	National Medical Products Administration (NMPA)	Vice-ministerial (merged into *the State Administration for Market Regulation* in 2018)

Note: The SPA existed between July 1978 and April 1998, and was the precursor of the Chinese National Medicine regulatory Authority. It was established as a designated "line department" for the pharmaceutical industry focused on industrial policy, not as a regulatory authority. Hence, SPA is not included in this table (see Table 4- 1 for institutional changes on SPA).

Another senior politician, the then State Council Deputy Secretary-General Ma Kai (马凯), speaking at the 2001 National Medicine regulatory System Reform Work Conference, stated that: "The fundamental purpose of medicine regulatory system reform is to strengthen regulation, enhance administration, ensure the quality of medicines" ("State Drug Administration Yearbook"

Editorial Board, 2002: 6) [*translated from Chinese by the author*]. Although there was some rise in political attention to medicine regulation from a public health perspective, the development of the SDA was far from satisfactory as an independent medicine regulatory authority. Behind the scenes, the importance given to public health was relatively minor, with economic policy goals still dominant.

5.2.2 Close relations between regulators and the industry

This research finds that the economism frame continued to dominate Chinese medicine regulation after 1998. Arguments to protect and promote public health did not seem sufficiently persuasive nor politically influential. As Rushton and Williams (2012: 159) argue: "Power matters, and outcomes are determined not only by the persuasiveness of a particular frame, but also by who is advancing that frame". This sub-section analyses how power, authority and ideas worked together to maintain the economism frame.

First, the SPA (1978-1998), who represented the pharmaceutical industry and promoted economic-oriented policy goals, shaped the policy priorities of the newly established SDA. The SDA established three separate pharmaceutical-related agencies: the SPA, Division of Medical Administration in the Ministry of Health, and Division of Traditional Chinese Medicine in the Traditional Chinese Medication Administration Bureau. The latter two assumed regulatory responsibilities for Western and traditional Chinese medicines, respectively. Historical analysis revealed that the SPA was the main constituent among the three and played a dominant role behind this institutional restructuring (Liu, 2011; Song, 2008a). The SPA was a vice-ministerial level government agency – one level higher than the other two, hence the SPA was equipped with more political and administrative power. The SPA was also a much bigger agency in terms of human resources, and a more highly structured agency due to its more established central-local institutional settings. As a result of the greater resources commanded by the SPA, a majority of the personnel forming the SDA came from SPA, i.e. the industry. Indeed, among the 120 members of staff employed by the new SDA, the former SPA (i.e., from the industry) had 80 positions; the

Division of Medical Administration from Ministry of Health was allocated approximately 30; and less than 10 were allocated to the Traditional Chinese Medication Administration Bureau (Song, 2008a). The ten affiliates of the SDA (later SFDA) continued to run 22 enterprises, while some incumbent SDA officials held stocks or part-time posts in pharmaceutical companies (Liu, 2007; Huang, 2013). The SPA's material power in the form of economic resources, allowed it to effectively advance its preferred framing of the regulatory response. With industry interests so well imbedded in the SDA, its intended independence to regulate in the interest of public health was highly questionable from the outset.

Second, and more importantly, the power of the political leadership, Zheng Xiaoyu's governing ideas and ability to persuade and justify the economism-oriented approach, shaped how the SDA continued to evolve. The appointment of Zheng as the inaugural Director General for the SDA, further strengthened the dominance of the SDA's economism focused policy objectives. Zheng had worked for a pharmaceutical company since 1968 and was the former Founding Director of the SPA (1994-1998). Upon taking office, he announced his governing principles "Regulate, Help, and Facilitate" (监帮促) as central tasks for the SDA to pursue in relation to pharmaceutical companies. A fuller interpretation of this slogan was, as explained by himself: "to regulate medicine quality, to help companies improve economic performance, and to facilitate pharmaceutical industrial development" [*translated from Chinese by the author*] ("State Drug Administration Yearbook" Editorial Board, 1999: 12-19). Speaking at the first National Forum on Drug Administration Work in June 1998, Zheng Xiaoyu framed medicine regulation from an explicit economic perspective, stating that "Medicine regulation is the driving force for stimulating pharmaceutical manufacturing and sales. The level of product quality is a key measurement of a country's economic and technological development. Medicine quality is the key to the existence and development of pharmaceutical enterprises." ("State Drug Administration Yearbook" Editorial Board, 1999: 15). [*translated from Chinese by the author*]. This gave the impression that the SDA's focus was on industrial development, and low-quality medical products were regarded as an economic rather than public health concern. In January 2000, Zheng further

elaborated on the SDA's three guiding principles, stating that "'regulation' is the means, while 'help and facilitation' are the objectives, and both are to be unified to promote the overall agenda of 'economic construction is the central task and development is of paramount importance'." ("State Drug Administration Yearbook" Editorial Board, 2001: 9) [*translated from Chinese by the author*]. These statements suggest that, despite the creation of the SDA ostensibly to protect public health and improve medicine quality and safety, the institution would continue to be dominated by the drive to promote economic objectives.

Third, the SDA's role in promoting economic development gained legal ground in the 2001 *Drug Administration Law*, which was drafted by the SDA. This legislation constituted a major revision to the previous *Drug Administration Law* (1985), to strengthen medicine regulation and impose tougher penalties regarding SF medicines. The SDA's responsibility to coordinate the pharmaceutical industry's contribution to economic policy was set out in Article 5 of the new legislation: "The medicine regulatory department under the State Council shall cooperate with the competent departments for comprehensive economic administration under the State Council in implementing pharmaceutical development programs and policies formulated by the State for the pharmaceutical industry" [*official English translation*].[24] In other words, under this law, the SDA was mandated to serve industrial development, which was potentially conflicted with its mission to safeguard public health, as set out in Article 1. Notably, the legislation did not state which takes priority – public health or economic goals – when the two are in conflict.

[24] Two versions, the *Drug Administration Law* and *Pharmaceutical Administration Law*, are both used in official translations. This research uses the Chinese SDA's version of the translation of the *Drug Administration Law* found at : https://www.unodc.org/res/cld/document/drug-administration-law-of-the-peoples-republix-of-china_html/Drug_Administration_Law_of_the_Peoples_Republix_of_China_2001.pdf ; http://english.nmpa.gov.cn/2019-09/19/c_408491.htm

5.2.3 Policy impact: Dominance of the economism frame

The creation of the SDA had a positive impact on tackling SF medicines in several ways. A senior researcher specialising in medicine legislation and regulation commented on the founding of the SDA as follows:

> Establishing an independent regulatory agency was definitely progress. Many stakeholders, including top politicians, media, public, and even the industry became increasingly concerned about rampant SF medicines, so institutional reform was an urgent matter. Although the new SDA had this problem and that problem, overall, it was a great move. (Interview, 08TJ250312) [*translated from Chinese by the author*]

More specifically, first, the government streamlined all medicine-related agencies into a unified independent regulatory agency (although this transformation took many years), assisting China's preparation for WTO accession and matching the practices of high-income countries. The SDA began to implement the GMP and other internationally recognised standards across the entire production and distribution process. Second, the SDA centralised power over medicine approval, through launching a project called "local standards transferring to national standards" (地标转国标) beginning in 2002. Hence all new and generics medicines were approved at the SDA in Beijing, rather than the provincial or prefecture medicine regulatory bureaus. Third, on bureaucratic structure, the SDA established a semi-centralised (半垂直, also called semi-vertical) regulatory system since 2001, under which provincial medicine regulatory bureaus assumed responsibility for staff appointments and funding allocation of the prefecture and town levels (Song, 2009). The SDA was responsible for providing technical guidance and appointing directors for provincial medicine regulatory bureaus (Interview, 19HZ250412). The main purpose of this semi-centralised system was to curtail local protectionism, through setting-up a top-down medicine regulatory structure and preventing complete ignorance of medicine regulation at local levels ("State Drug Administration Yearbook" Editorial Board, 2000; Song, 2009).

Despite the positive move, the SDA failed to effectively address the quality and safety of medicines. Public health objectives were undermined under Zheng's regime, as a result of the strong economism framing influencing policy priorities. Although there was some awareness of

the SDA's competing policy agenda – for example, Zheng Xiaoyu raised several times the importance of appropriately handling the relationship between administrative supervision and development of the pharmaceutical economy ("State Drug Administration Yearbook" Editorial Board, 1999: 12-19; "State Drug Administration Yearbook" Editorial Board, 2001: 6-13). However, the industrial policy carried too much weight within the work of the SDA, which undermined their regulatory responsibility for ensuring medicine quality and safety. The number of approved medicines per annum rose significantly under the centralised medicine approval system, from 996 in 1999 to 8,546 in 2005. According to official statistics, the SDA under Zheng's leadership approved 31,332 new medicines and 21,308 generic medicines from 1999 to 2006 (Table 5- 2). These were significant numbers, considering that the USFDA approved fewer than 150 new medicines each year (Santoro & Liu, 2009).

Table 5- 2 Approved new and generic medicines in China (1999-2006)

Year	**New medicines**	**Generic medicines**
1999	996	885
2000	1,175	222
2001	2,014	547
2002	2,945	740
2003	6,806	1,000
2004	4,357	3,279
By end of Oct 2005	4,493	6,040
2006	8,546	8,595
Total	**31,332**	**21,308**

Source: State Drug Administration Yearbooks (2000-2007)

The economism frame also resonated with the broader political context focusing on economic development. As commented on by a senior academic at the Chinese Academy of Governance, one of the top policy think tanks advising the State Council:

> The main task of the 1998 Zhu Rongji government was economic development. Reading the 1998 Yearbook, you can see that Zheng Xiaoyu proposed the objectives of the SDA as "regulation, help and facilitation". In addition, another of Zheng's proposal was seldom noticed, which emphasised dealing with the relationship between medicine regulation and industrial development. He clearly specified that, at least from my understanding, the policy objective for industrial development was absolutely not secondary to safety supervision. (Interview, 05BJ190312) [*translated from Chinese by the author*]

On the whole, the country's economic-centred development strategy, the SPA's past focus on industrial policy, and Zheng's professional background and political influence, all seem to have shaped the framing of medicine regulation policy priorities under the new SDA. During its early phase of becoming established, the SDA carried out the dual mandates of promoting industrial output and economic growth, on one hand, and ensuring the safety and efficacy of medicines on the other.

5.3 Responding to SF medicines: Pursuing "market order" and Leading Small Groups

From being largely framed as a problem of "disorderly markets" hindering the economy, during this period SF medicines then began to be linked to IPR violations (more explanation of IPR and SF medicines is provided in Chapter 7 in relation to MPCs). Building on the analysis presented in Chapter 4, since the 2000s market order became more widely associated with the government's effort to combat the growing production and sale of spurious, counterfeit, falsified, and substandard (假冒伪劣) goods across a wide range of sectors, including agriculture, food, medicines, automobiles, electronics, cultural products, and tobacco. Many ad hoc political campaigns (see Table 5- 3) were issued by dozens of government institutions, officially known as anti-counterfeiting activities, to "rectify and standardise market order" (整顿和规范市场秩序). As Jones (2003) notes, such campaigns and movements have been used since the Maoist era to achieve and advance change in thinking on a mass level. They remain widely used in China, often implemented in accordance with administrative rules and regulations, to achieve a quick impact on improving conditions or resolving an issue.

Table 5- 3 Major "market order" related policy documents on combating SF medicines

Year	Name of the Policy Document
1998	*Urgent Circular of the State Drug Administration Bureau and State Administration for Industry and Commerce on Seriously Investigating and Severely Punishing the Illegal Acts of Manufacturing and Sales of Falsified Medicines*
2001	*Decision of the State Council on Rectifying and Standardising Market Economic Order*
2001	*Circular of the State Drug Administration Bureau, the Ministry of Health and the State Administration for Industry and Commerce on Further Rectifying and Standardising the Pharmaceutical Market Order, and Severely Cracking Down on the Illegal and Criminal Activities of Manufacturing and Sales of Falsified and Substandard Medicines and Medical Devices*
2006	*Circular of the General Office of the State Council on Printing and Issuing the Plan for the Nationwide Special Campaign of Rectifying and Standardising the Pharmaceutical Market Order*

The meaning of "market order" became more sophisticated from the 2000s, to embrace social and political dimensions more explicitly. In his study of Chinese state policy in the twenty-first century, Ferchen argues that "market order" goes beyond economic considerations to include the goal of maintaining overall societal stability. Market order, he states, "refers to the balance between markets as the primary engine of economic growth and the maintenance of economic, social, and political stability" (Ferchen, 2008: p3). A cross-departmental *Circular* issued in 2001 (full name in Table 5- 3) emphasised that "market order for pharmaceuticals constitutes an indispensable part of the entire economic order" [*translated from Chinese by the author*] (State Drug Administration *et al*., 2001). By defining the concept in this way, "market order" extended beyond investigating and revoking illegal business licenses and shutting down unregulated trading markets. As elaborated in the State Council's 2001 *Decision* (full name in Table 5- 3), the meaning of market order was expanded to be associated with the political reputation of China's economic and social progress:

> Establishing good market order is both a major economic issue but also a serious political issue; both an inevitable choice to improve the overall quality and competitiveness of the national economy, but also a necessary condition for the further opening to the outside world; both a major initiative to consolidate the results of China's modernisation construction, but also the country's inherent requirement to comprehensively promote social progress and civilisation. (State Council, 2001) [*translated from Chinese by the author*]

As such, "market order" is a critical term in Chinese politics and social governance (Jiang 2009) and "any understanding of Chinese state capacity remains incomplete unless the crucial role of 'market order' as a concept of governance is taken into account" (Ferchen, 2008: p3).

In addition to ad hoc political campaigns, the government created various Leading Small Groups (LSGs) during this period, as another important policy instrument to support this broad conceptualisation of "market order". LSGs in China are a supplementary mechanism, in addition to the conventional governance arrangement of the party-state apparatus, and are regarded as a special governance tool of the CCP to deal with selected issues at specific times (Sohu News, 2013; Zhou, 2015). Zhou (2010) referred to LSGs as term-oriented (阶段性) small groups (i.e., temporary task forces), who have less guarantee of their long-term existence and operation. LSGs are not formalised bodies in China, rather they operate outside the formal bureaucratic structure, while playing a key role in policymaking and acting as an important policy enforcement mechanism (Miller, 2008, 2014; Martin, 2010; Zhou, 2010). In this context, LSGs shifted the policy response from ad hoc administrative campaigns to a more institutionalised governance structure, in order to support the enforcement of market order and sustain the economism policy framing, mobilise resources, facilitate consensus-building and coordinate implementation of policy actions.

Most LSGs on combating SF medicines (or "anti-counterfeiting" as used in official language) emerged after China's WTO accession in 2000 (Table 5- 4 lists major LSGs). In 2000, the *Leading Small Group for National Anti-Counterfeiting Work Coordination* confirmed the central position of anti-counterfeiting in the overall government policy on rectifying and standardising market order for the pharmaceutical sector. The group's 2000 *Circular of the State Council on*

Carrying out Joint Actions to Severe Crackdown on Manufacturing and Sales of Spurious, Counterfeit, Falsified and Substandard Goods stated that, "the State Council decides to position the anti-counterfeiting as an important part of the work on rectifying and standardising market order" (State Council, 2000). Another *Leading Small Group for Rectification and Standardisation of the National Market Economic Order* was formed in 2001. In the first official *Decision of the State Council on Rectifying and Standardising Market Economic Order* issued by the LSG, spurious, counterfeit, falsified, and substandard commodities was ranked as the top priority for the group to tackle. The Chinese government also established a high-level LSG in 2010 called the *National Leading Group on the Fight Against IPR Infringement and Counterfeiting*, led by a Vice Premier of the State Council and comprised of 27 institutional members. The executive office (*Office of the National Leading Group on the Fight Against IPR Infringement and Counterfeiting*) was based in the Ministry of Commerce. Its main responsibility was to provide central political leadership in nation-wide efforts to crack down on counterfeiting activities, with a strong emphasis on IPR protection. The 2009 group, led by the Ministry of Health and SFDA, was the only one to focus on SF medicines without an emphasis on IPR. It was joined by 11 other departments to combat SF medicines. The focus of the group was to enhance coordination, especially given a growing trend of distributing SF medicines through the internet and post, along with false advertising ("State Food & Drug Administration Yearbook" Editorial Board, 2010).

Table 5- 4 Major Leading Small Groups on combating SF medicines

Name	**Year of establishment**	**Lead agency**	**Coordinating agencies**
Coordination Small Group for National Anti-counterfeiting Work 全国打假工作协调小组	2000	The General Administration of Quality Supervision, Inspection and Quarantine	18+
Leading Small Group for Rectification and Standardisation of the National Market Economic Order 全国整顿和规范市场经济秩序领导小组	2001	The State Economic and Trade Commission (2001-2003), The Ministry	34

		of Commerce (since 2004)	
Inter-ministerial Joint Meeting System on Combating the Production and Sale of Falsified and Substandard Medicines 打击制售假药部际协调联席会议制度	2009	Ministry of Health and SFDA	13
Leading Small Group for the National Crackdown Work on IPR Infringements and Production and Sales of Spurious, Counterfeit, Falsified and Substandard Commodities 全国打击侵犯知识产权和制售假冒伪劣商品工作领导小组	2010	Ministry of Commerce	26

5.4 The people-centred approach after the SARS epidemic

Until the mid-2000s, as Chapter 4 and the first half of this chapter have illustrated, the issue of medicine quality and safety, by and large, had a limited presence in problem construction and policy priority from a public health perspective. Although the special attribute of medicines was sometimes reflected in policy thinking, the effort to tackle SF medicines and strengthen regulatory oversight remained inadequate. In an overall policy context with an overwhelming concern over economic growth, medicine regulation was weakened as a key driving force of pharmaceutical policy to erect regulatory barriers, to rather focus on creating privileged commercial opportunities for medicine production and local economic growth.

The SARS outbreak between 2002 and 2003 was a critical tipping point, for creating new impetus to re-think the relationship between public health and economic development in Chinese society; and subsequently shift perception and policy responses to SF medicines. SARS drew attention, not only to public health deficiencies, but broader social and political questions that demanded new perspectives and policies from Chinese leaders. Following the outbreak, other regulatory problems in the health system also received increased public attention (Yu, 2009). In 2003, poor quality baby formula in Fuyang, Anhui Province caused 13 deaths and 189 injuries.

State and local media extensively reported on deaths in small children and cases of babies suffering from "big head disease" (BBC News, 2004; CBS News, 2004; China Daily, 2004). These incidents led to concerted public outcry over the regulation of food and medicine safety. Wang Shaoguang, a political scientist at the Chinese University of Hong Kong, published an influential article "People's Health is also Hard Principle" in 2003. He warned of the grim reality caused by these incidents, and suggested that policy-makers re-balance public policy priorities away from the country's one-sided pursuit of economic growth and development (Wang, 2003).

These events served as a wake-up call for political leaders and society as a whole, of the need to review what was truly important in Chinese society, from a longer term and more sustainable perspective. The government subsequently pursued efforts to restore public trust after the initial covering-up of the severity of the SARS outbreak (Xu 2006). In fall 2003, Chinese leadership began to put forward a more people-centred approach as a defining ideological feature of the new CCP leadership. At its core was the "Scientific Development Concept" (科学发展观, also translated as "Scientific Outlook on Development") and "take people as the main thing" (以人为本, also translated as "the people are the basis"), known as "Hu Jintao thought", under the former president Hu Jintao (胡锦涛). The Hu-Wen leadership (with Premier Wen Jiabao 温家宝) aimed to establish a different development paradigm from the previous leadership, centred on human beings and the well-being of those left behind by rapid economic development over the past two decades (Fewsmith, 2004; Chan, 2010). President Hu held that the ultimate goal of scientific development was to achieve a harmonious society. Despite criticism as being vague, this people-centred approach to development was codified in an amendment to the Constitution of the People's Republic of China in 2004 as "puts people first and calls for comprehensive, coordinated and sustainable development" (Constitution of the People's Republic of China, 2004).

The statements of top political leaders had great impact on shaping broader perspectives on health and economic development, and policy approaches. As Du *et al*. (2010: 357) observed, political leaders' views about SARS, health issues in relation to China's broad national interests,

global priorities, and economic development directly influenced health policy at all levels. In particular, President Hu's statements were identified as the main drivers for health policy, "since they bring health to the foreground of social policy" and affirmed that health development and economic growth both served as subordinate objectives towards the higher political goal of achieving a harmonious society. A provincial medicine regulator interviewed for this research echoed this view:

> At the time when events such as the Fuyang poor quality infant milk formula was exposed in 2003, the "people-centred approach" had just come out. Before that, the government gave more consideration to the social panic caused by these incidents, but were less considerate about people. The key messages revealed in political leaders' speeches have an impact on the direction of how the government works. For example, Xi Jinping now emphasises that "The people yearn for a better life", which means that we are not satisfied with basic material requirements. So government agencies should work towards achieving that mission. (Interview, 05HZ210218) [*translated from Chinese by the author*]

The leadership under President Hu thus began to focus on the well-being of Chinese citizens, addressing concerns and rebuilding trust among the general public. Leaders hoped to steer the development process to deal with growing social problems and conflicts facing China, including public health deficiencies, inadequate food and medicine safety, widening urban-rural inequality, environment degradation, corruption and crime (Chan *et al*., 2008). The new leadership also aimed at promoting governmental efficiency, national capabilities, and social welfare (Fewsmith, 2004). At the beginning of 2004, Premier Wen urged senior government officials at all levels to guide their work in accordance with the *Scientific Development Concept* to improve the "governing ability" (执政能力) of the CCP, particularly with regards to regulatory and public service functions (Wen, 2004). For example, in May 2004, Premier Wen ordered a crackdown on safety violations in China's food market (General Office of the State Council, 2004).

5.5 The health and well-being frame: Core ideas and policy context

As evidenced above, the second core policy frame identified by this research is the health and well-being frame. Here I argue that, fundamentally, SF medicines is a public health problem affecting humanity, and it is vital to develop policy responses from a public health perspective

because all humans should have the right to access safe, effective and quality assured medicines. To resolve SF medicines, policy responses from nation states should focus on ensuring people's health as the foremost priority, strengthening political will and medicine regulatory authorities, enhancing coordination among the regulatory regime, health systems, law, and enforcement agencies.

In general terms, the health and well-being frame emphasises health as a fundamental human right, and healthy populations as a prerequisite for achieving societal goals. The Constitution of WHO defines health as a state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity (WHO, 1946). This holistic view of health resonates with the philosophy of traditional Chinese medicine, which emphases the harmony of the physical human body with its place and connection in the universe. The term *weisheng* (卫生, known as "health"), first coined by the Japanese and adopted by the Chinese in the early twentieth century, literally means "guarding life" (Yu, 2011; Wang & Yu, 2014). The definition of "well-being" was first delineated in the United Nations Development Programme's (UNDP) *1994 Human Development Report* and elaborated more explicitly in its *2004 Human Development Report*. The latter suggests four capabilities of human well-being which are considered critical for public policy priorities: "to lead a long and healthy life, to be knowledgeable, to have access to the resources needed for a decent standard of living and to participate in the life of the community" (UNDP, 2004: 127). Health and well-being as a whole go beyond fulfilling basic physical and material needs, and refers to the holistic quality of a citizen's life, including physical, social, psychological, emotional status, and general happiness.

In global health policy, the health and well-being frame draws attention to the social determinants of health, which are profoundly affected by globalisation including policies made in non-health sectors (Dodgson *et al*., 2002; Lee, 2003). This frame promotes awareness of the health consequences of other public policies (e.g., macroeconomic policy) and the need for governments to place health considerations higher on the political agenda as a whole. One

important report that shaped policy discourses on economic development and health, was *Macroeconomics and Health: Investing in Health for Economic Development*. The 2002 report was produced by the WHO Commission on Macroeconomics and Health, established by then WHO Director-General Gro Harlem Brundtland in 2000, to assess the positioning of health in global economic development. The report emphasised the mutually reinforcing connections between poverty and health, and advocated investments in health as a prerequisite for economic development. As noted by Du *et al*. (2010), this special report and the surrounding international policy discussions, influenced perceptions among the Chinese political leaders of the relationship between macroeconomic policy and health, particularly after the SARS outbreak. Investment in health began to be seen as essential for achieving other societal goals. Closely following the SARS outbreak in 2002-3, the report provided an important underpinning for an ideational shift towards a health and well-being frame, with investments in improving health moved to the foreground of Chinese policy-making.

Influenced by the SARS outbreak and the shifting policy discourse on health and economic development both nationally and internationally, the Chinese government started to place health system reform and strengthening at the top of its agenda (Meng *et al*., 2015). Meanwhile, the Ministry of Health was strongly criticised by the public for its market-oriented health policy and its failure to provide adequate and affordable services for ordinary citizens (Chan *et al*., 2008). The Hu-Wen government began to promote new political catchphrases such as "people's livelihood" (民生), "social well-being" (社会福利) and "harmonious society" (和谐社会). Meanwhile, the government increased financial inputs into public health institutions, greatly supporting public health service in aspects of infrastructure, capacity strengthening, and public health service delivery. Concurrently, China also supported nongovernmental investment in the medical service market (Meng *et al*., 2015). This represented a pivotal shift between 1997 and 2007: the former was carried out under the auspices of building a socialist market economy, while the latter shifted the focus onto equality and a people-centred approach to development (Lin, *et al*., 2010).

5.6 Policy impact of the health and well-being frame: Medicine regulation towards a "people-centred development" paradigm

It was within this broad policy context, that the *Scientific Development Concept* began to take centre stage and was embraced widely across policy-making circles from the beginning of 2004 (Fewsmith, 2004). This section discusses how a combination of material and ideational factors interacting in the post-Zheng Xiaoyu era, triggered the shift in policy framing and policy responses at SFDA towards a "people-centred" approach to medicine regulation. This analysis suggests that a shift in policy priority towards health and well-being was prompted by the events described above, along with a series of SF medicines incidents and corruption scandals., that ultimately led to the *Scientific Development Concept* and the people-centred approach becoming adopted by medicine regulatory agencies.

5.6.1 Material events and the shifting policy mindset on medicine regulation

Despite political statements by the SFDA, including by Director Zheng Xiaoyu himself, to acknowledge the Scientific Development Concept[25], the strategic shift at the top did not change the way the SFDA functioned until more drastic events occurred in the following years (see Table 5- 5). Two incidents involving SF medicines, caused by large GMP-certified pharmaceutical companies in 2006, were especially impactful. The first was falsified armillarisin A injections produced by the No. 2 Qiqihar Pharmaceutical Company in Heilongjiang Province, which killed 13 people and injured 49 others (Zhu, 2011). Two months later, a contaminated antibiotic injection (under the Chinese brand name "*Xinfu*"), produced by Anhui Huayuan Worldbest Biology Pharmacy, caused six deaths and illness in at least 80 people across ten provinces (China Daily, 2006).

[25] Zheng Xiaoyu acknowledged on several occasions that the food and drug administration was part of the people-centred development approach, and that the agency's responsibility in "paying attention to human health is an important manifestation of the scientific concept of development" (Zheng, 2005 Yearbook; SFDA, Yearbook 2006: 1).

Table 5- 5 Major SF medicines and food safety incidents (2003-2008)

Year	Incidents (major affected areas)	Death	Injury/disability
2004	Fuyang poor quality infant milk formula (Anhui Province)	13	189
2006	Qiqihar No. 2 Pharmaceutical Factory fake Armillarisin A injections (Heilongjiang Province)	13	49
2006	Yu Xing Cao (houttuynia cordata) injection adverse event (Beijing)	4	At least 222
2006	Xinfu antibiotic clindamycin substandard medicine adverse event (Anhui Province)	6	At least 80
2007-2008	Adulterated heparin as active ingredients sold by Chinese supplier Changzhou SPL to Baxter Healthcare Corporation in the US	81	785 serious injuries
2008	Melamine-adulterated infant formular milk by Sanlu Group (nation-wide)	6	Approximately 300,000 victims, with 54,000 babies hospitalised

Furthermore, a series of high-level corruption scandals at the SFDA became highly publicised in China and globally between 2005 and 2007. Zheng Xiaoyu, the SFDA Director, his family, and his senior officials including the Head of Drug Registration Cao Wenzhuang (曹文庄) and the Head of Medical Equipment Hao Heping (郝和平), were arrested due to taking bribes to approve untested medicines and medical equipment. Zheng was sentenced to death in 2007, as the highest-ranking official of the SFDA, on charges of taking bribes of 6.49 million RMB ($850,000 USD) for approving unsafe and poor quality medical products (Sohu.com 2007). Other senior SFDA officials and provincial medicine regulation officials were also charged with corruption and mismanagement (see Table 5- 6). These events placed strong pressure on the SFDA for policy change.

Table 5- 6 Corruption charges against senior Chinese officials concerned with SF medicines (2001-2007)

Time of Arrest	Name	Position	Immediate Penalty
October 2001	ZHOU Hang	Director of Zhejiang Provincial Food and Drug Administration (FDA)	Death penalty, deferred execution
July 2004	YU Qingxiang	Deputy Director of Jilin Provincial FDA	15 years in prison
July 2005	HAO Heping	Director of Medical Devices Department, SFDA	15 years in prison
November 2005	LIU Yuhui	Director of Advisory Services Department, Chinese Pharmaceutical Association (CPA)	Arrested on suspected bribery
	LIU Yongjiu	Deputy Secretary-General, CPA	Arrested on suspected bribery
Early 2006	CAO Wenzhuang	Director of Medicine Registration Department, SFDA	Death penalty, deferred execution
	LU Aiying	Head, Division of Chemical Pharmaceuticals, Medicine Registration Department, SFDA	14 years in prison
	WANG Guorong	Deputy Secretary-General, National Pharmacopoeia Committee	Death penalty, deferred execution
July 2006	MI Yangsu	Assistant Inspector of Shanxi Provincial FDA	10 years in prison
December 2006	ZHENG Xiaoyu	Director General, SFDA	Death penalty, executed in July 2007
December 2006	ZHANG Shusen	Director of Liaoning Provincial FDA	15 years in prison

February 2007	ZHENG Shangjin	Director of Zhejiang Provincial FDA	4 years in prison

Source: Hu 2009: 44 [*translated from Chinese by the author*]

The regulatory loopholes and extent of corruption exposed by these events, attracted widespread media coverage and further high-level political attention, giving impetus to the process of reframing the SFDA's governing principles. Zheng's death in some ways served as a symbolic event for the government to demonstrate that it would no longer tolerate medicine quality being sacrificed for economic development. It was also a gesture to the world that China was imposing tougher quality controls and regulations. This research argues that speeches and statements by senior political figures reflected this new prioritisation of public health and product safety. Following the prosecutions of Zheng Xiaoyu and other SFDA senior officials, CCP leaders including Premier Wen Jiabao, and Vice Premier Wu Yi (吴仪) who oversaw the SFDA, gave instructions to apply the *Scientific Development Concept* to strengthen medicine regulation. The term "well-being" (福祉) first appeared in Premier Wen's *Report on the Work of the Government*, delivered at the Fifth Session of the Tenth National People's Congress in 2007:

> We need to pay closer attention to promoting social development and improving the people's well-being. We must put people first, promote faster progress in social programs, work energetically to solve the most practical problems that are of greatest concern to the people and most directly affect their interests, safeguard social fairness and justice, and ensure that all of the people share in the fruits of reform and development. (China Daily, 2007) [*official translation*]

There were also concerns raised about the regulatory independence and accountability of the SFDA, and feasibility of its dual mandates to protect public health and promote the commercial interests of the pharmaceutical industry. Vice Premier Wu Yi attended almost all high-level SFDA conferences between 2006 and 2007. She pressed the SFDA to address corruption and poor-quality products, and criticised regulatory authorities in one of her speeches, stating

> Mispositioning the role of the agency; inappropriateness in handling the relationship between government duties and enterprises, the relationship between business interest and public health interest; sole emphasis on helping enterprises and promoting economic

> development; and poor implementation of the central task of protecting public safety was one of the main reasons behind Zheng Xiaoyu and his senior officials' corruption cases and the recent crises of falsified medicines. (Wu, 2008 Yearbook: 63) [*translated from Chinese by the author*]

Vice Premier Wu Yi also spoke at a SFDA's meeting on *Studying and Implementing the Spirit of the Fifth State Council Working Conference on Clean Government and Anti-corruption* in 2007, stating that "the work of building a clean government is the key to effective food and medicine administration" ("State Food & Drug Administration Yearbook" Editorial Board, 2008) [*translated from Chinese by the author*]. She emphasised that the SFDA needed to strengthen its anti-corruption efforts in order to "re-establish a new image and win the trust of the Party and the people" ("State Food & Drug Administration Yearbook" Editorial Board, 2008) [*translated from Chinese by the author*].

Following the 2007 incidents involving poisonous pet food and the export of children's toys made with lead paint from Chinese factories into the US market, Premier Wen called on domestic firms to improve product quality and secure the reputation of the *Made in China* label (Embassy of the People's Republic of China in the United States of America, 2007). Just before the 2008 Olympic Summer Games in Beijing, an adulterated heparin active ingredient imported by a US manufacturer killed 81 Americans and another nation-wide melamine-adulterated infant milk crisis injured thousands of babies in China. Public anger and distrust in food and medicine safety put the SFDA under intense public scrutiny, with questions raised about its competence, transparency and accountability. The Chinese government faced rising public pressure from within China and internationally, particularly from the US and other import markets, over the safety and quality of Chinese medicines and other products.

5.6.2 Decoupling the entwined relationship between regulation and industry

In the wake of the above-described incidents, the SFDA was urged to critically reflect on its dual mandates, and to decouple promotion of industry interests from its public health mandate to ensure medicine quality and safety. To curtail the SFDA's close-knit connection with industry and potential for corruption, the central government made leadership changes at SFDA in June 2005. According to the influential Chinese newspaper *Southern Weekend* (南方周末), the new Director General Shao Mingli (邵明立) and his new management team came mostly from health regulatory

authorities, rather than the SPA with its deep industry connections. The number of civil servants in the SFDA with close connections with the industry were also significantly reduced, and most senior positions at the SFDA were replaced by civil servants from the health system (Song, 2008c; Ma & Long, 2007). The main purpose was to detach regulation from the regulated, focusing the agency's mandate on the former. Led by Shao, the new SFDA management began to place greater importance on regulation for public health, showing their determination to apply a different approach to former leader Zheng Xiaoyu. Speaking at the Conference on Construction of CCP's Work Style and an Honest and Clean Government, Shao stated, "there are serious problems with food and medicine, that not only affect economic development, but also becomes a major social issue and public safety issue" ("State Food & Drug Administration Yearbook" Editorial Board, 2006: 23) [*translated from Chinese by the author*]. In his talks with senior regulators at the provincial and municipal levels, Shao proposed to "shift the focus of our work to meet people's food and medicine safety needs", and to "establish a science-based approach to regulation, which can provide a strong ideational underpinning for the development of regulation on food and medicine" ("State Food & Drug Administration Yearbook" Editorial Board, 2006: 27) [*translated from Chinese by the author*]. Meanwhile, the medicine regulatory system underwent a nation-wide restructuring, replacing local medicine regulatory directors who previously worked for the pharmaceutical industry, with officials from public health background.

To meet the new approach of "putting people first", the SFDA launched a series of reforms to improve medicine quality and safety, including new investments in the regulatory system. After Zheng Xiaoyu's execution, SFDA re-examined all approved medicines prior to 2007 when Zheng was in charge. Pharmaceutical companies voluntarily withdrew more than 7,300 medicine registration applications by the end of 2007 (Bate, 2012). SFDA revised the *Drug Registration Regulations* in October 2007 to tighten the approvals process for medical products. By December 2007, the SFDA also shut down 300 manufacturing facilities for making inferior quality medical products and withdrew 150 GMP certificates (Bate, 2012). Between 2006 and 2007, the central

government invested more than 3.7 billion yuan (US$475 million equivalent[26]) in the food and medicine regulatory system, 1.3 times the total from 1998 to 2005 ("State Food & Drug Administration Yearbook" Editorial Board, 2009: 15). Central and local governments' total financial investment in strengthening the regulatory infrastructure and law enforcement equipment during the 11th Five Year Plan (2006-2010) was 59.2 billion yuan (US$8.2 billion equivalent[27]) – five times more than the 10th Five Year Plan (2001-2005) ("State Food & Drug Administration Yearbook" Editorial Board, 2012: 2). One ground-breaking project SFDA initiated, was to improve the detection and testing of SF medicines using mobile lab vans. Jin Shaohong (金少鸿), Professor and senior expert at the National Institute for the Control of Pharmaceutical and Biological Products and his team developed mobile labs for field testing. According to Professor Jin:

> The SFDA first announced in 2003 that we needed to build a drug testing system from the ground-level up. This meant drug testing should not "stay at home" but actively reach out to rural and countryside areas. Our first mobile van came out on November 18th, 2003. Vice-Premier Wu Yi greatly supported this initiative and pledged to invest 300 million RMB (US$36.2 million equivalent[28]) in research and production of mobile lab vans when she came to visit us. Combating substandard and falsified medicines requires government support, without it, technology alone cannot go far. Our first generation of mobile labs was only suitable for preliminary testing, samples then need to be sent to laboratory for further confirmation of testing result. Now with the second generation of mobile labs, testing is improved, and confirmation can be done in the van. Many specific problems are being resolved step by step. (Interview, 06BJ200312) [*translated from Chinese by the author*]

As of 2006, China central government allocated US$70 million for 400 mobile labs to operate. By April 2011, 454 mobile labs had been deployed to 30 provinces, covering 88 percent of China's rural areas with 1,060 technicians being trained to use the labs (Bate, 2012). The mobile labs also cooperated with medicines inspection agencies across 28 provinces and municipalities to carry out raids to crack down on dubious distribution channels selling SF medicines (Tan & Willson, 2009).

[26] Based on the average exchange rate of 2006 and 2007: ¥7.79 = US$1.00.
[27] Based on the average exchange rate from 2006 to 2010: ¥7.224 = US$1.00.
[28] Based on the 2003 exchange rate: ¥8.28 = US$1.00.

While the benefits to public health gained momentum from the mid-2000s, policy discussions within central government sought to reconcile the social versus commercial attributes of medicines, and thus the relationship between regulation and economic development. When speaking about policy ideas and challenges in combating SF medicines, a retired senior SFDA official shared his view on this internal battle of policy debate due to different policy perceptions:

> From my long years working in medicine regulatory authority, there are two major problems. One is the lack of effective policy instruments; the other, in my view, a deeper problem is the differences in understanding the issue. The understanding of medicines as a special commodity is still relatively superficial and hollow, that is, they only say that medicines are a special commodity in words. But how to marry this special attribute with the commercial attribute of medicines is an on-going problem. In my view, this perhaps is the most important ideational issue that contributes to so many issues of falsified and substandard medicines and the regulatory chaos in our country. When this ideational issue is reflected at the government level, at the leadership level, this can be a serious problem. (Interview, 27BJ280512) [*translated from Chinese by the author*]

Following the Sanlu melamine-contaminated infant milk scandal in 2008, the Chinese leadership put forward system innovation (制度创新) and institutional innovation (体制创新), aimed at achieving a more balanced approach to quality regulation and industrial development. As a senior SFDA official later admitted, before the mid-2000s the agency had fumbled its handling of the relationship between public and commercial interests, and that between regulation and development (Huang, 2013). In 2010, it was the first time that food and medicine regulation was discussed at the Central Economic Work Conference (中央经济工作会议). The conference placed emphasis on the quality of development and that public interest is a higher priority than commercial interest, and that "only by guaranteeing the 'quality', can we achieve the ‘speed’ of development", and "only by putting public interest in the supreme position, enterprises can achieve healthy development. If we ignore public interest, we will eventually pay a painful price. We must learn profound lessons from the Sanlu incident and correctly handle the relationship between regulation and development." ("State Food & Drug Administration Yearbook” Editorial Board, 2010: 12) [*translated from Chinese by the author*].

At the macro-level, the State Council carried out three major *Special Actions of Rectification of Drug Safety* in 2006, 2007 and 2009 ("State Food & Drug Administration Yearbook" Editorial Board, 2011: 4). The Beijing 2008 Summer Olympics drove the SFDA to tighten safety measures and orchestrate more regular campaigns to combat wide-ranging food, medicine quality issues. In 2009, 13 departments set up a joint meeting system for inter-ministerial coordination to crack down on the production and sales of SF medicines (as shown in Table 5- 4). During the same year, the SFDA established another *Steering Group for Special Action on Rectification of Drug Safety* (药品安全专项整治工作领导小组) to consolidate efforts on improving medicine safety ("State Food & Drug Administration Yearbook" Editorial Board, 2010: 46). In April 2009, 13 government departments set up a joint meeting system for inter-ministerial coordination to crack down on manufacturing and sales of SF medicines ("State Food & Drug Administration Yearbook" Editorial Board, 2010: 45-46). The effort aimed at establishing a long-term mechanism to improve interdepartmental coordination amongst government agencies. An updated version of the stricter GMP was issued in 2010 and the number of certified institutions for Good Clinical Practice (GCP) increased by approximately 70% between 2007 and 2011 (RDPAC, 2012). The CCP's 11th and 12th Five-Year Plans (2006-2010 and 2011-2015 respectively) also established that improving medicine quality and safety, constitutes a critical national task on the path to realising a vision of human-centred, scientific development.

5.7 Conclusions

This chapter explains the beginnings of the transformation of China's policy responses to SF medicines, towards prioritising public health interests. It also provides further evidence of how framing and the material world are mutually constitutive; as argued by McInnes and Lee (2012), the material world provides the substance for framing and the framing in turn orientates action in shaping material events. With this in mind, I have argued that the major shift in framing on medicine regulation and SF medicines occurred around 2006, rather immediately after the founding of the SDA or the SARS epidemic, when Hu-Wen began to promote the new political

ideology emphasising social well-being. After the founding of the SDA in 1998, economism remained the dominant frame because of the SDA's positioning, leadership, guiding principles, and personnel structure, and medicine regulation was compromised due to the tight relationship between regulators and the industry. Responding to SF medicines relied on market order rectifications and more institutionalised LSGs to sustain these campaigns. Although the health and well-being frame received some endorsement from the top political leadership to the institutional level, it didn't really change the way the SDA operated. The health and well-being frame in the early 2000s served to legitimise the creation of the SDA, and helped to show the government's rising awareness of the need to incorporate public health needs into policy-making and the development towards a rule-based administration. The health and well-being frame became accepted by the medicine regulatory authorities when further disastrous events severed as catalysts to promote the new framing. Critical material events, such as a series of detrimental SF medicines and food safety incidents, and growing corruption allegations levelled at the SFDA, and change in the SFDA leadership, contributed to new strategic thinking and framing of public health from China's top leadership to the medicine regulatory authorities. Hence, prioritising health and well-being led to a new wave of efforts to strengthen medicine quality and re-balance the relationship between public health and economic development.

Chapter 6 The Rise of the Security Frame on Medicine Quality (2012–2021)

6.1 Introduction

As part of China's continued economic ascendance, the country has become increasingly prominent in the global pharmaceutical supply chain. China is now the largest producer and supplier of APIs globally, expanding exports in generics, biosimilars and vaccines, and holds ambitions to become the leading global pharmaceutical manufacturing power. Meanwhile, the issue of SF medicines has attracted growing attention from Chinese political leaders in the wake of numerous safety scandals (Liu, 2009; Tang, 2009; Hu, 2012b). As described in Chapter 5, the government under President Hu Jintao began to place greater emphasis on the importance of social welfare beginning in 2003, and put forward several strategies to strengthen social policy. Medicine safety further became part of the national security agenda after President Xi Jinping (习近平) took power in 2012 (Ma & Zhao, 2015; Liu, 2016). In 2015, President Xi pushed for the implementation of the "Four Strictest" (四个最严) to ensure food and medicine safety. The same year, the Chinese SFDA carried out a series of substantial reforms to strengthen medicine regulation. In 2017, China joined the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), adopting its technical standards and guidelines in regulatory authorities, industry, and research institutions (PharSafer.com, 2018).

Within this context of growing emphasis on medicine quality and safety under President Xi, this chapter analyses the emergence of a securitisation frame. In the first half, I discuss the emergence of the security frame in relation to SF medicines and explains its different dimensions, including national security, political security, economic/industrial security, and environmental security. The security frame does not simply arise as a material feature of the issue itself, but was socially constructed by top policy-makers who perceived SF medicines (and medicine safety in

general) as a threat to Chinese society and the state. The second half of this chapter analyses the effects of the security frame on policy responses, elevating SF medicines higher on the policy agenda. The securitisation of SF medicines changed perceptions of the issue as posing an imminent threat (clear and present danger) to Chinese society, and hence required exceptional policy responses. Here I further examine the interaction of the three core frames during this period – economism, health and well-being and security – together and with material factors.

6.2 The securitisation process

This section analyses the rise of the security frame and the subsequent securitisation of SF medicines in China. It's important to note that in the Chinese language, "safety" and "security" use the same phrase, *anquan* (安全). Thus, medicine safety (药品安全, also known as drug safety) in Chinese literally means either medicine safety or medicine security. In English, however, safety and security have distinct meanings when referring to medicines. This research finds that policy discourses in China focused predominantly on medicine safety (as part of quality concern) until around 2010, when a new interpretation of *anquan* as medicine security (as industrial security) began to emerge. These two meanings of *anquan*, and their policy ramifications, have subsequently attracted much scholarly and policy debate. This section seeks to understand this security frame within a Chinese context, and the resultant policy discourses.

6.2.1 Medicine safety: From public safety to national security

According to WHO (2002: 7), medicine safety (known as pharmacovigilance) is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." It focuses on the technical aspects of ensuring that a medicine is safe to use, and in practice is usually associated with a country's regulatory policy.

Medicine quality and safety in China was first incorporated into the policy discourse on public safety and later became part of the national security discourse.[29]

The introduction of "public safety" (公共安全) into food and medicine safety, constituted a major step towards securitising SF medicines in China. The concept of public safety was introduced under President Hu Jintao, when food and medicine safety, for the first time, was recognised as "an indispensable part of public safety" in the *11th National Five-year Plan* in 2007 ("State Food & Drug Administration Yearbook" Editorial Board, 2007: 13). In March 2011, the issue was elevated further into the *12th Five-Year Plan for National Economic and Social Development* as "safeguarding of food and medicine safety" became the top priority of "strengthening public safety system construction" under Chapter 41. The Chinese *Economic Daily*, founded by the State Council, reiterated in a major news report in June 2012 that "medicine safety is a major issue of social well-being and public safety" (Yan, 2012). In this context, "public safety" was institutionalised (as written into the above national strategies) and communicated publicly by senior CCP leaders. Policy discourse on safety in relation to SF medicines, then reached a new level because of who was deploying this phrase, the institutional context, and how it was being communicated publicly by senior political figures were all different. Ma Huaide and Zhao Peng, senior academics at China University of Political Science and Law, suggested that once an issue is defined by decision makers as "public safety problem/issue" in China, it means that the issue is seen as presenting an "existential threat" to society and requires immediate policy action (Ma & Zhao, 2015: 66). They elaborated that "[w]hen food and medicine problems were elevated to being a public safety issue, and gradually came to the centre of the political agenda, it

[29] Recognising SF medicines as posing risks to society is not a recent phenomenon. As early as 1979, the production and sales of SF medicines was defined by the 1979 *Criminal Law* as a crime "obstructing the administration of public order" (Chapter VI Article 164). A State Council's policy document in 1980 stated that "the manufacturing and sales of SF medicines have posed serious harm to the people, undermined public security (社会治安)"[29]. These early efforts didn't count towards securitisation per se, as the term "threat" was not deployed and exceptional actions were not observed – which were the requirements of successful securitisation (Kamradt-Scott & McInnes, 2012).

demonstrated that the highest policy-making levels perceived this as an 'existential threat'" (Ma & Zhao, 2015: 66) [*translated from Chinese by the author*].

The closer connections between medicine safety, public safety and national security became unequivocal in 2013 under President Xi, who also became General Secretary of the CCP in 2012. In November 2013, the Third Plenum of the 18th Central Committee of the CCP explicitly set out as a priority goal improvement to the public system, to ensure food and medicine safety, in a major CCP document *Decision of the Central Committee of the CCP on Some Major Issues Concerning Comprehensively Deepening the Reform*. As a continuation of Hu-Wen's political legacy, food and medicine safety was given continued importance in the list of priority public safety issues. As further defined by the *Decision*, public safety was also linked to governance of Chinese society, which was seen as key for safeguarding national security. In 2014, President Xi constructed a new concept of "holistic national security" (总体国家安全观) to elevate the importance of non-traditional security issues (discussed in Section 6.3). Food and medicine safety were explicitly presented as part of a new public safety agenda, constituting a vital element of holistic national security. To support this new concept, a Central National Security Commission (CNSC) was created with the mission to improve existing national security systems and guarantee the country's national security. At this time, improving regulation of food and medicine safety was incorporated into the CNSC's mandate for promoting good governance on social issues.

6.2.2 Medicine safety: Corruption and political security

In this context, securitisation in China connects SF medicines with national security, and ultimately elevates the issue higher on the policy agenda. Following the prosecution of Zheng Xiaoyu and other SFDA officials, the CCP began to elevate the severity of SF medicines towards a higher political level. Further to Vice Premier Wu's remarks on medicine regulation and

corruption described in Chapter 5 (Section 5.6), Qu Shuhui, the Head of the Party's Discipline Inspection Group[30] at the SFDA, gave a speech in April 2006:

> The severity and danger of the recent series of cases must be understood from a political and holistic view. Some leading cadres of the SFDA abused their power, accepted bribes, particularly in the areas of registration and approval for medicines and medical devices. This had a very bad impact on society and damaged the image of the party and the government ("State Food & Drug Administration Yearbook" Editorial Board, 2007: 367). [*translated from Chinese by the author*]

It was suggested that the new SFDA leadership under Shao Mingli, reached a consensus that corruption was the main root cause of successive SF medicines incidents ("State Food & Drug Administration Yearbook" Editorial Board, 2007: 357). Observing high-level corruption cases, Henry Chen, a lawyer and legal expert suggested that SF medicines, "[f]rom the perspective of the Chinese government, it is not only a legal issue but also a political issue. As a result, the pharmaceutical industry and companies will be under constant examination, not only on counterfeits but also on related issues such as commercial bribery" (Dai, 2011). After President Xi took power, food and medicine safety became securitised more intensively. *People's Tribune* (人民论坛), CCP's theoretical journal run by the *People's Daily*, conducted a national survey in 2013 called *National Anxiety Diagnosis*, which revealed that corruption, food and medicine safety ranked number 2 and 3 among the Chinese public's list of concerns (top 1 was inflation). In 2013, one year after becoming the country's leader, President Xi warned officials: "If our party can't even address food safety issues properly, and keeps on mishandling them, then people will ask whether we are fit to keep ruling China." (www.gov.cn, 2013). A commentary in *The Economist* stated that this was a remarkable statement from the head of the CCP, suggesting "Mr Xi understood how grievances about official incompetence and corruption risked boiling over" (The Economist, 2016). In 2013, Vice Premier Wang Yang (汪洋) published an article, *Focusing on Food and Medicine Safety Supervision* in *Qiushi*, the Party's theoretical journal. In it, he explicitly stated

[30] Deployed by the Central Commission for Discipline Inspection, the internal-control institution of the CCP which defends party discipline and punishes cadres for wrongdoings (中央纪委监察部驻 SFDA 纪检组监察局)

that food and medicine safety in China was of paramount importance for social well-being, economics and politics. On the potential political implications, he wrote:

> Food and medicine safety is a great political problem. In our highly technological modern society, people are concerned about health and safety. Even a minor matter can spread rapidly and has the potential to become a focus of public and media attention. Without sound management, minor and local issues can evolve into major problems, causing major public crises and directly corroding the government's credibility. (Wang, 2013: 3) [*translated from Chinese by the author*]

Similarly, in August 2017, Liu Yandong (刘延东), the Chinese Vice Premier for healthcare, published an article in *Qiushi* to promote the "Healthy China" strategy. She wrote that health-related problems including environment pollution, food and medicine safety, water safety, and occupational safety, are not only issues of great importance for people's well-being, but also a major social problem, a political problem (Liu, 2017).

The above quoted speeches reflected efforts by high-ranking Chinese politicians to frame medicine safety in a way that garnered more political attention, by tying the issue to social stability, the Party's governing ability, and ultimately the political sustainability of the CCP. Core messages from these speeches were highly publicised through mainstream Chinese media, including *Xinhua News*, *People.*com and *Caixin,* and through leading Chinese academics across disciplines in public administration and political sciences. The purpose seemed to be to communicate to the public that the issue had been elevated to a high level of CCP's policy concern (higher than under normal circumstance), and that determined effort would be made to address it.

6.2.3 Medicine safety vs security: Quality vs. industrial security

The two meanings of *anquan* in policy-making – safety and security – were integrated by Dr Hu Yinglian (胡颖廉), Associate Professor in public administration at the Chinese Academy of Governance, who interpreted safety as quality and security as quantity and access (Hu, 2012a, 2013). He suggested that medicine safety means medicines should be of good quality, safe and effective, which is also part of the national public safety concept (Hu, 2013, 2017; Hu & Mu, 2017).

Medicine security, as Hu argues, is equivalent to industrial security (产业安全), which means that the quantity and variety of domestically produced medicines should meet the needs of the public and are part of the economic security discourse (Hu, 2017; Hu & Mu, 2017). The economic implications of product quality and safety, were articulated in Vice Premier Wang Yang's remarks on food and medicine safety, where he stated: "If people lose confidence in these industries, it will severely hinder industrial security and economic development." (Wang, 2013: 3) [*translated from Chinese by the author*].

The concept of pharmaceutical industrial security first publicly emerged in 2008, when the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), a Ministry of Commerce affiliated industrial association, published a *Report on Conditions of the Chinese Pharmaceutical Industrial Security*. The report proposed the term "pharmaceutical industrial security" and suggested that the enormous influx of foreign pharmaceutical companies and investments threatened the security of the Chinese domestic pharmaceutical sector (CCCMHPIE, 2008). MPCs influence in China has increasingly become an industrial security concern (further discussion in Chapter 7), as commented on by Dr Hu Yinglian:

> The field of medicines in China is largely influenced by foreign multinational companies. It is a problem of industrial security rather than a medicine quality and safety problem. It is a quite disheartening topic. For example, do you know who sponsored research projects for various departments of the SFDA? Those big enterprises. Foreign companies mainly sell innovative medicines, high-price medicines, and new and special medicines in China. Domestic manufacturers sell large varieties, but mainly generic medicines. (Interview, 05BJ190312) [*translated from Chinese by the author*]

The Ministry of Commerce launched a project in 2010 to establish an "early warning mechanism" (预警机制) for determining industry damage, aimed at maintaining the security of domestic industries including the pharmaceutical sector. Another seminal book named *Annual Report on China's Medical Industry Security* jointly published by China Centre for Industrial Security Research and Peking University First Hospital in 2014, made a further contribution to the discourse on pharmaceutical industrial security (which includes medicines and medical devices). Researchers suggested that both the survival and development of the medical industry

were key to the security of China's medical industry and should not be threatened (Zhang, 2014; Qin, 2014). The authors advanced that industrial security is the foundation of economic security and the core of national economic security, hence policy goals should focus on improving the nation's industrial competitiveness, enhancing healthy, stability and secure development of the Chinese medical industry (Zhang, 2014; Qin, 2014). The Director of Government Affairs of a leading Chinese pharmaceutical manufacturer, interviewed for this research, shared her views on the importance of industrial security:

> In a developing country like China, where the industry has just begun to develop, it's important to consider medicine security. The pharmaceutical industry is a sensitive industry which engages health security, such as substitution of medicines. The government may be concerned when foreign companies withdraw from the market. Some medicines are not replaceable, patients will then have no medicines available to them. The government's efforts in recent years to vigorously encourage R&D/innovation, in my view, they hope to strengthen indigenous innovation capability, reduce dependence on foreign medicines, and protect domestic health and industrial security. (Interview, 13BJ110412) [*translated from Chinese by the author*]

The concept of medicine security is essentially associated with domestic self-sufficiency (or self-reliant) of production and supply (i.e., the security of medicine supply). This was consistent with one of the fundamental ruling principles of the CCP for commodities such as grain and medicines – i.e., not to rely on imports and foreign products. Overreliance on foreign supplies in CCP's view would partly undermine the growth of the domestic pharmaceutical industry, and partly pose serious national security concerns in emergency events, such as a pandemics and warfare.

6.3 The security frame: Core ideas and policy context

Compared to other global health issues such as HIV/AIDS and pandemic influenza, SF medicines have rarely been framed as a global security issue. A report published by the Stimson Center, a US international peace and security think tank suggested SF medicines "is not only a public health hazard of highest magnitude; it is also a national and international security threat", because it provided material support to criminals and terrorist organisations (Finlay, 2011: 1). Another US Pharmacopoeia policy paper refers to SF medicines during the COVID19 pandemic as "a threat to

global health security" (US Pharmacopeia, 2020). Within China, however, the security frame has been one of the core frames perceived in the Chinese policy responses to SF medicines. It depicts the problem as potentially posing multiple types of security threats – human security, industrial (economic) security, national security, and ultimately the political security of the CCP. This section thus analyses the general security discourses in a global health and Chinese policy context.

6.3.1 Security discourse in global health

The concept of security, traditionally related to the military and defence sectors (Buzan *et al.*, 1998), has been extended to a wide range of public policy issues in the post-Cold War era, perceived to pose existential threats. These include perceived economic, food, health, crime, and environment risks. The number and nature of such risks have been growing due to the interdependencies created by globalisation. Global health scholars identified how a certain type of health issue began to be framed as a security issue "when it is presented as a threat to someone or something, and as something against which defensive measures (either in the form of prevention or response) must be taken" (McInnes & Lee, 2012b: 19). The security frame, more generally, argues that primary importance should be given to protection from a "clear and present danger". When an issue is accorded the status of a security issue, it is deemed to need urgent addressing with extraordinary measures (Buzan *et al*., 1998).

According to Kamradt-Scott and McInnes (2012), securitisation of an issue needs to fulfil two requirements: first, the positioning of an issue through speech acts by the securitising actor (usually by political leaders, senior civil servants and renowned academics) as a security threat; and second, policy-makers accept securitising claims by enabling emergency measures or exceptional policy responses. Global health scholars also identified different meanings of the security discourse, with each reflecting different normative frameworks, agendas and interests. For example, Labonté identifies three arenas of security within which health is strategically framed in national foreign policy: namely, national security, economic security and human security (Labonté, 2014). While Elbe distinguishes three frames used in international

organisations for formulating HIV/AIDS as a security issue: human security, national security and international security (Elbe, 2009). Each concept of security represents a particular construction of social reality, and thus promotes a particular worldview, material interests and policy preferences. Nevertheless, "the underlying logic common to all forms of security is that of threat and defence" (McInnes & Lee, 2012b: p19).

6.3.2 Security discourse in the Chinese context

In China, security is a multidimensional concept which has evolved over time. The Chinese security discourse prior to the mid-1990s was largely dominated by the military and defence agenda, conventional "power politics", and counter-espionage concerns (Ong, 2007; Li, 2008; Liu, 2014). Although non-military aspects of security, notably economic security, were given strong emphasis from the late 1970s, "non-traditional security" (NTS), as it is referred to in China, did not become prominent until the mid-1990s. Zhang and colleagues (2013) suggest that the UNDP *1994 Human Development Report* first brought new thinking about NTS to China as a "new security concept" (新安全观)[31]. The Asian financial crisis in 1997, September 11th terrorist attack in 2001, SARS outbreak in 2003-2004, and H5N1 influenza pandemic in 2005 further increased China's policy attention to NTS (Cui & Yu, 2010). In particular, NTS became a flourishing subject among Chinese academics after the SARS and H5N1 epidemics, when the government positioned such perceived threats as part of the national defence agenda (Chan *et al.*, 2010; Zhang *et al.*, 2013). Research shows that the number of published Chinese journal articles on NTS increased significantly from an average of 2.5 articles between 1999 and 2002 to an average of 38.4 articles between 2004 and 2008 (Chan *et al.*, 2010).

While the Western non-traditional security discourse (Buzan, 1991; Buzan *et al*., 1997) had already reached high-level discussion by the mid-1990s, a fundamental shift in Chinese security thinking did not occur until the *18th Party National Congress Political Report* in 2012,

[31] The UNDP Report defines human security as people rather than state-centred, and proposes seven categories of security concerns: economic, food, health, environmental, personal, community, and political securities (UNDP 1994).

when a number of issues including food safety, medicine safety, grain security, ecological security, and resource security began to form part of the national security agenda. Hu (2014) suggested that Chinese perceptions of security were transformed, from a "traditional dual" (传统的二元) concept to a "non-traditional inexhaustible" (非传统的无穷尽) concept. The former covers military and political sectors and the latter refers to the expansion of the concept to include ever more issues under the umbrella of "national security", particularly under President Xi's "holistic national security". This new concept consists of an array of security domains, and is intended to strengthen the linkage between external and internal security in Chinese thinking (Lampton, 2015). Among the eleven security domains, most of them are targeted at domestic security threats including economic security, cultural security, social security, science and technology security, information security, ecological security, and resource security (Xinhuanet, 2014; Tiezzi, 2014).

Section 6.2 discussed how China's shifting thinking on security has influenced understanding and responses to SF medicines in the last fifteen years. Through this frame, the new leadership of the SFDA politicised and thus elevated the importance of medicine safety, and the need for a concerted regulatory strategy and policy approach to tackle it. This was linked to re-gaining credibility domestically and internationally. After Xi Jinping took power in 2012, the securitisation process intensified: from low intensity securitisation (politicised as an NTS issue i.e. public safety) to high intensity securitisation (part of traditional national security). Medicine safety was thus closely associated with economic and political security. Political security, which is seen by the CCP as the ultimate existential threat, was seen as being undermined by corruption and threatened the Party's legitimacy to rule China. The CCP reiterated in the 2021 *Resolution of the CPC Central Committee on the Major Achievements and Historical Experience of the Party over the Past Century*, that "Corruption is the biggest threat to the party's long-term governance" (Central Committee of the CCP, 2021). As Shan Chunchang (闪淳昌), the Leader of the State Council's Emergency Management Expert Group and his colleagues suggested, "Regardless of how China's national security interests change, political security has always been the top priority,

political interests have always been the most important national interest" (Shan *et al*., 2015: 39) [*translated from Chinese by the author*]. In 2017, President Xi Jinping reiterated that safeguarding political and regime security remains the top priority, and "political security determines and influences security in all other areas including economic security, social security, cultural security" (Li, 2017) [*translated from Chinese by the author*].

6.4 Policy impact of the security frame

Successful efforts to securitise an issue, not only involves consistent speech acts to raise more awareness among policy circles and society, but also leads to the adoption of exceptional policy responses. This chapter has discussed how the security frame in China was positioned medicine safety as a security or threat by political leaders, senior civil servants, renowned academics, and the media. This section examines how the security frame influenced the formulation and implementation of exceptional policy responses (outside the routine policy environment) to increase the political priority given to medicine quality and safety issues. Here, I uncover that the security frame had two major policy effects: first, it led to more comprehensive and re-occurring strategic plans for tougher measures on quality and regulation; second, it fast-tracked national programmes and legislations to improve medicine quality and safety.

6.4.1 National 5-year plans: Better quality medicines and stronger industry

The securitisation process of SF medicines spurred considerable activities in developing more comprehensive strategy and policy plans. Following the *11th Five-year Plan on National Food and Drug Safety* in 2007, a combined Plan on both issues, the State Council issued separate plans on medicines known as the *12th Five-year* and *13th Five-year Plan on National Drug Safety* in 2012 and 2017. Producing regular strategic plans by the State Council on one specific social issue and with some continuity was unusual, hence a notable achievement. Both plans emphasised the importance of addressing public safety as a national security concern, and improving the health and well-being of the nation (State Council, 2012; State Council, 2017). Plans set out strategic steps to improve quality and regulation on medicine standard setting, production, distribution,

and sales. After the toxic capsule incidents in 2012 (nine pharmaceutical manufacturers with 13 batches of medicine capsules laced with the toxic metal chromium), the SFDA and provincial counterparts implemented a nationwide information disclosure system called *the Drug Safety Blacklist* (药品安全黑名单) on all SF medical products (SFDA, 2012b). In 2015, President Xi urged implementation of the "Four Strictest"– "strictest standards, strictest regulation, strictest punishments, and strictest accountability mechanism" as the guiding ideology for the *13th Five-Year National Drug Safety Plan*.

Alongside national medicine safety plans, the government promulgated the *12th and 13th Five-year Development Plan of the Pharmaceutical Industry* in 2012 and 2017, to elevate the pharmaceutical industry as a strategically important industrial sector. The *12th Plan* was issued by the Ministry of Industry and Information Technology (MIIT), and the *13th Plan* was issued by 6 key departments including MIIT, National Development and Reform Commission (NDRC), Ministry of Science and Technology, Ministry of Commerce, National Health Commission and the CFDA. It is important to note that, since 2012, as well as public health protection, medicine quality became central to industrial policy. The *12th Plan* made frequent reference to the message that speed and quantity of manufacturing were no longer the primary goals. Instead, the new focus for the pharmaceutical industry should be industrial transformation and technological upgrading through improving measures on product standards, safety and efficacy, and the quality assurance system (Qin, 2014). In 2015, the State Council released another major document *Made in China 2025*, a 10-year national plan for transforming China into a global leader in manufacturing. This plan intended to put China on a path to further industrialisation, with greater emphasis on innovation and the biomedicine and medical devices industry incorporated as one of ten key sectors. Biotechnology was also listed as one of the key industries in China's *13th Five-year National Development Plan for Strategic Emerging Industries* (State Council, 2016).

As China began its the *13th Five-year Plan*, Premier Li Keqiang emphasised in the first State Council's Executive Meeting of 2016 that, "we are determined to improve medicine quality, in

particular quality of essential medicines" (Li 2016). For the first time, medicine quality was was top of the agenda at the government's weekly executive meeting and was recognised as the key element for advancing industrial upgrading. Bi Jingquan (毕井泉), the General Director of CFDA also stated in a press conference in 2016 that "powerful supervision makes powerful industry", underscoring that quality was key to achieving a more successful and competitive industry (State Council Information Office, 2016).

6.4.2 The *Quality Consistency Evaluation* programme

In November 2012, as part of the *12th Five-year Plan on National Drug Safety* to improve quality of generic medicines and restore public confidence in domestic-produced medicines (People's Daily, 2018), the SFDA issued its most critical programme since its inception in 1998 to enhance medicine quality produced by Chinese manufacturers. The *Work Plan for Quality Consistency Evaluation for Generic Medicines*, known in short as *Quality Consistency Evaluation* (QCE) programme, called for re-evaluation of all oral pre-2007 generics by 2015 and all injectable pre-2007 generics by 2020 (SFDA, 2012c). QCE aimed at ensuring consistency of composition and clinical efficacy between the test (domestic produced generic medicines) and reference medicines, which mostly were off-patent medicines by MPCs (known as "innovative medicines", see Chapter 7). While the security frame has helped attract more policy awareness on medicine quality, this research finds that actual policy action only took place when the authority of relevant institutions and actors aligned with this framing.

The implementation of QCE stagnated for nearly three years after being launched in 2012, until two major events spurred quality reforms. The first was institutional reforms in 2013 which increased the political ranking of the SFDA to ministerial level, renaming it as the China Food and Drug Administration (CFDA). This higher ranking within the Chinese bureaucracy enabled improved policy coordination and mobilisation, which was previously a major challenge for the SFDA, located at the vice-ministerial level, because it was difficult to mobilise other relevant departments at the ministerial level (Tan *et al*., 2015; Liu, 2008). The second was the

appointment of Bi Jingquan as CFDA Director General in January 2015, under whom the CFDA initiated substantial regulatory reforms, including furthering progress on QCE. Bi's ability to initiate far-reaching reforms and issue policy documents beyond the title of CFDA, seems to be due to his political experience and connections. As one Government Affairs Manager of a leading domestic pharmaceutical company commented in an interview for this research, "Bi previously served as a Deputy Secretary General of the State Council, so under him many policies could be issued on behalf of the State Council or higher." (Interview, 04HZ210218) [*translated from Chinese by the author*]. A provincial medicine regulator interviewed made a similar observation, stating that "Bi used to be the secretary of Wang Qishan, the Vice Premier, and Wang was close to the big boss." (Interview, 07HZ240218) [*translated from Chinese by the author*].

The relaunch of QCE hinged on two major policy documents which were at the core of Bi's regulatory reforms. The first one was the 2015 *Opinions of the State Council on the Reform of the Evaluation and Approval System on Medicines and Medical Devices* (*guofa* 国发 No.44). No. 44 required all 289 essential medicines to complete a QCE by 2018. The second was the General Office of the CCP Central Committee and the General Office of the State Council jointly issued in 2017 *Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging the Innovation of Medicines and Medical Devices* (*tingzi* 厅字 No.42). On the significance of these two documents, a senior provincial medicine regulator interviewed stated:

> The second was version 2.0. The first was to kick off the reform and contained relatively principle-based contents. Some specific issues emerged during the implementation of the first one which could not be resolved at the State Council level. So, the second one was issued by the higher level - the Party Central Committee. It was the first time in our country that a policy on medicine regulation was issued by the Party Central Committee. (Interview, 19HZ150318) [*translated from Chinese by the author*]

The latter one was also known as "*Innovation Opinions*", which stipulated six components of a total of 36 reform measures, including simplifying regulation of clinical trials, accelerating the review and approval process on medicines, promoting medicine innovation and generics including the launch of the Chinese "Orange Book" – the *Marketed Medicine Catalogue* (launched in December 2017), and implementing a fuller Market Authorisation Holder scheme.

Furthermore, the provincial regulator explained that the effectiveness of a policy document depended greatly on whom the issuer was:

> With regard to *Notices* or *Decisions* issued by the State Council (*guofa* 国发), the General Office of the State Council (*guobanfa* 国办发), and the General Office of the CCP Central Committee (*tingzi* 厅字), they all represent different hierarchal levels. The Market Authorisation Holder scheme, Quality Consistency Evaluation, those specific programmes are all *guobanfa*. *Guofa* is to issue a policy on behalf of the State Council, *guobanfa* is higher than *guofa*. When we implement these policies at the provincial level, the corresponding issuer would not be the same. If it's *guofa*, our correspondent is "the xx Provincial Government"; if it's *guobanfa*, our correspondent is "the General Office of the xx Provincial Government". On effectiveness, as the Party controls everything, *tingzi* has the highest effect, which raises an issue to the height of the Party Central Committee. (Interview, 19HZ150318) [*translated from Chinese by the author*]

Director General Bi's personal power and connections greatly contributed to elevating the political awareness of, and enabling effective policy responses to, medicine quality. In addition to formulating policy documents at a higher political level, the CFDA under Bi conducted several special programmes to address SF medicines. As part of the regulatory reform programme, CFDA began unannounced flying inspections on pharmaceutical and medical device manufacturers beginning in 2015, following the issue of *Measures for Unannounced Inspections of Pharmaceutical and Medical Devices*. On 22 July 2015, the CFDA issued another *Announcement on Carrying out Self-inspection and Verification on Drug Clinical Trial Data* (known in China as the "7.22 Storm") to combat clinical data fraud. The *Announcement* came unexpectedly, and with short notice, mandating applicants for a total of 1,622 pending medicine registration applications, covering both imported and domestic medicine applications, to conduct self-inspection on clinical testing data and submit final reports to the CFDA by 25 August 2015. The purpose of this was to ensure the authenticity and proper record-keeping of the clinical trials data (Sidley, 2015). By 12 January 2016, 1,151 medicine applications were either withdrawn (77%) or failed inspection (3%), accounting for more than 80 percent of the total 1,429 inspections required. The scale of incomplete and fraudulent clinical data that came to light was viewed as highly alarming. In a report released in September 2016, the CFDA described the findings of widespread fraud as

shocking and vowed to crack down on what it described as a chaotic situation in the country's clinical trials industry (Generics and Biosimilar Initiative, 2016).

6.4.3 Toughened environmental policy

In 2013, President Xi called for China to become an "ecological civilisation" (生态文明), which, meant pursuing a more sustainable form of development through promoting a balanced relationship between nature and humanity. Xi's concept of ecological civilisation became an important element in China's policy discourse and policy-making across the environmental, economic, and social domains (Kuhn, 2019). Ecological and environmental security became part of national security, and the concept of "ecological civilisation" was written into the *Chinese Constitution* in 2018 (Xinhuanet, 2018). The Chinese government tightened measures against pollution and the pursuit of economic goals was thus no longer the sole policy priority. With revisions to the *Environmental Protection Law* in 2015, and imposition of the Environmental Protection Tax from 2018, heavy polluting industries were directly impacted. This included the pharmaceutical industry given its production of chemicals, intermediates, APIs, and excipients were severely affected. Nearly 150 manufacturers of APIs shut down their facilities between 2016 and 2018, with thousands of factories suspended that were unable to meet the new production standards (Jayakumaran, 2019). A representative from an API/intermediates trading company interviewed for this research, corroborated this:

> In the wake of recent administrative orders on environmental protection, particularly after Xi Jinping famously said "*Clear waters and green mountains are as valuable* as *mountains* of *gold and silver*"[32], chemical plants and industrial parks were all closed down, especially by municipal and country governments. More than 1,700 chemical/raw material manufacturers were shut down along the Yangtze River banks. (Interview, 18HZ140318) [*translated from Chinese by the author*]

The closure of these factories had a knock-on effect on both local and international supply chains and led to soaring prices across wide-ranging therapies, including anti-diabetic, cardiovascular, central nervous system, vitamins, antibiotic, and oncology APIs. A senior manager

[32] Xi Jinping's "Two Mountain theory" (Chinese: 綠水青山就是金山银山)

from an import and export company for chemical and pharmaceutical intermediates in Zhejiang province, China's major pharmaceutical ingredients exporting province, described the economic consequences of these factory closures:

> Our company's sales revenue dropped 4% last year (in 2017). In monetary value, we lost 100 million RMB of sales. The most important reason was the closing down of many chemical manufacturers. Now the situation is that we have clients, for example from India requesting certain products, but these products are no longer manufactured. So it's very frustrating that we have business opportunities, but no products to sell. (Interview, 10HZ280218) [*translated from Chinese by the author*]

Despite the potential disruption to production and loss of business opportunities, the reforms were seen as a positive move from the perspective of environmental protection and improving overall health and well-being. A senior officer from CCCMHPIE was very supportive:

> Because many chemical plants were closed, the export prices of Chinese API soared last year. With ever increasing prices, this made Indian companies more competitive. However, it is a good thing for China as the environmental situation is improving. We have smog, all our soil and air is polluted. Many varieties of API are not allowed to be produced now. I think this is a good thing in the long run. (Interview, 14TEL050318) [*translated from Chinese by the author*]

The environmental clean-up program was expected to be a key driver for industrial upgrading and consolidation, because manufacturers needed to invest and upgrade to survive. Small- and medium-sized companies that could not keep up-to-date with ongoing regulatory changes, and meet public audit requirements, would ultimately go out of business. In this context, environmental security concerns were well aligned with health and well-being objectives.

The case of API is a good example of how China has combined its ambitions to move up the global value chain, by producing more innovative APIs while taking more responsibility for environment protection. The shifting policy attention on quality and safety of medicines from 2012 onwards, and strengthened environmental protection policies, led to the closure of many API producers. The complementarity of these two policies was viewed by Chinese leaders in the long-run, as a win-win situation. They could bring positive health benefits by providing safer and better quality medicines, while the policies would also contribute to the global competitiveness of Chinese medical products and thus increase exports. This strategy embodied President Xi's call

for "ecological civilisation", and suggests the government had shifted strategy, from short-term rapid economic growth, to more of an emphasis on population health and well-being, and more sustainable pathways for industrial development.

6.4.4 Fast tracking new laws and legislations

The framing of medicine safety as a security issue accelerated the revision of relevant legislation and promulgation of new laws which, in turn, impacted on the material factors shaping SF medicines in China. In the second draft of the *National Security Law* published on 6 May 2015, following the founding of the CNSC, Article 24 specified that the state should "appropriately handle types of emergencies, including food and drug safety incidents, and infectious diseases which affect national security and social stability, promote social harmony, maintain public security and societal tranquillity" [*official English translation*]. Although the final version (passed on 1 July 2015) replaced "food and drug safety" and "infectious diseases" with broader terms of "public health" and "public safety", it still signified a heightened political awareness of medicine quality and safety as key aspects of an evolving national security agenda.

With the 2017 *Innovation Opinions* containing 36 major regulatory reforms, much of the contents of the 2001 *Drug Administration Law* were regarded as outdated and no longer in line with newly adopted regulatory reforms and industrial development strategies. On 23 October 2017, a month after adoption of the *Innovation Opinions*, the CFDA urgently called for legislative amendments to provide the legal basis for regulatory reforms. The revision process was spurred by a 2018 Chinese film, *Dying to Survive* (《我不是药神》, popularly known as the Chinese Dallas Buyers Club), based on the real-life story of leukaemia patient Lu Yong (陆勇). Over the period of a decade, Lu helped 1,000 leukaemia sufferers to buy safe and good quality cheap generic medicines[33] from India, which were officially unapproved by the Chinese medicine regulatory

[33] The originated medicine Glivec, used to treat leukaemia, and made by a Swiss company, was unaffordable for most Chinese patients, costing RMB 23,500 (US$3,777) a month.

agency, without profiting himself. Several issues from the film, including the definition of SF medicines, medicine prices, and lack of access to essential medicines, aroused much debate by the Chinese media and the public (Kuo, 2018; Xinhuanet, 2019; CCTV.com, 2019; China News, 2019; Finance.sina.com, 2019). The new *Drug Administration Law* came into force in 2019 with many substantial changes to the previous 2001 version. The national medicine regulatory authority's responsibility to coordinate economic policy (Section 4.2) was removed from the new legislation, as Article 3 states that "drug administration shall focus on public health". In response to the film and Lu Yong's case, the 2019 *Drug Administration Law* also refined the definition of SF medicines (see Appendix D on China's legal definitions of SF medicines), removed manufacturing and importing of unapproved medicines from the definition of falsified medicines, and reduced the penalty for importation of small amounts of unapproved medicines (Art. 98, Art. 124).

A scandal over vaccines in 2018 prompted legislators to extend reforms, by adopting a new *Vaccine Administration Law* in June 2019. Changsheng Bio-Technology, China's second largest vaccine producer, exposed vaccine production and data falsification during a flying inspection by the CFDA. The vaccine scandal caused significant public concerns as 13,000 rabies vaccine doses were found to be substandard, and 252,600 doses of ineffective vaccines for diphtheria, whooping cough and tetanus were given to thousands of young children (Ng, 2018). The *South China Morning Post* reported this incident as "China experienced its worst public health crisis in years" (Gan, 2018). General Director Bi resigned from the National Medical Products Administration (CFDA underwent reconstruction in 2018 and renamed to NMPA) after the Changcheng incident. Changsheng was fined by the NMPA to the sum of RMB 9.1 billion (US$1.3 billion) in November 2018, and the company was delisted from the Shenzhen Stock Exchanges in October 2019 for endangering public health and national security, under the new rule imposed by the financial regulator China Securities Regulatory Commission (Ng, 2018; Ren & Wong, 2019; Wang, 2019). This incident led to vaccine legislation being fast-tracked, and came into force in June 2019 as a response to the increased priority on medicine and vaccine safety to strength vaccine regulation (China Daily, 2019).

China's leadership further expanded on the national security frame in the country's fight against COVID-19. At the beginning of the pandemic, President Xi Jinping stressed the importance of improving the mechanism for major epidemic prevention and control, and the national public health emergency management system (Xinhuanet.com, 2020). In a speech to experts and academics on COVID-19 response held in June 2020, President Xi elevated the importance of human security, emphasising that "Human security is the cornerstone of national security (人民安全是国家安全的基石). Life is weightier than Mount Tai (生命重于泰山, which is also translated as: life is of paramount importance)." (Xi, 2020) [*translated from Chinese by the author*]. Further to this, President Xi published an article in *Qiushi*, the Party's flagship magazine, titled *Building a strong public health system to safeguard people's lives* where he advocated that public health as an overall and long-term issue should be integrated in all policy-making processes (Xi, 2020). The COVID-19 pandemic has also prompted Chinese authorities to fast-track biosecurity legislation and elevated biosafety and biosecurity to a national security issue (Cai & Zhuang, 2020). President Xi remarked at the 12th meeting of the Central Commission in February 2020, that:

> Biosafety and biosecurity are vital to people's health, national security and long-term stability of the country, and must therefore be included into the national security system. A systematic plan on risk control and management system must be formulated to comprehensively improve China's governance capacity on biosafety and biosecurity. Legislation on a biosecurity law must be accelerated to establish the legal and institutional frameworks needed to ensure biosafety and biosecurity of the country. (Xi, 2020) *[official translation]*

The Biosecurity Law (生物安全法) was passed on 17th October 2020 and came into force in April 2021. Furthermore, the COVID-19 pandemic raised more policy attention on the further development (including manufacturing and R&D capabilities) of the pharmaceutical and vaccine industries. A strong domestic industry is key to safeguard people's lives, particularly in the event of a pandemic and geopolitical turbulence which can cause distrust and disruptions in global supply chains. The COVID-19 pandemic has further re-enforced the importance of industrial security, in terms of maintaining a reliable and sufficient production capacity and supply of medical products. In the forthcoming *14th Five-year National Plan* (2021-2025), China seeks to

make significant financial investment to enhance the core R&D and innovation capabilities of the pharmaceutical and biotechnology industries.

6.5 Conclusions

This chapter analyses the rise and proliferation of the security frame, from growing fears over the two dimensions of medicine safety (quality-related) and medicine security (industrial security). While the economism and health and well-being frames continued to play a part, the security frame came to dominate policy discourse and helped elevate the issue to a higher political level. This led to a heightened political will within central government to address SF medicines, and to this end they advanced special policy responses consistent with the security frame.

This chapter discusses the different security discourses and how SF medicines was addressed by regulatory reforms, when different dimensions of the security frame - national security, political security, economic security, and environmental security – became aligned. It has shown the national political priority is present when: 1) political leaders and senior government officials express persistently the political will to address SF medicines; 2) fast-track and enact national strategic plans, regulations, and legislations to address the issue; 3) increase the provision of financial, technical and human resources which are commensurate with the severity of the issue.

Chapter 7 Multinational Pharmaceutical Companies' Framing and Policy Influence Since the 1990s

7.1 Introduction

This research suggests that any study of SF medicines, regulation of medicine quality and safety, and overall pharmaceutical policy in China, must incorporate an understanding of the power and influence of MPCs on market competition and policy processes. For the Chinese government, the importance of foreign investment lies in attracting capital, advanced technology, and innovative medicines for evolving clinical needs; creating jobs and growing the economy. In this context, I argue that MPCs, given their importance to the Chinese pharmaceutical sector, have also contributed to the social construction of SF medicines. This chapter thus analyses MPCs' framing of the SF medicines problem (referred to as "counterfeit medicines" and "anti-counterfeiting" activities) and policy influence since the 1990s. Specifically, it deepens understanding of the economism frame through understanding three key arguments MPCs used in advancing the economism frame in China.

Section 7.2 introduces the key policy actors in Chinese policy-making representing MPCs, and how they worked cooperatively to address the problem of SF medicines. Sections 7.3 and 7.4 analyse MPCs' influence on China's policy responses through three economic-oriented arguments. First, MPCs focussed heavily on IPR protection, framing issues of poor quality associated with SF medicines as largely an issue of patent infringement. Second, MPCs put forth the concept of "innovative medicines" to distinguish medicine quality from domestic produced generics. Third, MPCs consistently used the term "innovation" to advance their policy position on IPR and pricing. Finally, Section 7.5 analyses other tactics of MPCs in influencing Chinese pharmaceutical policy and how they differed from domestic pharmaceutical companies.

7.2 Key MPCs actors in China and the policy context

The pharmaceutical sector was one of the first industries in China opened to foreign trade and investment (Capie, 2005; Wei, 2009; Liu, 2011). China Otsuka Pharmaceutical, Sino-Swed pharmaceutical, Sino-American Shanghai Squibb Pharmaceuticals were amongst the first joint ventures established with Japan, Sweden, and United States respectively in early 1980s (Yeung, 2002; Tang, 2007; "China Health Yearbook" Editorial Board, 1985). Since the 1990s, MPCs in China have contributed to technology transfer, capital investment, job creation, supply of high quality medicines, building production facilities, and increasing R&D to help improve local production and quality management. By the end of 1999, 40 percent of Chinese pharmaceutical companies had established relationships with foreign firms, including over 1,800 joint ventures representing a total investment of US$ 1.5 billion (Cooke, 2008). After China's entry into the WTO in 2001, large MPCs increased their presence further. By early 2004, the world's top 20 pharmaceutical companies had established either joint ventures or wholly-owned firms in China. Although the domestic pharmaceutical industry has grown rapidly since the late 1990s, MPCs became significant players in market share and competition structure. For example, in 2015, the products of MPCs represented 70 percent of medicine sales in Chinese city hospitals (The Economic Observer, 2015).

Alongside significant profit-seeking business interests in China, MPCs have actively sought to influence policy in China related to industrial policy and medicine regulation. Existing research shows MPCs seek to influence the Chinese government at every stage of the policy process, from setting the agenda, to identifying policy options, and shaping regulatory/legal implementation (Deng & Kennedy, 2010). Aside from direct interaction with policy makers, which is less documented by existing research, is that MPCs very often engage the government through intermediaries. The most common ones are to engage industrial associations and chambers of commerce to reach policy makers. This section describes the key policy actors representing MPCs in China which have actively participated in policy discussions about SF

medicines, the key issues they have been concerned about, and how they have cooperated on anti-counterfeiting.

7.2.1 Key policy actors representing MPCs in China

There are four key industrial associations representing MPCs, which act to combat SF medicines as well as seek to influence broad pharmaceutical policy in China. **The R&D-based Pharmaceutical Association Committee (RDPAC)** is regarded as the most important industry group, lobbying and coordinating for member companies (Hu, 2012a; Wang & Fan, 2013). According to Hu Yinglian, Associate Professor at the Chinese Academy of Governance: "I know about 30-40 foreign pharmaceutical companies in China, big ones, all of them have joined an organisation called RDPAC. This organisation engages in political lobbying on behalf of these pharmaceutical companies" (Interview, 05BJ190312) [*translated from Chinese by the author*]. Lobbying is effective, and large companies and associations exert substantial influence over Chinese public policy (Deng & Kennedy, 2010).

RDPAC was founded in 1987 as one of four sub-committees of the China Association of Enterprises with Foreign Investment (CAEFI 中国外商投资企业协会) under the Ministry of Commerce. RDPAC is also a member of IFPMA, and began operations in China in 1995 and formally opened its Beijing office in 1999. As of 2021, membership of RDPAC was comprised of 42 MPCs with business operations in China, mainly from the US, EU and Japan. According to RDPAC's official website, as of 2020 its member companies have established 49 manufacturing facilities and 31 R&D centres in China. Annual investment in R&D in China from RDPAC member companies, is 8 billion RMB (RDPAC, 2016). RDPAC acts as the intermediary communicating between member companies and Chinese policy-makers in order to promote trade, investment, and R&D in China. Anti-counterfeiting has long been the focus of RDPAC's mission in China, and RDPAC used to have a separate taskforce on anti-counterfeiting (打假工作组) – but now they no longer cite this on their website. The anti-counterfeiting taskforce used to work closely with RDPAC's IPR Protection and legal taskforces (anti-counterfeiting and legal taskforces were

managed by the same person). I downloaded several RDPAC internal documents including on IPR and medicine-counterfeiting from its official website (http://www.rdpac.org/) prior to 2012. However, these documents had disappeared from their website when I checked back in 2016. RDPAC now has five working groups: R&D and Innovation, Drug Quality and Safety, Patient Access, IPR Protection, and Ethical Business Practice. It is not certain where anti-counterfeiting is now located.

The Quality Brands Protection Committee (QBPC) is an industry body that works with central and local Chinese governments to address counterfeiting across many sectors, through improvements in administrative and judicial protections for IPRs. QBPC was founded in 2000 as another sub-committee of the CAEFI, and as of 2020, QBPC is comprised of 194 foreign companies investing in China with parents' companies headquartered in America, Europe, Asia and Oceania. QBPC's activities are organised into six committees: Best Practices/Enforcement, Customs, Government Affairs and Public Policy, Legal, Membership Services, and Patent and Innovation. QBPC has 17 Industry Working Groups, including one on Pharmaceutical and Medical Devices, responsible for the study of IPR issues concerning MPCs. It cooperates closely with RDPAC and individual MPCs on pharmaceutical anti-counterfeiting, to ensure brand protection.

The **American Chamber of Commerce in China (AmCham)** and the **European Union Chamber of Commerce in China (EUCham)** advance business interests in China. These organisations provide member businesses with communication and lobbying channels to Chinese government authorities, business associations and media at both the central and local levels. AmCham was established in 1919 representing American businesses, with membership comprises 4,000 individuals from 900 companies (as of 2020) operating in China. AmCham maintains more than 30 Working Groups and operates in five Chinese cities. EUCham was founded in 2000 to represent European businesses operating in China. As of 2020, EUCham has more than 1,600 members, operating in nine major Chinese cities with 25 Working Groups. These two Chambers also help organise and facilitate bilateral and multilateral senior level trade talks,

such as the US-China Joint Commission on Commerce and Trade (JCCT)[34], the EU-China Business Summit. Each has a Pharmaceutical Working Group and produce annual White Papers (by AmCham since 2011) and annual Position Paper (by EUCham since 2007), which serve as the primary lobbying tool for improving market access and better operating conditions for MPCs in China.

7.2.2 MPCs' effort on "anti-counterfeiting" in China

A review of MPCs activities highlights that anti-counterfeiting is an important component of their operations in China. These efforts take place through either the Global Security Division or the Legal Affairs Division. According to a Senior Legal Counsel of the US pharmaceutical company Eli Lilly:

> All R&D-based MPCs in China established individual divisions to combat counterfeit medicines. Many companies such as Astra Zeneca, Pfizer, Johnson & Johnson, and Sanofi set up the Global Security China Division to oversee and coordinate anti-counterfeiting affairs. Whereas other firms such as Eli Lilly located anti-counterfeiting operations within the Legal Affairs Division. (Interview, 50SH160712) [*translated from Chinese by the author*]

On anti-counterfeiting, MPCs have been strengthening their voice and influence by acting cooperatively. As a senior Global Security manager described, "The multinational companies are competitors in business, but we are partners in fighting against counterfeit medicines" (Interview, 46SH120712) [*translated from Chinese by the author*]. Senior Global Security staff of many MPCs serves as committee members in the Pharmaceutical Working Groups at AmCham and EUCham. The Pharmaceutical Working Groups of AmCham and EUCham work closely with the RDPAC. According to a senior key informant at RDPAC:

> As the European Union Chamber of Commerce only set up the pharmaceutical working group recently, they are the "newcomer" in drafting and submitting Position Paper compared to RDPAC and AmCham. So, in their workshops preparing for the position paper, in addition to inviting their member companies such as Novartis, they would also

[34] The JCCT was founded in 1983 as a dialogue between the U.S. and Chinese commerce departments. The JCCT bilateral trade talk formally started in 2004 and takes place once a year. Attendees usually include senior officials of USTR, the US Ambassador to China, the Chinese Vice Premier for trade and commerce and other Chinese commerce ministers. SF medicines and API quality in China has been addressed frequently at JCCT.

invite representatives from RDPAC and AmCham to provide comments and suggestions. (Interview, 01BJ120312) [*translated from Chinese by the author*]

Since 2010, MPCs have expanded their anti-counterfeiting efforts in China, to a large extent through increased personnel and financial resources. According to a senior manager from a MPC Global Security China Division: "In terms of resource inputs, MPCs had to invest much more in China than in most other countries. For example, Johnson &Johnson has allocated 7-8 permanent personnel for Global Security China which is our largest Global Security division in the world, but we are still short-handed. Whereas our counterparts in most other countries only recruited 1-2 personnel" (Interview, 46SH120712) [*translated from Chinese by the author*].

MPCs have become important partners for the Chinese government to combat SF medicines, particularly in rural areas where resources are scarce. Corporate security teams serve as the arms and ears not only of corporations, but also for local governments for detection, data collection and sharing. Owing to their greater resources, MPCs have made important contributions to investigation and reporting on SF medicines. Research suggests multinational companies that produce more expensive (branded) medicines, have been more likely to seek to protect their brands with highly trained security personnel and post-market surveys and laboratory tests (Bate, 2012: 196). According to a senior manager of an MPC Global Security China Division: "The Global Security teams of most MPCs conduct investigations of counterfeit medicines in urban and rural areas by themselves especially when the local medicine regulatory authority's capacity is lacking. We also sometimes hired private/third-party investigators to do more field and supply chain analyses" (Interview, 46SH120712) [*translated from Chinese by the author*]. An RDPAC informant also revealed that every time the national medicine regulatory authority held meetings on addressing SF medicines, the RDPAC was always invited (Interview, 39BJ120612).

7.3 MPCs' framing of SF medicines: IPR and economic arguments

With increased resources, MPCs have positioned themselves as part of the solution for combating SF medicines in China. By providing much needed data, training materials, and other necessary material resources, I argue that it is also critical to understand how MPCs have shaped issue framing. This section focuses more on the use of the economism frame by MPCs to justify their central concern with IPR protection in China. With the growing presence of MPCs in China and their increasing stake in the pharmaceutical market, IPR protection became an important agenda since the late 1990s. MPCs considered violations of IPRs to be a serious problem and one of the most pressing policy issues harming their pharmaceutical businesses in China (Clark, 2003). There are two major issues MPC have been concerned with in relation to SF medicines in China. The first relates to infringement of IPR, including brand, trademark and patent, what MPCs refers as "counterfeit medicines". The second relates to the quality of APIs and pharmaceutical ingredients produced in China. The latter receives some discussion in Section 7.4, but is not the focus of this analysis.

This section discusses the many different ways that MPCs and their business associations raise awareness of IPR protection and seek to influence enforcement in China. Here, I suggest that legitimate protection with regards to branding and trademarks can positively contribute to China's efforts to combat SF medicines. However, IPR enforcement can create problems when it conflates good quality generics with protection of private interest, in particular in the case of patent rights.

7.3.1 MPCs' concern with brand protection

As suggested by key industry informants, brand protection is an important driving force behind the MPC's effort to combat SF medicines. A Johnson & Johnson's Global Security Manager interviewed for this research, stated that "anti-counterfeiting, of course, from the perspective of an enterprise, is to protect the brand, in other words the interest of the right holder" (Interview,

46SH120712) [*translated from Chinese by the author*]. Another senior Legal Counsel from Eli Lilly also acknowledged that there are two main motivations behind MPCs' efforts to combat SFC medicines: "One is brand protection and the other is to ensure social public safety" (Interview, 50SH160712) [*translated from Chinese by the author*]. Brand and trademark protection are not only important concerns of MPC concerned with losing profits to copycats, which are often illegitimate manufacturers but are also key to the identification of poor quality products. Research suggests that trademark violation can often be used as an effective signal of the quality of medicines (Bate, 2012). Economic analysis has revealed that the pharmaceutical industry has invested as much money in marketing and brand building as they been invested in R&D (Sutton, 2001). MPCs and increasingly some of the large domestic Chinese pharmaceutical producers have invested considerably in fostering trusted brands and cultivating their reputations for high-quality products. In this sense, MPCs argue that private interests can be seen as a strong and useful force in ensuring product quality and maintaining a healthy environment for competition.

Box 7- 1 Definitions of Brand, Trademark and Patents

A **brand** is a name, term, design, symbol or any other feature that identifies one seller's good or service as distinct from those of other sellers. ISO brand standards add that a brand "is an intangible asset" that is intended to create "distinctive images and associations in the minds of stakeholders, thereby generating economic benefit/values."

A **trademark** is a legally protected brand name, brand mark, or trade character (or some combination of the three). A trademark identifies one seller's product and thus differentiates it from products of other sellers. It also aids in promotion and helps protect the seller from imitations.

Patents are considered incentives to inventors, and the law recognises the inherent inconsistency between antitrust laws, which are designed to foster competition, and patent laws, which restrict competition.

An invention is patentable if it is a useful, novel, and nonobvious process, machine, manufacture or composition of matter.

Source: Common Language Marketing Dictionary (https://marketing-dictionary.org/)

Pricey MPCs' branded medicines have had especially serious issues with falsification in the Chinese market, although little is still known about the true extent of the problem. As a senior informant from RDPAC explained: "One major issue of counterfeit medicines we are concerned is oncological medicines with high price and high profit, and it's difficult to know whether the worsening condition of a patient was because of falsified medicines they took or their own deteriorating health conditions. Rural and remote areas are the hardest hit areas, especially given vulnerabilities in the supply chain." (Interview, 39BJ120612) [*translated from Chinese by the author*]. In addition to supply chain issues, the problem of falsification of high-cost medicines also reflects problems of affordable access, especially in rural and remote areas (more on quality and price in Section 7.4). Due to the popularity of MPCs' branded medicines, even less expensive medicines have been major targets for counterfeiters. As Bate (2012) suggests, because a familiar product can be more easily accepted in a market without suspicion, more counterfeits can be sold before detection. A Johnson & Johnson internal report conducted by the Shanghai Global Security team, revealed that their branded medicines with well-known trademarks such as Motilium[35], Daktarin[36] and Velcade[37] have been most frequently falsified, undermining legal sales and, where poor quality is involved, damaging the brand reputation of the company (Ma, 2010).

7.3.2 Conflating patent protection with medicine quality

The complicated relationship between IPR and medicine quality, as described in Chapter 1, has impeded international cooperation against SF medicines for many years. Proponents of stringent IPR protections, led by OECD countries and MPCs, have claimed that stronger IPR protection would improve medicine quality in emerging markets (Bate, 2012). While framing the problem as one of quality, it is also clear that MPCs are strongly concerned with IPR protection, namely misrepresentation of identity and/or source. Thus, the term "counterfeit" rather than

[35] Domperidone, Chinese trade name Motilium, is an antidopaminergic medicine to treat digestive system issues.
[36] Miconazole, Chinese trade name Daktarin, is an anti-fungal medicine.
[37] Bortezomib, marketed as Velcade in China, is an antitumor medicine to treat multiple myeloma and relapsed mantle cell lymphoma.

"substandard" or "falsified" has been preferred. Yet even though the term "counterfeit", as defined by the WTO, implies trademark violations (full definition in Section 1.2), MPCs tended to frame anti-counterfeiting in an even broader sense, incorporating any IPR infringement especially patents. Even a proven patent infringement has no basis for necessarily classifying a medicine (or any other product) as counterfeit under either the WTO or WHO definition (Maybarduk, 2010). Under IP law, patent enforcement is a civil matter between two patent holders and separate from medicine quality. Pharmaceutical patents are granted in three areas of innovation: compound, composition, and process (Schweitzer, 1997: 205). The first Chinese *Patent Law* was promulgated in 1984 under which patent protection was granted to the process of manufacturing pharmaceuticals for 15 years. Chemical entities were excluded from protection (Art 25, 1984 *Patent Law*).

As a result of China-U.S. bilateral negotiations in the early 1990s on China's WTO accession, the two governments signed a *Memorandum of Understanding between the Government of the United States of America and the Government of the People's Republic of China on the Protection of Intellectual Property* (*the 1992 MOU* hereafter) in 1992. This agreement fundamentally changed pharmaceutical patent protection in China. China revised the *Patent Law* in 1992 to grant protection on chemical and pharmaceutical entities, and extended the duration for patent protection to 20 years (Art 45, 1992 *Patent Law*). Another important outcome of *the 1992 MOU*, was a retrospective *Regulations on Drug Administrative Protection* (hereafter *Administrative Protection*) system under which China agreed to grant patent protection on chemical entities patented in the US and twelve foreign (mainly EU) countries between 1986 and 1993, but which entered the Chinese market after 1992. Under this protection, foreign pharmaceuticals were given exclusivity for seven and half years on the Chinese market, which prohibited domestic generic manufacturers to make and sell these pharmaceutical products in China. The 1992 *Administration Protection* also had implications for the creation and consistent use of the concept of "innovative medicines" by MPCs, which differentiated the quality of foreign generic medicines from domestic generic medicines (more in Section 7.4). A senior official from

the pharmaceutical and biological invention branch of the Chinese Patent Office, commented that China's committed to open patent protection on pharmaceuticals through *the 1992 MOU* was mainly because of U.S. political pressure (Interview, 38BJ110612). A senior RDPAC staff also suggested that the *Administrative Protection* could be viewed as compensation granted after *the 1992 MOU*:

> China's 1984 *Patent Law* only protected the process, not the compound. The 1993 *Patent Law* gave patent protection both on chemical compound and process. Foreign companies felt unfair after the law was revised, particularly during the Sino-US WTO accession negotiations between 1992 and 1993. In response, the Chinese government provided compensation through so-called *Administrative Protection*. In other words, the National Development and Reform Commission granted retrospective administrative patent protection to foreign companies' products which had not obtained patents in China between 1986 and 1993 but had foreign patents; and even with expired patents in foreign countries. (Interview, 39BJ120612) [*translated from Chinese by the author*]

Both the 1992 *Administration Protection* and the 1993 *Patent Law* significantly increased the willingness of foreign investors to enter the Chinese market, by providing the right holders with market monopoly and solid economic benefits. It also opened potential access for Chinese patients to more innovative medicines from the international market. The assertion for patent protection by MPCs seemed to be ostensibly about protecting their economic interests. Patents provide many years of market exclusivity and monopoly profits for a new medicine, which block competitors including generic manufacturers from entering the market. In the 1998 *National Trade Estimate Report on Foreign Trade Barriers*, prepared by the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group represents leading pharmaceutical and biopharmaceutical companies in the United States, stated:

> Counterfeiting of pharmaceuticals is a significant problem in China. Counterfeit versions of patented medicines are believed to have been manufactured in China, both for sale within the country and for export. PhRMA requests that the Chinese government exert greater pressure and apply stronger penalties to stop this highly dangerous practice. (PhRMA, 1998)

However, the statement mixes the issues of quality, trademark, and patent violation together. The first EU-China IP Working Group in 2005 devoted an entire session to IP-related issues in China. The meeting report also associated counterfeit medicines with patent violations,

stating that in anti-counterfeiting, "The Commission insisted on the importance of preventing products infringing patents put on the market." (European Commission, 2005). IPR protection then began to emerge as a major policy concern for AmCham, with counterfeiting coming under the IP agendas in their annual position papers. In its 2008, 2009, 2010 White Papers, AmCham repeatedly urged the Chinese government to amend its definition of counterfeit medicines to be consistent with WHO's definition, incorporating those "deliberately mislabelled as to source or identity" which was controversial in its own term. Industrial associations representing MPCs also called for more stringent criminal sanctions against IP counterfeiting with an emphasis on "deliberately mislabelled with respect to identity or source". In 2002, RDPAC proposed that:

> Amending the *Supreme Court Interpretation* is a short-term solution. For the longer term, the Chinese laws and regulations should be amended to add detail and clarity to the definition of counterfeit drugs. All activities related to the counterfeiting of drugs (deliberately mislabelled with respect to identity or source), including manufacture, sale, possession, distribution, advertising, aiding and abetting, must be considered criminal, regardless of sales amount. Provisions of the *IFPMA Model Medicines Anti-counterfeiting Law* could be referenced. (RDPAC, 2004: 21-22)

AmCham's 2010 White Paper recommended legal changes to combat counterfeit medicines:

> We urge China to enforce and amend its drug laws as necessary to prohibit and criminalize the manufacture, distribution, import or export of any pharmaceutical that is deliberately and fraudulently mislabelled with respect to source or identity (consistent with the WHO definition of a counterfeit medicine), without the need to prove harmful effects or deficient quality. (AmCham White Paper, 2010: 262)

MPCs' conflation of counterfeiting with quality concerns was seen as controversial, particularly from the perspective of many Chinese generic producers. These producers suggested MPCs were using disputes over patents to deter competition, rather than to protect public health. As described by the Director of Government Affairs of a leading Chinese pharmaceutical manufacturer:

> Many foreign companies have tried to crack down on local pharmaceutical companies in the name of "fighting against counterfeit/falsified medicines." There are few trademark disputes, most of the disputes concern patents. Foreign companies have specialised working groups to write documents, investigate other products, especially similar products. These disputes are aimed at crowding out local competitors. In my view, it contradicts the promotion of public access to affordable medicines. (Interview, 13BJ110412) [*translated from Chinese by the author*]

Similarly, the manager of the International Trade Division of a Chinese biopharmaceutical company, suggested the MPCs' effort to combat counterfeit medicines was a means to limit sales of domestic competitors:

> Disputes on pharmaceutical intellectual property rights are mainly centred on patents. In China, disputes between domestic companies are minor, the major disputes are between large foreign companies and local generic competitors. Foreign enterprises would use all possible measures to crack down on domestic enterprises, some are on trumped-up charges. It's almost like a person sees your handbag resembles his, then he seizes you and tells you that you are a thief and won't let you go. If you argue with him, he takes you to the police station. By the same token, he claims that a certain product you are selling infringes on his patent and goes to the Patent Office to sue you. As a result, your product might be frozen and can't be sold on the market until the investigation is completed. (Interview, 31BJ020612) [*translated from Chinese by the author*]

In short, patent and other IPR infringements were primarily concerns of MPCs and their industrial associations. Falsified or counterfeit medicines may infringe IPR, but whether goods are considered counterfeit from a public health perspective, is independent of whether the product infringes IPR (Clift, 2010). The primary goals of patent and trademark laws are not to the benefit of public health (Brant & Malpani, 2011). Bate (2012: 56) suggested that although IP rules can be useful in combating goods that violate trademarks (counterfeits), they often do little to remove substandard medicines from the market, and for poorest nations their enforcements should not be viewed as a priority.

7.3.3 MPCs' engagement with enforcement agencies on IPR protection

On implementation, IP-related anti-counterfeiting in the context of SF medicines has successfully become part of efforts to address "market order" after China's accession to the WTO in 2001 (see Section 5.3), and through the mechanism of LSGs at the central level. Behind the scenes, MPCs and their industrial associations worked with various government agencies, central and local governments to enhance IP-oriented enforcement activities to combat SF medicines. With regards to influencing policy enforcement, over time MPCs seemed to have developed their understanding of what worked in China. A senior RDPAC informant described the way MPCs approached anti-counterfeiting:

> Be really careful and cautious when dealing with an activity in China such as anti-counterfeiting, considered unpleasant to the government. The Chinese government is sceptical about anti-counterfeiting activities led by or involved with international forces. Mainly because of its concern with the extent of counterfeit medicines from China. So it is important to work with the right partners in China – the way one may provide a political or programmatic platform and to whom you give this platform to, is extremely crucial in China. Hence, finding the right person in China is as important as finding the right organisation. (Meeting, SMBJ190612) [*translated from Chinese by the author*]

For example, QBPC works with the National People's Congress (the highest legislative body), the Procuratorate System at the national level, and local governments, local courts, and local industries to promote stricter IPR protection and enforcement in China. To encourage local enforcement agencies to take tougher action on IP protection, QBPC organised annual events such as *QBPC Ten Best IPR Case Award* since 2002 (alongside with QBPC's Annual Anniversary event) and *Outstanding Achievement Agency in IP Enforcement* to reward effective local enforcement agencies in handling IPR infringements cases and raising more IP protection awareness. For example, in 2008 twenty-one local government agencies were rewarded as winners of *Best Cases of IPR protection 2007-2008*. To demonstrate the relevance of local governments' work and recognition of their efforts, QBPC invited high-level central government officials to present these awards, including the Directors from the General Administration of Customs and the Ministry of Public Security, Chief of the Supreme People's Court IP Division, and senior officials from Interpol (QBPC, 2008). In addition, QBPC also provided IPR enforcement training to the Department of Economic Crime Investigation under the Ministry of Public Security since 2002.

My research finds that emphasis on IPR can even lead to confusion among policy makers and divert attention away from addressing medicine quality. Advocating for IP-related enforcement over a significant period of time, by a wide constellation of actors, could lead to the perception that strengthening IP protection was an essential component to improving medicine quality. For example, since 2007, QBPC began to co-sponsor the joint annual *China IPR Criminal Protection Forum and China High-Level Forum on Intellectual Property Protection*, attended by over 300 officials including the Ministry of Public Security, Ministry of Commerce, State Intellectual Property Office (SIPO) and provincial/municipal governments (QBPC, 2008). In the

2008 annual forum, two cases of "fake drugs" presented by Anhui and Shandong provincial public security bureaus were falsified medicines associated with criminal activities (SIPO, 2008), which had nothing to do with IPR. However, being presented at the IPR forum conveyed the message that the problem of falsified medicines was associated with the lack of IPR protection in China. This type of activity reinforced MPCs' framing of SF medicines in ways that potentially misinformed policy-makers.

According to a RDPAC's document, Chinese Vice Premier Wu Yi gave a speech at QBPC stating that "medicine falsification has already caused serious public health crisis", and she emphasised that "poor-quality medicines not only presented a serious danger to public health but could also be detrimental to the stability of China" (RDPAC, 2008: 3). As Wu rightly pointed out, poor-quality medicines were serious concerns to public health safety in China. However, giving such a speech in an organisation focused on IPR protection, which was primarily the concern of trademark and patent holders, suggested that senior Chinese policy-makers were by then associating IPR protection with medicine safety and quality issues. As a senior consultant from a Beijing-based law firm described: "The government tends to mix the issues of safe use of medicines, medicine quality, falsified medicines and counterfeit medicines." (Meeting, SMBJ190612). With IP being prioritised in local enforcement and more local authorities empowered to seize products on suspicion or allegation of IP violation, I argue here that this creates a vicious cycle and diverts attention and resources away from public health safety as a separate, and arguably more serious, issue related to SF medicines.

7.4 Furthering MPCs' economic argument: quality differentiation and innovation

At the core of MPCs' marketing strategy to Chinese consumers, is positioning themselves as manufacturers of high-quality medicines and high-end innovative healthcare products and services. This section further explores how MPCs' have advanced their material interests, through: 1) creation of the "innovative medicines" concept to distinguish medicine quality from

domestic produced generics; and 2) consistent use of term "innovation" to advance their preferred policies on IPR and pricing.

7.4.1 "innovative medicines" vs. generics medicines: Different quality, different price

The concept of "innovative medicines" (原研药) was coined by MPCs in China to refer to off-patent generic medicines manufactured by the originating pharmaceutical companies, mostly the MPCs in China (patent medicines should be called "patent medicines"). In practice, this a tricky concept because "innovative medicines" has been persistently used by MPCs since the adoption of the *Administrative Protection* in 1992 (Section 7.3), to refer to all foreign/imported medicines regardless of whether the medicine is patented or not. I observed during fieldwork that even key informants with fair knowledge about the pharmaceutical sector, confused "innovative medicines" with other types of medicines. For example, one senior consultant interviewed who works on China's overseas aid and pharmaceutical policy, perceived "innovative medicines" as equivalent to new medicines (Interview, 20BJ050512). An academic specialising in pharmaceutical administration understood "innovative medicines" to refer to both patent and off-patent medicines produced by MPCs (Interview, 16NJ200412). MPCs and their industrial associations have not tried to clarify the concept. For example, EUCham annual position papers used the terms "innovative medicines", "patent medicines" and "branded medicines" interchangeably when referring to the government's price reduction affecting MPCs.

Whether the confusion has been created intentionally or not, the main purpose of MPCs' creation of "innovative medicines" is to distinguish generic medicines produced by MPCs from generic medicines produced by Chinese domestic manufactures. In China, the former is known as "innovative medicines" and the latter is known as generic medicines (仿制药). The confused definition and persistent use of the concept over two decades, has influenced how issues of medicine quality and safety are then framed within the Chinese pharmaceutical market, and by doctors, health professionals, and the general public. Innovative medicines are perceived to adhere to the international manufacturing standard (those of innovator pharmaceutical

companies), which is stricter than the Chinese standards met by Chinese pharmaceutical manufacturers (e.g., the Chinese Pharmacopoeia, Chinese GMP), and hence have higher quality. On quality discrepancy between innovative medicines and domestic generic medicines, a provincial senior officer of the Chemical Drug Testing Department shared some insights:

> When China just opened up, the country's pharmaceutical industry was nascent with only a few medicines available, so the most pressing problem we needed to solve was access to different types of medicines. After 20-25 years' development, we now have a wide variety of medicines. What is the problem we are facing now? There is a wide discrepancy in clinical efficacy between medicines produced by our domestic manufacturers and imported or foreign medicines – we call them "innovative medicines". The innovative ones are more effective than the domestic ones. This difference in efficacy inevitably reflects the difference in quality. (Interview, 12HZ010318) [*translated from Chinese by the author*]

Ai's research on comparing the quality of generic Bicalutamide for treating prostate cancer, found that Bicalutamide from domestic manufacturers showed considerable deviations in 3 of 4 in vitro dissolution curves from the originator manufacturer Astrazeneca ((brand name Casodex), resulted in bioequivalence result and hence could contribute to lower level of clinical efficacy (Ai, 2019). Another piece of research revealed the differences in release rates between the originator's generic Lansoprazole Enteric-coated Tablets and those from domestic manufacturers. Domestic generics had either lower percentage of release rate in 45 minutes or zero release in first 15 minutes, which could lead to negative therapeutic effect (E-Pharm, 2015). Doctors in large tertiary hospitals are more inclined to prescribe innovative medicines because their efficacy is more assured than the domestic generics (Med.sina.com, 2018). A provincial senior officer of the Chemical Drug Testing Department provided another example:

> The differences in clinical efficacy in cardiovascular and antihypertensive type of medicines could be stark. For example, an old lady who with high blood pressure was prescribed with domestically produced generics, had little or no improvement in her condition after finishing the course of the treatment. But when she instead took expensive imported medicines, her blood pressure became normalised within 2 to 3 days. (Interview, 12HZ010318) [*translated from Chinese by the author*]

Quality differences in APIs, excipients, manufacturing equipment and processes could lead to quality differences in the finished medicines (Gu, 2018). RDPAC published a report in 2010 evaluating quality management system of Chinese domestic pharmaceutical manufacturers,

found that even amongst Chinese GMP certified generics manufacturers, discrepancies in quality management system could result in big discrepancies in medicine quality (RDPAC, 2014). The current Chinese GMP improved significantly from the 1998 version but was not enforced strictly until after 2011 (new Chinese GMP was updated in 2010 and came into force in 2011). The quality of Chinese APIs has long been a major concern for MPCs, as a RDPAC informant revealed that:

> We received many complaints from abroad about the quality of Chinese APIs. From the information we gathered, we felt the problem of APIs could be the root cause of counterfeit medicines in and outside China. Some of our member companies have been trying to switch to domestic suppliers, but there were still issues they were not assured about. (Interview, 39BJ120612) [*translated from Chinese by the author*].

MPCs have made various efforts through RDPAC, EUCham and AmCham to urge the Chinese government to address this important issue affecting the safety and security of the global pharmaceutical supply chain. Quality of excipients is another important issue causing quality differences between generic medicines of MPCs and domestic manufacturers (E-Pharm, 2015). According to a senior official from a major domestic pharmaceutical association:

> The biggest problem in China is the poor quality of excipients. The standard of our excipients such as sugar, capsules is relatively low. This has something to do with the development of our industry. Strictly speaking, there are only a few manufacturers who produce pharmaceutical excipients in China. Many basically produce food, and incidentally produce some pharmaceutical excipients. (Interview, 14TEL050318) [*translated from Chinese by the author*]

The quality differences described above between innovative medicines and domestic generics, has been a powerful tool used by MPCs in their quest for favourable pricing policies in China. The economic argument behind the persistent use of "innovative medicines" was that MPCs believed quality differentiation should lead to price differentiation, because higher medicine quality means more investments in R&D and more stringent production and quality management – hence, higher quality medicines deserve higher prices. Independent pricing for innovative medicines was granted by the *Measures related to the Government Fixed Pricing for Pharmaceuticals* (effective as of December 2000), which was a quality-based pricing policy. As one academic specialising in international pharmaceutical business suggested:

> RDPAC has a strong policy orientation. What they meant was that we are innovative medicines, and the quality of my products is better than your generic medicines, so you have to set a separate price for me. Eventually, this was really what MPCs and RDPAC were pursuing together, through the concept of "innovative medicines": better price for better quality. They wanted to set prices separately." (Interview, 16NJ200412) [*translated from Chinese by the author*]

Innovative medicines with independent pricing policy, occupied approximately one third of China's pharmaceutical market (people.com.cn, 2012; The Economic Observer, 2015), contributing to high medicine prices. The association between high pricing and SF medicines cannot be ignored because "price and quality are fundamentally linked and that the fight against poor-quality medicines cannot be isolated from medicine affordability" (Bate, 2012: 304). GSK's Lamivudine was priced at ￥142 in Mainland China, while it only cost ￥18, ￥26, ￥30 in Korea, Canada and the UK, respectively (finance.china.com.cn 2014). The price difference between innovative medicines and domestic generic medicines was also stark. Roche's ceftriaxone injection (1g) was priced at ￥65.7 in 2012, but domestic generics of the same variety was only priced at ￥1 yuan in some provinces and cities (people.com.cn, 2012). China's NDRC, which sets guidance on medicine price regulation, initiated more than 20 rounds of price reductions on medicines between 2000 and 2015, but with little to no effect to bring down the prices of innovative medicines. High pricing contributes to lack of access, hence has created more room for SF medicines to enter the market. As mentioned in Section 7.3, MPCs' expensive oncology medicines have been frequently targeted by criminals. For example, falsifications of Johnson & Johnson's Bortezomib (Velcade®), a targeted therapy medicine selling at ￥13,636 per pack to treat multiple myeloma and mantle cell lymphoma, were popular in China. Ma's research found demand remained high for falsified Bortezomib sold at half price (￥7,000-8,000) in many cities across China (Ma, 2010).

Major price discrepancies between innovative medicines and domestic generics have become increasingly controversial in Chinese pharmaceutical policy-making. It has also been challenged in recent years by a growing number of domestic pharmaceutical manufacturers, as

Chinese manufacturers are developing capabilities in catching up with higher production and quality standard. A few key informants mentioned that there were several proposals from the domestic industry and academic circles to call for halting the use of the "innovative medicines" concept in Chinese pharmaceutical policy (Interviews, 22BJ080512; 05BJ190312; 38BJ110612; 33BJ070612; 17NJ210412). Academics, the domestic industry and media raised questions such as what differences in quality should lead to what difference in prices? How big the quality difference is between "innovative medicines" and domestic generics, and how much should this be reflected in pricing, and who has the final say? Can the NDRC reveal their medicine pricing strategy to the public? (people.com.cn, 2012)

It was not until the Chinese government put quality and affordability at the centre of its healthcare policy, and Director General Bi's medicine regulatory reform in 2015 (see Chapter 6), that MPCs were put under pressure to reduce the price of their so-called innovative medicines. On the one hand, the government toughened its stance on pricing during market access negotiations (e.g., the 4+7 procurement scheme launched in 2018), targeting mainly innovative medicines. On the other, to curb soaring healthcare costs, the government launched the QCE programme to improve quality and safety of domestically produced medicines, and to ensure more domestic producers could provide such medicines (equivalent to innovative medicines) at more affordable prices.

7.4.2 MPCs' strategic framing after 2010: Innovation

From 2010 onwards, this research finds that MPCs shifted their strategies from concerns about counterfeit medicines and IPR enforcement in China, to increasingly emphasising innovation and medicine quality. As reflected in the annual position papers of EUCham, from urging the government to strengthen actions on counterfeit medicines, the term "counterfeit medicines" has not appeared since 2016. Instead, "innovation" and "pricing" have come to be used in EUCham's position papers between 2016 and 2020.

This research argues that such terms as "innovation" and "pricing" seem to have been strategically selected by MPCs, to reframe and thus align their policy agenda with the Chinese government's shifting policy priorities. This shift is supported by my fieldwork in Beijing in 2012 upon being invited by a key informant to attend one of the EUCham Pharmaceutical Working Group meetings, in preparation for the production of its annual Position Paper. Meeting attendees included five to six employees of the Pharmaceutical Working Group Beijing team, one representative from RDPAC, one from AmCham and a couple of representatives from individual MPCs. The Shanghai Pharmaceutical Working Group team joined the meeting through video call. The purpose of the meeting was to discuss the main issues to be included in the annual Position Paper. Importantly, attendees spent a considerable amount of time deciding on the most appropriate wording for issues to be presented in the Position Paper. The Working Group said that since each Position Paper would only be allotted just 30 seconds of reading time by government officials, using one "eye-catching" term (what they also called an "umbrella term" in the meeting), under which all content could be put together, was deemed critical for the Position Paper to be effective. After intense discussion and consultation among representatives from member companies, RDPAC and AmCham, the EUCham Pharmaceutical Working Group decided on using the two terms: "innovation" and "pricing" (Meeting, EUCBJ120312).

RDPAC's publicly available research reports over the past ten years (see Table 7- 1), also reveal that "innovation" has been used as the key term to help bring together MPCs' policy pursuits. Why innovation? First, innovation encompasses MPCs' concerns over both IPR and pricing. As MPCs suggested, IPR is key to foster innovation, and pricing and innovation are mutually reinforcing. MPCs called for the government to provide a supportive regulatory environment to protect IP and reward innovation through pricing. They argued that pricing was a useful tool to reward quality, ensure safety, and encourage innovation (AmCham, 2013; RDPAC, 2016; EUCham, 2017). This again is in line with the concept of "innovative medicines" described above, with MPCs advocating that higher medicine quality deserved higher pricing and higher pricing can reward innovation. Second, the term innovation elicited more positive feelings for

Chinese policy-makers, which could enhance the persuasiveness of MPCs' argument, unlike the more negative accusation of Chinese firms engaging in "counterfeiting" which the government might find potentially offensive.

Table 7- 1 Research reports published by RDPAC after 2010

Year	Title of the Report
2012	Building an Innovation-driven Pharmaceutical Industry in China
2016	The Faces of Innovation: Meeting the Challenge of Diabetes
2016	Fostering a Sustainable Ecosystem for Drug Innovation in China
2016	Healthier China Through Innovation
2017	Improving Patient Access to Innovative Medicines for a Healthier China
2018	The Faces of Innovation: Meeting the Challenge of Cancer
2019	Visioning the Next 10 Years from the Standpoint as a 2nd Tier Country of Drug Innovation (a joint publication with China Pharmaceutical Enterprises Association, China Pharmaceutical Industry Association, China Chamber of Commerce for Import & Export of Medicines & Health Products)
2020	Reflections on the Relationships between Drug Quality, Price and Supply

Sources: RDPAC official website http://www.qbpc.org.cn/

Third, and most importantly perhaps, innovation aligned MPCs' policy goals with the Chinese central government's evolving goals focused on combining health and well-being with economic development. To strengthen their voice in the policy debate, evidence suggests MPCs and their associations sought to match their policy goals with the government's five-year plans and other key national policy strategies. For example, QBPC's mission to improve administrative and judicial protection for IPR in China emphasised that their objectives were in line with China's national IP strategy and innovation policy. RDPAC associated the vision of its member companies with the government's national healthcare and industrial development goals, placing emphasis on innovation and access to new medicines. RDPAC stated in various publications that they would be a valued partner in delivering the *Healthy China 2020* (advocated by former Health Minister

Chen Zhu in 2007) and *Healthy China 2030* (policy outline published by the CCP Central Committee in October 2016) goals, to promote Chinese patients' access to high quality and innovative medicines as well as to sharpen the competitive edge of China's pharmaceutical companies in the global market. Since 2016, RDPAC reports have constantly cited President Xi's speeches on national health agenda and China's direction of placing people's health as the new top priority in national strategy. RDPAC emphasised that the "patient-centric" concept established in *Healthy China 2030*, was in close alignment with MPCs' mission to meet the medical needs of Chinese patients and improve their health and quality of life (China Pharmaceutical Enterprises Association *et al*., 2019; Chen & Zhang, 2020). RDPAC's 2017 research report on *Improving Patient Access to Innovative Medicines for a Healthier China* systematically assessed practical experiences of models from China and around the world, to discuss how to both improve patient access to innovative medicines and promote sustainable development of the medical insurance system to achieve a win-win situation for the Chinese government and MPCs (RDPAC, 2017).

On innovation-led development strategy, MPCs were eager to establish that they were a valued partner to the Chinese government, helping to integrate into the global R&D innovation system. Both EUCham (EuCham, 2017) and RDPAC reports cited the Chinese government "*Made in China 2025*" strategy published in 2015, which emphasised developing an innovation-driven country. China's new vision of "becoming a leader among innovation-oriented countries by 2030" set out by the CCP Central Committee and the State Council in 2016, was welcomed by MPCs as they see themselves as an important contributor. In 2016, RDPAC collaborated with three major Chinese pharmaceutical industry associations and published a report called *Fostering a Sustainable Ecosystem for Drug Innovation in China*, stating that innovation is 1) fundamental to people's well-being, 2) can provide enduring impetus for sustainable economic development, and 3) shows a country's core competitiveness. The report emphasises that "China must rely on developing innovation to transform from a country with a sizeable pharmaceutical market to a country with a strong pharmaceutical industry" (RDPAC, 2016).

7.5 Other tactics of MPCs in influencing Chinese pharmaceutical policy

Previous sections argued that MPCs' ways of framing SF medicines – conflating quality with IPR, creation of the concept "innovative medicines" and the consistent emphasis on "innovation" – enhanced efforts at policy influence. This section analyses how the ideational factors enhancing policy influence of MPCs, were supported by material factors. These include sponsoring research projects, organising tours for government officials to learn from experiences of developed countries, participating in legislative amendment processes, etc. Broadly speaking, MPCs influence on Chinese pharmaceutical policy has long been a topic of concern (Song, 2008d; Xu, 2010; Wang & Fan, 2013). According to Hu Yinglian, who has spent many years researching policy influence of MPCs in China:

> Foreign enterprises have great influence in China on medicine registration, pricing, tendering practice, and others. They may lobby in many ways, such as sponsoring research projects. I conducted a study using data from RDPAC, AmCham and EUCham between 2000 and 2009, about a decade, they proposed a total of 15 policy proposals, and most were proposed by RDPAC. My research showed that most policy requests were met except a few (Interview, 05BJ190312) [*translated from Chinese by the author*]

This analysis is supported by two leading scholars on Chinese policy-making, Wang Shaogang and Fan Peng, who have studied the RDPAC's lobbying strategies. Their findings suggested MPCs put forth what they claimed to be evidence-based positions, encouraging the government "to converge with international standards" as a way of making their arguments more persuasive:

> Compared with domestic pharmaceutical industry associations, RDPAC has better financial resourcing and uses political resources in different ways. In many cases, they influence the policy process of health care policies not through "persuasion" via personal relationships, but through expressing opinions by providing government departments with various scientific and technical research reports that appear to have sufficient arguments and analysis. These reports include both international experience and domestic research analysis. Although most of these reports are based on detailed data analysis and use "convergence with international experience" as a persuasive argument, the premise of all data selection and analysis is to help express their member companies' agenda and goals (Wang & Fan, 2013). [*translated from Chinese by the author*]

Examples of such reports are described above (in Section 7.4), including RDPAC's reports on domestic medicine quality, and the gap between China and other world leading countries in

pharmaceutical innovation. Another RDPAC report put forth in 2020, on the *Relationship between Drug Quality, Pricing and Supply*, was based on the USFDA 2019 report *Drug Shortages: Root Causes and Potential Solutions* (USFDA, 2019). RDPAC used the USFDA's data to argue that the root causes of medicine shortages were associated with lack of incentives for manufacturing less profitable medicines, and the lack of recognition and incentives for quality and production management. Hence RDPAC proposed that manufacturers with high-standard quality management and high-quality products should be rewarded with good pricing strategy and incentives for further innovation (RDPAC, 2020).

Another important strategy MPCs use in China to influence the policy process, is to use their material resources to foster close relationships with policy-makers. For example, one known method is for companies to hire "princelings" (红二代), namely children of senior Chinese political officials to facilitate access to senior policy-makers. As one government affairs specialist from a leading MPCs described, "It's common for MPCs to recruit princelings to take charge of government affairs or some called public affairs divisions. Because they could help the enterprises to access and engage effectively with policy-makers." (Interview, 09BJ270312) [*translated from Chinese by the author*]. Another way is to offer government officials the opportunity to attend overseas study tours, training, conferences and workshops. For example, to promote their stance on IPR and anti-counterfeiting, RDPAC organised a study tour for Chinese officials to the EU (Brussels, France, UK and Germany) in 2004, co-sponsored by EUCham and the European Federation of Pharmaceutical Industries and Associations. A group of twelve delegates included high-ranking officials from the State Council, NDRC, SIPO and SFDA. In RDPAC's summary report, the causal relationship between IPR and economic development was highlighted: "The result of substantial increased pharma R&D investment would bring more new medicines to Chinese patients quicker, spawn other related high-tech industries, and help China retain key top-level scientists. As such, this industry is a key pillar of China's tomorrow, and therefore progress on IPR should be continued today" (RDPAC, 2005) [*official English document*].

On behalf of research-based MPCs, RDPAC also participated in proceedings to discuss legislative amendments related to SF medicines. Evidence reviewed in this research, suggests that the RDPAC actively participated in the process of national legislative reform, mainly through working with the People's Supreme Court (the top Chinese legislative department). RDPAC actively put forward proposals and sponsored the reviewing process on law amendment. A senior manager from a MPC Global Security China Division revealed that:

> RDPAC sponsored the People's Supreme Court's taskforce in 2009 to amend the legal interpretation on counterfeit and substandard medicines. RDPAC's proposals were accepted for the revision of the 2009 *Interpretation of the Chinese Criminal Law on IP-related Crime* issued by the People's Supreme Court, and the 2009 *Judicial Interpretation of Handling Criminal Cases on Counterfeit and Substandard Drugs* issued by China's Supreme People's Court and Supreme People's Procuratorate. (Interview, 46SH120712) [*translated from Chinese by the author*]

These *Interpretations* are legally binding documents in China and provide a list of conditions for stricter threshold of criminal prosecutions on production, sales and distribution of SF medicines. For example, RDPAC urged the government to treat IP counterfeiting as a criminal offense and to set lower thresholds (such as sales amount) of criminal prosecution on counterfeit medicines. RDPAC also proposed to the People's Supreme Court to amend five Articles to promote tougher criminal sanctions on counterfeiting, including trademark violations and patent infringement.

Several key informants interviewed for this research suggested that, compared to domestic pharmaceutical companies, MPCs and their industry associations were better resourced, organised and more professional in their lobbying approaches to policy-makers. As a Director of Government Affairs from a leading Chinese pharmaceutical manufacturer pointed out:

> By contrast with Chinese companies which primarily engage policy-makers to address company-specific problems and depend heavily on *guanxi*, the Western enterprises tend to use the formal ways and address issues in a more concerted approach, e.g., provide evidence-based information to officials, commission research projects, and produce position papers. (Interview, 13BJ110412) [*translated from Chinese by the author*]

A senior academic interviewed for this research corroborated this:

> Compared with domestic pharmaceutical enterprises, foreign companies are better at influencing the process of policy-making. Domestic enterprises are good at dealing with individual persons and issues. For example, they may bribe a person and ask him to do

> something for them. Foreign multinational companies seek to influence the entire policy which is more powerful and influential. Besides, embezzlement and bribery violate the law and will be subject to punishment if detected. (Interview 05BJ190312) [*translated from Chinese by the author*]

The difference in approach was also described by the Director of Government Affairs of a leading Chinese pharmaceutical manufacturer:

> The foreign companies mainly focus on high-end government affairs, they are more professional and the policy impact is more profound. They could have influenced or changed policies through some channels before the policy is introduced. Foreign enterprises have a high degree of division of labour. If someone deals with an official in the National Development and Reform Commission, others are not allowed to deal with him. To do the same task, foreign companies may hire ten staff, but domestic enterprises may hire only one person. Domestic private enterprises organise small-scale activities and are interested in private contacts – we have limited financial resources with little manpower investment. Some of the domestic state-owned enterprises established public relations departments – they started to develop more awareness in government affairs, but overall they remained weak and lacked professionalism. (Interview 13BJ110412) [*translated from Chinese by the author*]

7.6 Conclusions

This chapter analysed the role of MPCs in deploying ideational and material factors to influence policy responses to SF medicines. In it, I argued that MPCs exercise privileged access and policy influence over China's responses to SF medicines, in favour of their own interests. Following this, I articulated four key industrial associations representing MPCs, which contributed to the framing of SF medicines and influence in Chinese pharmaceutical policy. The analyses demonstrated that the economism frame has been central to MPCs' strategy to present their arguments persuasively and exert policy influence in a more strategic manner. MPCs and their industrial associations were primarily concerned with patent and other IPR infringements, and used many different ways to raise awareness of IPR protection and influence policy-making and enforcement in China. MPCs framed issues of poor quality associated with SF medicines as largely an issue of IPR infringement. I argued that prioritising IPR in local enforcement, creates a vicious cycle and diverts attention and resources away from public health safety as a separate, and arguably more serious, issue related to SF medicines. This research found that MPCs have positioned themselves as important partners for the Chinese government, adjusting their framing of SF medicines over time to achieve this. MPCs put forth the concept of "innovative medicines" to distinguish medicine

quality from domestic produced generics, and consistently used the term "innovation" to advance their policy position on IPR and pricing. By doing so, MPCs' framed their arguments in terms of making positive contributions to foreign investment, innovation, and medicine quality within the Chinese market. I also analysed other tactics employed by MPCs to influence Chinese pharmaceutical policy, and how they differed from the approach adopted by domestic pharmaceutical companies.

Chapter 8 An Expanded Understanding of China's Policy Responses: From Framing Competition to Cooperation

8.1 Introduction

Chapters 4-7 have addressed the first two objectives of this thesis: a) *identify core policy frames through understanding how the SF medicines problem has been socially constructed (framed) by key policy actors and interest groups in China*; b) *analyse the effect of framing, in combination with material factors, on China's policy responses to SF medicines*. This discussion chapter begins by bringing together objectives a) and b) to provide a brief summary of the key findings from the preceding chapters. The remainder then addresses the third objective of this thesis: c) *explain the rise and fall of frames, the interaction among frames and the implications of framing on priority setting*. Section 8.3 describes the rise and fall of policy frames in accordance with the timeframes outlined in chapters 4-7, and then analyses the major effects of framing on China's policy responses to SF medicines. Section 8.4 examines the trajectories of each frame over the past 45 years, identifying four key facilitating conditions as shaping the rise and fall of frames. Finally, Section 8.5 examines the interrelationship of frames and discusses the extent to which they compete or cooperate can shape policy perception, action, and priority setting.

8.2 Summary: Core frames shaping China's policy responses to SF medicines

One of this research's point of departure, is that public policy making is a complex process involving varied actors over time with diverse material interests, holding different worldviews, beliefs, and perspectives. On the issue of SF medicines, with data on the problem often limited and incomplete, the social construction of the problem and solutions can exert an even greater influence over how the material world is engaged with. The findings of this research suggest that in China, ideational factors have been highly influential in shaping how policy actors have perceived the issue of SF medicines and developed policy responses. These factors include belief and value systems, cultural and academic backgrounds, and past experiences. This research does

not disregard the importance of material factors in public policy-making. In fact, analysis of SF medicines in China would significantly benefit from more comprehensive and reliable longitudinal data on the nature of the problem. However, I argue that material factors alone, such as scientific data, institutional competencies, leadership changes, technology, and major events, do not fully explain China's policy responses to SF medicines.

To understand the role of ideational factors, this research has applied the lens of framing theory. As described in Chapter 2, framing constitutes the collective creation of a new reality through mental construction, which helps shape the co-creation (and re-creation) of an issue and subsequent policy responses. Applied within this research, framing analysis suggests that SF medicines in China has been framed in multiple ways by different actors, contributing to different policy pathways over the past four decades. Based on a thorough review of primary and secondary document sources, along with 70 in-depth interviews across a wide array of key informants, this research identified three dominant policy frames - **economism**, **health and well-being**, and **security**. While these are unlikely to have been the only frames that have shaped China's responses to SF medicines, the analysis presented in Chapters 4-7 finds them to have been the dominant ones in influencing policy responses. Within the context of Chinese society, politics, economy and culture, each frame had varying influence over time.

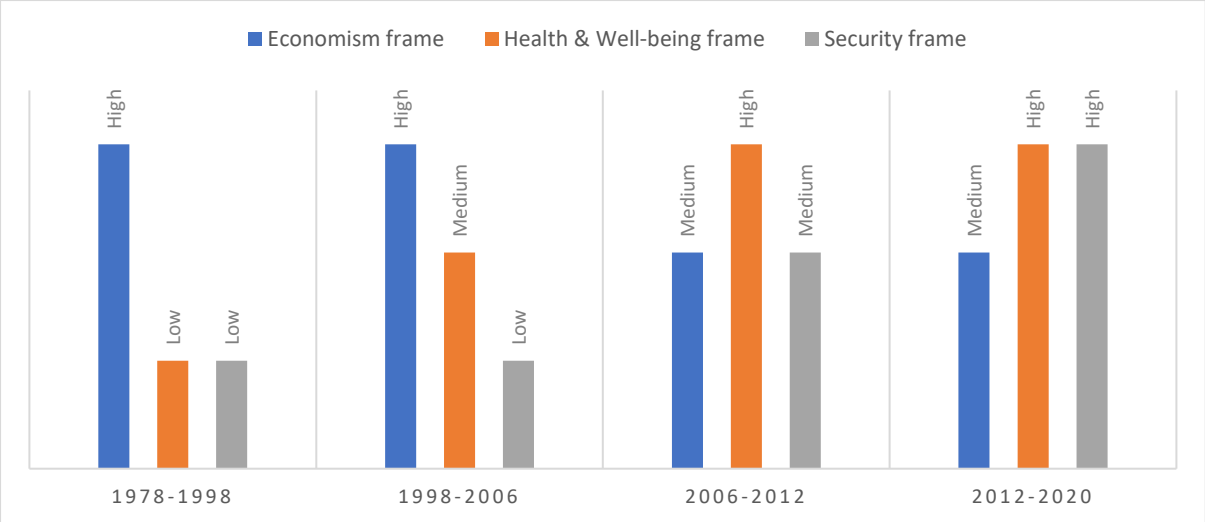
8.3 The rise and fall of frames and their policy effects

This research finds that frames vary in their policy influence over time. The first half of this section describes the rise and fall of the three dominant frames identified. The second half then discusses the main effects of changes in the levels of influence of different frames on China's responses to SF medicines, including changing regulatory frameworks, privileging certain interests over others, legitimising certain policy actions, and elevating the issue higher or lower on the policy agenda.

8.3.1 Ascendance and descendance of policy ideas

Figures 8- 1 and 8- 2 summarise how the three frames identified in this research have changed over time in their level of influence over policy responses. Influence is assessed as Low, Medium or High based on the degree to which this research found evidence of their associated core beliefs, ideas and normative frameworks in primary and secondary document evidence about China's response to SF medicines over time. This visualisation compares the relative influence of each frame and helps explain China's policy response at different points in time. Figure 8- 1 shows the relative influence of each frame by period of shifting policy on SF medicines in China, as set out in Chapters 4-7. For each period of policy, while each frame was present, the graph illustrates which frames dominated and how this changed over time. Figure 8- 2 brings the rise and fall of the three frames together to show the relative influence of each frame over time. Importantly, these graphs are not intended to imply that frames alone can provide a cause-effect analysis to explain policy outcomes. As will be discussed below, the complex interaction of ideational and material factors need to be considered together. The coexistence of multiple frames, with variation in influence over time, helps explain differences in how the problem of SF medicines has been defined and policy responses put forth.

Figure 8- 1 The rise and fall of three policy frames on SF medicines in China



Looking at how each frame fared overall, it is notable that economism was the most dominant and persistent frame until around 2006. During the entire period of study, the economism frame remained constant but never goes down to "low" policy influence. Since 2006, when other frames were in the ascendence, the findings suggest that the economism frame (growth-oriented policies) was not so much superseded but became more moderate in policy influence as the focused shifted to strengthening regulation for medicine quality and safety assurance. The health and well-being frame remained at a low level of policy influence during the first twenty years of economic reform (between 1978 and 1998), with dominant priority given to commercialisation to expand pharmaceutical production and revenues. The later rise of the health and well-being frame, to exert substantial policy impact on SF medicines, as Chapter 5 deduced, came after a series of critical events, notably domestic and international food and medicine safety incidents, and the corruption scandal involving the then SFDA's Commissioner Zheng Xiaoyu and his senior officials. After the prosecution of Zheng Xiaoyu and other SFDA officials, the CCP elevated the policy priority given to SF medicines to an unprecedented political level. Since 2006, through incorporating the issue of medicine safety into the broader public safety system, medicine safety in China became a component of the national security agenda. Since 2012, SF medicines have been framed as a multi-dimensional security issue, including national security, political security, economic security, and environmental security. At its core, the security frame was constructed to elevate the severity of the issue and include consideration of a wider range of risks.

Overall, the findings of this research reveal that perceptions of SF medicines in China, as a problem and the appropriate solutions to address it, has evolved over time. The use of frame theory provides new understanding of what perceptions prevailed over time and at a given times, as part of the rise and fall and interaction of the three dominant frames.

8.3.2 The effects of framing on policy responses to SF medicines

This research has found that framing (and re-framing) of the SF over time in China, contributed to shifts in policy direction. Chapter 4 analyses how between 1978 and 1998, the rise of the economism frame introduced a new policy direction. The economism frame led policy-makers to overturn the then existing policy approach, based on the idea that medicines were not for profit but served social welfare, and to support policy responses oriented towards economic reform and then growth. Decentralisation of pharmaceutical production, multi-tier medicine standards, and a reduced role of the state in the health care sector from the 1980s, added further impetus to the rise of the economism frame at the local level. This shift led local governments to be more concerned with adopting policies to increase pharmaceutical production and consumption, as a driver of economic growth, than quality and safety of medicines. As a consequence, policy priority was given to industrial rather than social policy, promoting increased outputs and growth. The rise of the health and well-being frame around 2006 marked another change in policy direction. The normative shift towards health and well-being after the SARS epidemic, and a series of scandals involving SF medicines, underpinned this shift in framing away from economism towards prioritising public health interests. With the re-emergence of policy attention to the special attributes of medicines as a public good, and supported by a shift in political thinking, China began to emphasise policies for enhancing medicine safety and quality. This, in turn, led to the building of stronger regulatory capacity centred on protecting and promoting public health.

Importantly, this analysis suggests that framing in China was not simply a reflection of changing ideational power. Rather, the findings suggest that framing had a degree of instrumentality, and was used strategically at times by policy actors concerned with SF medicines to maintain or challenge certain policy positions, and to thus assert policy influence. For example, Chapter 7 showed that MPCs strongly relied on narratives based in the economism frame in their social construction of the SF medicines issue. MPCs in China since the 1990s have consistently framed SF medicines from a perspective focused on the protection of their commercial interests,

conflating IPR (particularly patent) infringements with medicine quality and safety. MPCs put forth the concept of "innovative medicines" to distinguish medicine quality from domestically-produced generics and consistently used the term "innovation" to advance their policy position on IPR and pricing. Through such framing, MPCs' promoted perceptions that their commercial interests were aligned with positive contributions to China's priorities on attracting foreign investment, increasing innovation, and improving healthcare quality. Framing the issue in this strategic way, helped MPCs maintain privileged policy influence. However, MPCs' success in using the economism frame in this way also created confusion and, it is argued in this research, distracted policy attention away from public health concerns about medicine quality and safety.

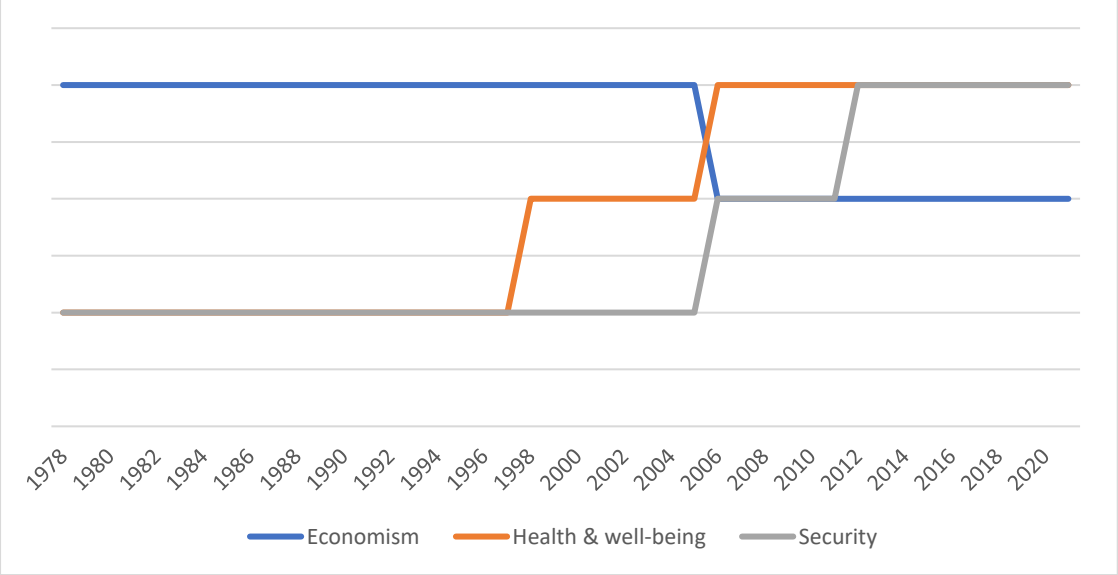
Framing assumes a critical role in elevating political positioning of the issue. The emergence of the health and well-being frame first served in legitimising the creation of SDA in 1998, long before the frame was used to develop a public health-centred policy approach to SF medicines in 2006. Importantly, China's new mission towards a rule-based administration required a public health based frame to provide legitimacy to the new SDA and was written into the revised *Drug Administration Law* (2001). The rise of the health and well-being frame was then manifested by a series of policy responses, including making political statements on the importance of health and safety, change of SFDA leadership to be led by public health officials, top-down institutional reforms, and new investments of the SFDA on enhancing medicine quality, testing and conducting more raids on SF medicines. The Chinese government realised the pressing need to address the quality issue seriously, and the industry could not develop sustainably without sufficient recognition of quality and regulation. Hence, prioritising health and well-being led to a new wave of action to strengthen medicine quality and re-balance the relationship between public health and economic development. The security frame, as argued in Chapter 6, was socially constructed by top policy-makers who perceived SF medicines (and medicine safety in general) as a threat to Chinese society and the state. The rise and acceptance of the security frame appeared critical in elevating SF medicines higher up the policy agenda, through continuous effort of Chinese policy-makers and academics associated medicine safety

with national security, political security, economic/industrial security, and environmental security. This led to a heightened political will from central government to address SF medicines and special policy responses were advanced under the security frame.

8.4 Factors influencing the rise and fall of policy frames

Figure 8- 2 describes the changing level of influence of the three frames identified in this research over time. This section identifies four main factors contributing to the rise and fall of these frames, emerging from the empirical analysis presented in Chapters 4-7, and the corresponding effects on policy responses. These factors concern the powerful policy actors promoting the issue, political context inhibiting or enhancing policy influence, events serving to focus policy attention, and the use of policy language. Here, I argue that a policy frame is likely to be more influential when at least two or more facilitating factors are present.

Figure 8- 2 The rise and fall of policy frames on SF medicines



8.4.1 Actor power

Actor power, as defined in Shiffman and Smith (2007), is the strength individuals and organisational actors possess to influence a policy issue. The power of actors and policy ideas are often deeply intertwined. As Rushton and Williams (2012) argued, policy outcomes are determined not only by the persuasiveness of particular frames, but also by who is advancing that frame.

This research identifies three prominent policy actors in shaping ideas and perceptions on SF medicines: political leaders, relevant institutions and corporate actors. Unlike studies in GHG examining different health issues with different types of actors and governance structure in place, the analysis of SF medicines in China has not had a wide range of actors engaging in the policy process. In combating SF medicines, Chinese policy-making has been mostly a top-down process led by political leaders and senior policy-makers, specialists, academics/experts, large MPCs and their representative industry associations. In the context of this research, there has been limited bottom up processes involving participation of advocacy groups such as patients, public health professions, non-governmental organisations. Health associations such as China Medical Associations seemed overwhelmed with issues around the structure and efficiency of health systems, and thus issues such as SF medicines have not received attention (Meeting, SMBJ200612). Domestic industrial associations such as Chinese Pharmaceutical Association, China Pharmaceutical Industry Research and Development Association, China Pharmaceutical Enterprises Association seemed more interested in R&D and innovation, which could generate more financial resource (Interview, 22BJ080512; Meeting, SMBJ200612).

Political leaders have included high-ranking political figures, officials and others possessing significant political influence and authoritative power within the Chinese policy-making system. The CCPs political leadership has historically played a critical role in shaping public perception and understanding of Chinese policy decisions, and setting the stage for the development and implementation of policy changes. Chapter 4 has shown that since the 1980s,

Vice Premier Wu Bangguo, Minister of Health Qian Xinzhong and many other political leaders made many speech acts and wrote articles on the economic importance of medicines. Senior policy-makers started to consciously re-frame medicines as an economic commodity vis-a-vis a social welfare commodity or public good, as part of efforts to increase the commercialisation of medicines amid market reform. In the 2000s, Hu-Wen leadership after the SARS epidemic renewed the CCP's emphasis on "putting people first". This ideational shift and the introduction of the Scientific Development Concept after SARS, as discussed in Chapter 5, opened the way for the health and well-being frame to emerge and become influential. Vice-Premier Wu Yi's attention on corruption and support for improving drug testing and detection, and other senior political officials' commitment to attend public health aspects of the issue, represented high-level political support for this frame, which had been previously insufficient. Since 2012, President Xi's reframing of a broad range of public policy issues in terms of national security, extended to understandings of medicine quality and safety including SF medicines. The findings in Chapter 6 suggest that the securitisation of SF medicines was largely a top-down process in China, which helped elevate the issue higher on the policy agenda. Food and medicine safety first became part of "public safety", which was communicated publicly by senior CCP leaders under Hu Jintao. Frequent speeches and published articles by high-ranking political figures such as President Xi, Vice Premiers Wang Yang and Liu Yandong, all contributed to this process of securitisation. These actions constituted a major effort by political leaders to present medicine safety in ways that linked the issue with social stability, the Party's governing ability, and ultimately the political security of the CCP.

Institutional actors also played an important role in advancing or hindering certain frames. The main institution, the Chinese national medicine regulatory authority, seemed to struggle to reconcile the somewhat conflicting policy frames of economism and health and well-being. Chapter 5 describes how the agency underwent restructuring every five years since its establishment in 1998 (Table 5- 1), when economism was the dominant frame. Because of the close nexus between regulators and the Chinese pharmaceutical industry, the SDA's leadership,

guiding principles, personnel, and policy mandate, and thus medicine regulation, were framed by economism. The agency worked hard to repair its reputation, by prioritising the health and well-being frame and distancing itself from industry, following the Zheng Xiaoyu's corruption scandal in the mid-2000s. The agency's authority and independence peaked between 2013 and 2017, when the political ranking of the new CFDA was raised to the ministerial level for the first time. This further strengthened the leadership power of the CFDA in medicine regulatory reform and policy coordination, and reflected China's growing political attention to food and medicine safety issues after President Xi took power – manifesting in a series of ambitious regulatory reforms under the Director General Bi. However, after the CFDA's new institutional restructuring in March 2018, the political influence of the national medicine regulatory authority was weakened by its return to a vice-ministerial-level institution, renamed NMPA under the administration of a new economic agency, the State Administration of Market Regulation (SMRA, 国家市场监督管理局). The NMPA maintains its own branches at the provincial level, but municipal and county levels of medicine regulatory authorities were dismantled. The SMRA[38] became the single most powerful market regulator to address public's growing concerns, including food and medicine safety, quality inspection, fair competition, commercial bribery, and industries' concerns of IPR infringements. The shift in the institutional environment for the Chinese national medicine regulatory authority, suggests a return to economism at the expense of the health and well-being frame, particularly at local levels of government.

Corporate actors, represented by MPCs and their industry associations, have also been influential. Chapter 7 analyses how foreign MPCs in China made concerted efforts to influence the portrayal of the SF issue and policy responses in ways that furthered their vested interests, notably focusing on IPR protection including branding and patent, and pricing. Drawing on a

[38] The majority of constituents under the new SAMR were economic agencies, including the State Administration for Industry and Commerce, the Price Supervision and Anti-Monopoly Bureau (from the National Development and Reform Commission), the Anti-Monopoly Bureau (from the Ministry of Commerce), the Anti-Monopoly Commission (from the State Council), and the State Intellectual Property Office (Wang *et al*., 2018).

larger toolkit, there are three aspects that made MPCs stand out with regards to policy influence in comparison with Chinese domestic pharmaceutical companies. First, MPCs have been highly skilled at using the power of ideas through developing appropriate framing. For example, through persistently impressing on the concept and policy implication of "counterfeit medicines", MPCs conflated patent infringements with medicine safety and quality. Second, MPCs leverage their financial, human resources, technological capacities, and their home-country governments to engage every stage of the policy process. Through investing in anti-counterfeiting investigations and government affairs divisions, MPCs advanced particular ideas and policy influence either publicly or behind the scenes. Third, the network of individual companies and associations produce a concerted voice for more extensive policy influence, through providing information in formal setting, commissioning research projects and publishing regular position papers. In contrast to domestic companies, MPCs have a stronger collective capacity to produce evidence-based studies and ability to make sure their voices are heard by policy-makers.

8.4.2 The political context

Political environments shape public policy-making processes in all countries. To understand Chinese policy responses to SF medicines over time, this research highlights how shifts in the Chinese political environment, exerted influence on which frames gained or lost political leverage. I therefore argue that the political environment enhances the persuasive power of a particular frame which resonates with the political environment (the broader policy paradigm).

Since 1978, the CCP made economic development and modernisation central to all party work, resulting in increased emphasis on market forces in the Chinese economy (Saich, 2011). The CCP established the path of a socialist market economy in the 1990s, later inherited by Jiang Zemin who focused on a pragmatic approach to advancing economic development. The dominant policy mindset of the CCP centred on poverty reduction and raising living standards. During this time, many public policies were subsumed to meet these objectives (Hu, 1998; Magnus, 2011; Saich, 2011). Reforms of the domestic economy were accompanied by an unprecedented opening

up to the outside world in the search for export markets, foreign investments, technology transfer and higher-quality consumer goods. Within this political climate, conditions were favourably for the ascendence of those advocating for the economism frame to shape China's policies on SF medicines. Moreover, economic reform towards promoting a competitive market environment, opened doors for corporations to influence the policy process and shape policy ideas. Chapter 7 emphasised that MPCs' lobbying became an integral part of China's policy process at both the central and local levels.

After twenty years pursuing economic efficiency over protecting and promoting public health during the post-Mao era (Duckett, 2003; Ngok & Huang, 2014), China faced a series of challenges in maintaining the balance between economic growth and social protections. Environmental degradation, rising corruption, widening income disparity, and growing social vulnerability, became major political concerns, with education, healthcare, and housing identified as the "new three mountains" (Ngok & Huang, 2014; Duckett, 2017; Howell & Duckett, 2019). When social policies and social development rose to prominence in the early 21st century under Hu Jintao and remained so under President Xi Jinping, this new political environment brought back the special attribute of medicines to policy discussion and created the space for the rise of the health and well-being frame. With President Xi Jinping's vision to achieve common prosperity, consolidating CCP's leadership and strengthening national security, from 2012 an importance policy window opened in China that enabled the security frame to emerge, encompassing both industrial security (self-reliance on medicine production) and medicine quality and safety.

8.4.3 Focusing events

The third facilitating condition is the ability of frames and their agencies to connect to focusing events. Kingdon (2003) defines focusing events as crises or disasters that come along, and whose manifestation draws attention to a problem. Shiffman and Smith (2007) argue that policy windows can open after major disasters, and present favourable conditions for an issue to rise in priority and opportunities for advocates to influence policy-makers.

Several major incidents in China involving SF medicines have caused substantial injuries or deaths (although sometimes quantifiable data can be difficult to acquire), and this research has found that these events have contributed to policy change. They generate greater visibility of the problem in question among the public, and often serve as a catalyst for impactful responses, such as intensified local and national raids on SF medicines, enactment of new regulations or legislations. As analysed in Chapter 4, a series of disastrous SF medicines cases in the 1990s including the notorious Bai Wusong and Zhoukou incidents, led to the return of the old narrative of medicines being a "special" and "social welfare" commodity to the policy debate. Chinese policy-makers began to reflect on the prioritisation of commercial attributes of medicines and conducted several high-level cross-departmental meetings on the impact of SF medicines on public health, social stability and government reputation. These catastrophic events also contributed to the establishment of the central-local medicine regulatory system in 1998 and the major revision to the *Drug Administration Law* (2001). The 2018 vaccine scandal involving China's second largest vaccine producer Changsheng Bio-Technology, led the Chinese government to fast-track the passage of the new *Vaccine Administration Law* in June 2019. A focusing event can also take the form of a movie, as highlighted in Chapter 6, when the *Dying to Survive* movie in 2018 generated immense public and media attention on access to cheap generic oncology medicines, which were unavailable to Chinese patients. The movie led to the overturning of the results of Lu Yong's court case, facilitated the revision to definitions of SF medicines and fast-tracked the revision process of the *Drug Administration Law* (2019).

This research finds that focusing events can either help promote a new frame or strengthen an existing frame. The 2002-2003 SARS epidemic was a critical trigger of paradigm shift in China's new development in social policy (Ngok & Huang, 2014), which opened the pathway for the health and well-being frame to rise. After several high-profile domestic and international food and medicine safety scandals and the corruption scandal of Zheng Xiaoyu and his senior officials, the health and well-being frame gained political purchase with medicine regulatory authorities in combination with leadership change. The health and well-being frame

tiggered a shift in governing mentality at SFDA, a new wave of strengthening medicine quality and medicine regulation with the mandate to protect public health. Another parallel process, as revealed in Chapter 6, was the evolution of the CCP's fight against corruption since the 2000s, which created a favourable environment for strengthening medicine regulation and conducting high-level impact raids on SF medicines. The COVID-19 pandemic further strengthened the security frame, elevating the importance of human security and industrial security, and enabled the government to take stringent measures (zero COVID approach) in response to the pandemic. Human security emphasises safeguarding people's lives as a top priority and industrial security focuses on self-sufficiency in production and supply of medical products.

The research findings suggest that efforts to learn and change policy accordingly, are likely to be accelerated in the wake of major focusing events. When disasters happen, policy-makers had the desire or urge to "do something" and were more receptive to adopt a longer term and more sustainable perspective under the pressure of focusing events. The focusing events analysed in this research served as a wake-up call for political leaders and broader society, prompting a reframing of the SF problem and co-creating policy change.

8.4.4 The use of language

Language is fundamental to the social construction of reality. As discussed in Chapter 2, language conveys what we think and feel, and the experiences we perceive. The use of language in policy-making contributes to the generation and advancement of certain concepts, and perceptions about material reality, which in turn influences the issues deemed worthy of policy attention (Swaffield, 1998). This research argues that the use of language in policy-making, given previously little research attention in relation to Chinese pharmaceutical policy, has been central to the rise and fall of the three dominant frames influencing how SF medicines have been defined as a problem, and the policy solutions advanced over time.

With regards to SF medicines, using encompassing language with broad and sometimes ambiguous meanings, was strategically useful to bridge different frames and thus achieve broader

consensus among diverse stakeholders. "Anti-corruption" and "market order" are two of such examples highlighted in this research. Describing efforts to tackle SF medicines as a form of anti-corruption, was an important use of language for promoting SF medicines higher on the policy agenda. This phrasing also helped achieve wider recognition of the problem among important policy constituents and supported coordination with the agencies involved in anti-corruption efforts. In the absence of a unified national regulatory authority before 1998, campaign-style enforcements on anti-corruption were a critical part of the government's response to curtail the rise of SF medicine. Two major policy documents – the 1994 *Urgent Circular of the State Council on Further Strengthening Drug Administration* and 1996 *Circular of the General Office of the State Council on Continuing to Rectify and Standardise the Market Order in Pharmaceutical Manufacturing and Business Operation and Strengthening the Work of Drug Administration* – emphasised that investigating activities of SF medicine at all government levels, should be a focal point for anti-corruption work. The increasing international distrust in China's pharmaceutical exports and scandal of the high-ranking SFDA officials in the 2000s, led to a more intensified wave of anti-corruption in medicine regulation and attempts to address SF medicines, with more extensive use of the term anti-corruption in policy documents and the speeches of political leaders and senior officials.

"Market order" is another ambiguous phrase used over time to influence perceptions and ideas that advanced certain policy actions on Chinese SF medicines. Ferchen's research on the political economy of the term "market order" in China, suggests that "the very ambiguity of 'market order' makes it a powerful tool of governance at different levels of politics and the economy" (Ferchen, 2008: 3). This research argues that the flexibility of the market order phrase met the government's strategic need to incorporate different meanings at different times. "Market order" in SF medicines was initially used to refer to the problem of dysfunctional commercial markets (poorly regulated, illegal activity), local protectionism and corruption, IPR violations (more prominent after 2000s), and the state's governance of the economy. As analysed in Chapter 5, in addition to supporting the economism frame, using the language of "market order"

advanced the goal of social and economic stability championed by the security frame. Findings suggest both "anti-corruption" and "market order" were commonly used phrases by LSGs to enhance the political acceptability of proposed policy changes and help build wider consensus across government agencies. In this regard, language has been deployed strategically to advance or hinder specific frames.

8.5 Interrelationship among frames and priority setting

This section examines the interrelationship among the dominant frames from three perspectives: competition between the economism and health and well-being frames, convergence of the economism and health and well-being frames, and cooperation with the security frame, acting as an umbrella frame. Here, I argue that the changing perceptions of how frames interact with each other helps to explain Chinese policy responses to SF medicines. Overall, China's policy responses can be seen as evolving over time, from misalignment to alignment.

8.5.1 Competition between economism and health and well-being frames: Navigating between industry expansion and medicine regulation

Tensions between the economism and health and well-being frames were very much in evidence in China's responses to SF medicines during the initial two decades of Chinese medicine regulation. In the early stages of economic reform, Chinese policy-makers emphasised growing the pharmaceutical sector and paid limited attention to medicine quality and safety. Applying Sutton's Three Phases theory of economic globalisation, during Phase I, when China first joined the world economy, the domestic industry faced various technological and quality gaps (Sutton, 2007, 2012). Medicine quality, like the quality of many other products, is associated with a country's level of industrial development. Improving quality is a consistent process of raising awareness and building industrial capability. The Chinese pharmaceutical industry during this phase of development faced a series of challenges, including lack of capital, technology, trained labour, and manufacturing capacity. Quality and regulation were compromised at this stage, as the Chinese government during the 1980s and 1990s allowed more firms to survive by lowering

market entry barriers and tolerated multiple medicine standards to exist. Fiscal decentralisation also provided localities with more freedom to develop and regulate their own pharmaceutical market and set their own quality standards. The main policy objective at this time was to resolve shortage of medicines for basic health needs, and not to achieve higher quality medicines (i.e., policy-makers believed that having some form of medicines was better than nothing).

The regulatory debate created competition between commercial vs social welfare goals in the production of medicines. If underregulated, the pharmaceutical market could be filled with SF medicines, and patients and health care would suffer. This is what happened in China during the 1990s. If overregulated and market entry barriers were set higher (e.g. GMP criteria, medicine standards) than the capability of firms at the current development level of the country, fewer enterprises could meet the standard and enter the market, and hence production levels would suffer. Even when the Chinese medicine regulatory authority was established in 1998, with the mandate to develop a national regulatory system and protect public health, the regulatory framework was hindered by the institution's tight nexus with the pharmaceutical industry and the co-existing mandate of promoting industrial economy. This research concludes that, during the first twenty years, Chinese policy-makers perceived economic and public health objectives as competing policy goals in responding to SF medicines. The belief was that health and well-being could not be attained until economic development reached a certain level. Hence, the competition between these two frames led to opposing policy pathways.

8.5.2 Convergence of economism and health and well-being frames: Strong regulation, strong industry

Since the mid-2000s, the interrelationship between the economism and health and well-being frames shifted from competition to convergence. Phase II and III of Sutton's economic globalisation model, suggests adjustments by domestic companies to global competition through capacity building and quality enhancement (Sutton, 2007). After China's accession to the WTO in 2001, addressing product quality and competing in the global market become a more prominent concern among Chinese companies and economic policy-makers. As high capability companies

(mainly MPCs in this context) transferred their higher-level capacities to the low-wage Chinese market, the Chinese government and domestic pharmaceutical companies realised that they had to improve quality and innovation capacity to compete in this process. From a health and well-being perspective, as China became wealthier and people's living standards continued to improve, patients began to demand higher quality medicines and healthcare services.

Policy-makers began to perceive more alignment between the economism and health and well-being frames. The frames were less often seen as being opposed, but as mutually reinforcing, with one able to promote the other. Beginning in the later phase under Hu-Wen leadership, and expanding further under President Xi Jinping, policy-makers began to advocate for a different policy direction: stronger regulation contributes to the strengthening not weakening of industry, and a stronger industry producing quality assured products better serves health and well-being goals. Ultimately, economic growth is not an end goal, but a means to serve overall development goals and help achieve higher status of well-being for the entire society. Hence, the mid-2000s saw a re-balancing of the relationship between public health and economic development as mutually reinforcing each other.

8.5.3 Cooperation between the three frames: Merging policy pathways

A further important concept drawn on in this research is *frame alignment* from social movement theory, which asserts that individuals overcome collective action problems by developing shared frames about their predicament, and then agreeing on a course of action (Klandermans, 1984; Snow *et al*., 1986; Benford & Snow, 2000). This concept offers useful insights on when and how contestation has given way to collective action in public policy. As Klandermans (1984) notes, framing alignment can be a critical tool to elicit consensus and action among policy actors, by constituting their relationships of interest and worldviews.

Section 8.3 discussed how the security frame was useful in elevating the political position of the SF medicines issue since 2012. This section further argues that the security frame acted as a "meta-frame" (or an umbrella frame) and a potential bridge for creating more synergies and

coordinated policy response by linking all three policy frames. Despite the fact that the security frame depicts SF medicines as posing multiple types of security threats (Box 8- 1), my research findings suggest that this frame served to merge the three frames towards a more coherent policy goal, centred on improving medicine quality.

Box 8- 1 Different dimensions of the security frame

National security: Medicine safety in China was first incorporated into the policy discourse on public safety (part of social governance) and later became part of the national security discourse.

Political security: Medicine safety is recognised as a national emergency, and a type of event that would harm social stability and ultimately the political hegemony of the CCP.

Industrial/economic security: The innovation and competitiveness of the indigenous pharmaceutical industry is at the core of national economic security. Over reliance on foreign medicine supplies in CCP's view, would undermine the security of the domestic pharmaceutical industry and pose serious national security concerns during emergency events, such as pandemic and warfare.

Human security: Safeguarding people's life is the top priority. Access to safe, quality-assured, and affordable medicines is an important component to human security.

The previous section discussed how, when economic and public health objectives aligned, they supported perceptions that stronger regulation led to a strengthening of the domestic pharmaceutical industry; which, in turn, served the country's need for high quality medicines. Similarly, when public health and national security goals were aligned, this advanced perceptions that policy responses focused on improving access to safe, quality-assured, and affordable medicines was an important component of human security. When economic and national security objectives aligned, it supported perceptions that China's ability to build a strong, resilient and self-sufficient pharmaceutical (and medical products in general) industry lay at the core of economic security. This research argues that the security frame served, not as a counter-frame (i.e., to compete with other frames), but as an umbrella frame to align all three frames towards a more coherent policy response. Improving medicine quality was at the core of policy responses

to address SF medicines, rather this research argues that it is this convergence across the three frames which explains the greater policy priority given to SF medicines.

8.6 Conclusions

This chapter discusses the role of three dominant frames influencing China's response to SF medicines since the late 1970s. Here, my analysis articulated how each frame fared over time, with their rise and fall influenced by four key facilitating conditions: the role of powerful policy actors, the broader political context, the influence of focusing events, and the use of language in policy-making. The interrelationships among the three frames – competing, converging and cooperating – further explains shifts in SF medicines policy. This suggests frames can exist, as part of the policy-making milieu, but can also be deployed deliberately and strategically by policy-makers seeking to advance particular policy actions. In this sense, this research concludes that framing theory provides new understandings of the importance of both ideational and material power.

Chapter 9 Conclusions

9.1 Introduction

Building on this research's findings, this concluding chapter is divided into two parts. Sections 9.2 to 9.4 discuss the policy implications which address research objective d) *discuss wider policy implications for China's efforts to strengthen policy response to SF medicines, global policy responses to SF medicines, and China's expanding role in global health governance*. Sections 9.5 and 9.6 then discuss research implications including limitations and future research directions.

9.2 Implications for strengthening China's responses to SF medicines

The findings of this research suggest that advancing effective policy responses to SF medicines, must be grounded in recognition that it is an inherently political issue, which is not limited by technical solutions based on evidence, prevention and detection (Table 9- 1). The rise of the security frame in China serves as an important catalyst to create synergies among policy pathways, by emphasising that improving medicine quality rests at the core goal to safeguard public health and advance industrial development. In going forward, ensuring access to safe, quality assured, and effective medicines is vitally important for China. However, the tension between industrial development and medicine regulation still has a strong presence at local levels. Although beyond the scope of analysis of this research, it is important to highlight that reconciliation between special and commercial attributes of medicines and their corresponding policy goals, is still an ongoing debate within the Chinese medicine regulatory system, even more so at local levels. Local regulatory authorities still find it challenging to detach themselves from their industrial ties, particularly when they are required to impose tough regulation on enterprises which are highly valued and protected by local governments. There are choices to be made by policy-makers about the values that underpin the medicine regulatory space, including what they want to achieve through different regulatory practices and what goal(s) they prioritise. This is not going to be resolved by scientific or technical arguments.

Clearly defined definitions of SF medicines are critical to the effectiveness of China's long-term policy responses to SF medicines. Definitions are not neutral technical descriptions but are rather underpinned by particular value systems. They should not only be clearly defined but also transparent in what interests they uphold. The removal of unregistered medicines from the definition of falsified medicines (in response to the movie *Dying to Survive*) and the reduced penalties on importing unregistered medicines in the revised *Drug Administration Law* (2019), could be a dangerous move (see Appendix D for China's legal definitions of SF medicines). Defining falsified medicines in a less stringent way, may potentially foster intentional smuggling of unapproved medicines (outside personal use) into the Chinese market – which creates further chaos in medicine regulation and undermines patients' safety. China should define SF medicines more clearly in public health terms and bring in additional categories on "unregistered medicines" which aligns with WHO's current categorisation. Ambiguous definitions or blurry boundaries between falsified and substandard medicines, can cause confusion in practice and hinder law enforcement.

A competent national medicine regulatory authority with more institutional stability is critical for China's success in addressing SF medicines (particularly substandard medicines, as criminal fraud is regarded outside the mandate of medicine regulatory authorities), and improving medicine quality. This research finds that the constant shifting in affiliation, institutional structure, political ranking, and authoritative power of the national medicine regulatory authority, can disrupt both technical and political sustainability in combating SF medicines. While medicine regulatory authorities are supposed to be the lead agency in coordinating issues concerning safety and quality of medicines, lower political ranking has been found to disempower the authorities in policy coordination and political mobilisation. Hence, a robust national medicine regulatory authority with consistent institutional mandate and political status, would help improve policy effectiveness in working with various agencies –including health institutions, customs, post offices, commerce, police, law enforcement agencies, and in partnership with the industry, to fight SF medicines.

Regarding MPCs' emphasis on IPR protection in the fight against SF medicines, it is important to disentangle IPR enforcement from China's policy responses to SF medicines, by focusing primarily on public health implications. Although the legal definitions of SF medicines in China do not involve IPR explicitly, this research finds IPR enforcement is a constituent of policy responses in many circumstances. With regards to global responses to SF medicines, we have seen a positive shift towards disentangling IP enforcement from quality concerns, reflected in both the revision of definitions and policy actions led by the WHO. This research, however, finds that such conflation still exists within a country context, which can lead to distracting policy attention and resources from medicine quality and safety. High prices, inadequate access to affordable medicines, and medicines in short supply are incentives for actions, activities and behaviours that result in SF medicines (WHO, 2017a), and these problems must be tackled from the public health perspective.

9.3 Recommendations for global responses to SF medicines

Fidler (2010) pointed out that concerns about global health governance are not limited to these epidemiological, economic, and environmental crises; but also to institutional failures to prevent HIV/AIDS pandemic, spread of antimicrobial resistance, and the proliferation of SF medicines. The issue of SF medicines becomes ever more challenging in a globalised world, where countries are increasingly interdependent with regards to medicine production and consumption. This research recognises several challenges in the global response to SF medicines. The key problems have been inadequately understood, with only fragmented data and evidence available, insufficient high-level political support at both the national and international level, and difficulties in achieving collective action given the fragmented nature of global governance on SF medicines.

Findings of this research contribute new understanding of China's policy responses to SF medicines. Research has demonstrated that global health issues such as HIV/AIDS, AMR and access to medicines attracted significant political attention, but some issues such as maternal

mortality, despite twenty years of effort, have struggled to generate the needed political support (Shiffman & Smith, 2007). Analyses in GHG demonstrate that establishing a framing that resonates, is a critical factor for aligning different perceptions, gaining political influence, prioritising and undertaking actions. The WHO developed "Prevention, Detection and Response" strategy in 2017 under the Member State Mechanism framework (WHO, 2017b). This research proposes an expansion of WHO's strategy from technical dimensions, as outlined in Table 9- 1, which requires coordination across sectors and disciplines, to further embrace the ideational aspect of policy process (the non-physical realm focuses on the thinking mind). I therefore argue bringing together the material world in the form of hard evidence with appropriate social construction and issue framing, can help achieve more effective policy responses. Our way of thinking determines our perceptions about the reality we experience and affect, which in turn shapes our response to issues/problems, which then generates results. Policy frames reflect policy ideas and worldviews, and can be developed intentionally to change perceptions on the issue and assert policy influence. At a deeper level, even if we could generate more extensive and reliable data on SF medicines, how policy-makers perceive this data, attach meaning to it, shapes the level of importance the issue assumes on the policy agenda, as well as policy responses.

Table 9- 1 WHO "Prevention, Detection, Response" strategy to combat SF medicines

	Prevention	**Detection**	**Response**
Objectives	Demand quality	Improve detection	Protect public health
	Secure supply	Increase reporting	Prevent recurrence
Actions	Supply chain integrity	Border control	Alerts and recalls
	Education and awareness	Reporting system	Regulatory strengthening
	Multi-stakeholder engagement	Risk-based inspection and surveillance	Transparent legal process

	Comprehensive legal framework	Access to laboratories and screening technologies	Evidence-based policy and procedure
Impact	Increased technical capacity	Improved access	Strengthened governance

Source: WHO, 2017b: 47

Successful global responses to SF medicines "require advocacy and political commitment spanning diverse sectors, to mobilise sustainable investment in people and infrastructure through collaborative capacity building, sustainable financing mechanisms, and good governance" at sub-national, national and international levels (Newton & Bond, 2019: e1609). China's example demonstrates that priority setting and policy responses can be advanced through alignment of framing. For instance, the security frame conveys a sense of threat and risk, feelings of fear and uncertainty, and hence policy-makers were more likely to develop emergency responses and act with a sense of urgency. This involves challenging the existing (often competing) visions of an issue by finding a new way of framing which embraces diverse stakeholders, interests and perceptions of the problem. This research urges the community concerned with global medicine quality to establish a resonant frame in a constructive manner which could help facilitate a more coherent multi-sectoral approach to SF medicines. National governments may use these findings to understand the perceptions, policy ideas and framing in policy-making and re-assess their policy responses to SF medicines.

Furthermore, this research proposes that awareness, consistency, and coherence can help policy-makers achieve framing alignment for more coherent policy objectives and concerted efforts in response to SF medicines. Awareness means that policy-makers need to be aware of different interests, perceptions, and end goals amongst different interest groups and decision-making participants. It is important to establish mutual understanding of different perceptions on the problem of SF medicines, which requires coordination across sectors and disciplines. Consistency means that policy-makers need to better understand their deeper core values in

pursuing their policy goals, and be more consistent in framing and responding to the issue or an aspect of the issue. Coherence means that the end goal is to achieve greater synergy in policy-making and facilitate multi-stakeholders work towards a common goal.

9.4 China's role in global health governance: SF medicines and beyond

Ensuring equitable global access to medical products, is a critical component for a well-functioning GHG. Global pandemics like COVID-19 can disrupt the supply of quality-assured medicines and lead to increased proliferation of SF medicines (US Pharmacopeia, 2020). China is now the only major economy that has returned to steady economic growth (Myers *et al.*, 2021) and is likely to remain dominant in the global supply chain. Hence China's capability in ensuring safe, quality assured and effective medical products are vitally important for the functioning of the global pharmaceutical supply chain during COVID-19 and beyond. China needs to work continuously to instil trust in the reliability of Chinese supply chain and the quality of Chinese medical products. In the global supply of medical products, China's effort has been centred on donation, bilateral trade, manufacturing capability transfer, and joint production. Within China's expanding role in the global pharmaceutical supply chain and GHG, this research suggests that Chinese policy-makers need a paradigm shift in their policy mindset. James Clear states in his book *Atomic Habits* that "The biggest barrier to positive change at any level – individual, team, society – is identity conflict" (Clear, 2018). His research demonstrates that identity shift (the perception of who you are) is at the core of sustainable change in attitude, behaviour and results. China on one hand still perceives itself as a developing country and has a long way to go to assure medicine and food safety. On the other hand, China is rapidly becoming a global pharmaceutical power and eager to expand its influence in GHG. How to reconcile these two conflicting identities is a pressing issue for Chinese policy-makers. This research suggests that a paradigm shift from a "survival" mindset to a "contributor" mindset could fundamentally help China. In other words, China needs to go beyond a survival mentality and become a more responsible contributor to supplying quality-assured medicines, as well as dealing with global public health threats.

At the 2021 Global Health Summit, China's President Xi Jinping put forward a vision of "building a global community of health for all" (Xi, 2021). What could Chinese value and experience do to contribute to this vision? What kind of leadership role can China assume in reconstructing GHG? The COVID-19 pandemic has revealed that national governments' responses to public health crisis are deeply divided, and global responses highlighted inadequacies in leadership, financing, and resource mobilisation, particularly in ensuring equitable access to medical products across the globe to save lives. The UK's former Prime Minister Gordon Brown highlighted in his book *Seven Ways to Change the World*, a mismatch between the complex global nature of the problems we face and our capacity and willingness to resolve the problems as a global community (Brown, 2021). China's President Xi Jinping framed the lack global governance capabilities to resolve the rising global problems as "deficit in global governance", and called for improvement in governance and cooperation to tackle global challenges (Jiang, 2021). COVID-19 also heightened political confrontations between the West and China, and generated a growing Sinophobia or fear of China sentiment. Nevertheless, the pandemic created opportunity for us to re-think the relationship between control and freedom, community and state, market and state, individualism and collectivism, altruism and selfishness, nationalism and internationalism, etc. This research argues that more effective cross-broader cooperation requires conscious politics, that goes beyond egotistical mindsets and selfish goals, rather acknowledging our shared interests and need to work together to collectively flourish. While cooperating with existing GHG mechanisms, this research concludes that China needs to expand its role in GHG with purpose and vision drawing on a higher level of consciousness, improving public health and advancing human development as the first priority.

Thus, I propose that from the material realm, there are five areas Chinese policy-makers should consider on how China could potentially contribute: institution and structure, actors (who is involved in what), science and technology, economics and finance, policy and legal framework. More importantly, this research argues that addressing the ideational realm (mindset) is even more critical. How China advances its leadership in GHG in a harmonious and constructive

manner with positive Chinese values, requires collective wisdom and more clarity on purpose, vision and goals; because purpose, vision and goals determine attitudes, actions, and results. The purpose relates to *why* you are doing what you are doing, which needs to match your core values. The vision relates to *what* you want to do to serve your purpose. And the goals concerns *how* you are going to deliver your vision, which can include both short-term and long-term considerations.

9.5 Limitations

With regards to data collection, I was aware of the opaque process of policy-making that takes place in China, and therefore sometimes documents and information are not publicly accessible. During interviews some medicine regulators and generic producers could be defensive about questions on SF medicines, hence providing less helpful information. The acknowledges the length of time that has elapsed between the start of my PhD in 2010 and thesis submission. During this period, some data collected during fieldwork in 2012 could be outdated due to a rapidly changing context in China. Further fieldwork in 2018 was used to update understanding of policy developments, perception on SF medicines, and central-local policy dynamics. I had limited access to policy-makers at the national medicine regulatory authority in Beijing in 2012, interviews with provincial medicine regulators in 2018 were an important remedy (I was introduced mainly through personal connections) to help understand central-local policy process on medicine regulation.

As documented in my Ethical Approval section, investigating criminal fraud of falsified medicines including visiting illegal manufacturing and sales sites, was not the main objective for this PhD. This decision was made based on personal safety concerns, my lack of experience and resources, and the political sensitivity of SF medicines. I contacted two well-known independent investigators in China on criminal activities of falsified medicines but received no response. Hence, news reports were my main channel for more fully understanding the criminal aspect of the problem.

I recognise the changing format of media communication in China and the need to update the methodology applied in this research. From 2015 onwards, news reports from the Chinese social media platform WeChat have become an increasingly important source of information. Central and local medicine regulatory authorities, specialist news agencies in pharmaceuticals and medical industry, switched to WeChat official accounts and some only publish on WeChat official accounts (instead of using "official websites"). Information on WeChat public accounts is more abundant than the traditional internet websites. With the rapid change in technology and diversified sources of information, I realised that there is a need to develop a systematic way to review and analyse data from platform such as WeChat.

9.6 Future research directions

Based on the findings of this research, there are five areas proposed for future research. First, research on SF medicines in China remains circumscribed by data scarcity and fragmentation. This research provided quantitative data wherever available on major incidents and the scale of SF medicines problem. The lack of quantitative data is partly due to the illicit nature of the problem, and partly due to the lack of research in this field. Further efforts to generate data and evidence on the prevalence of SF medicines (e.g., different therapeutic categories of medicines) in China and its health, social and economic impact, is required. Hence, more research investment in SF medicines is critical in China to inform future policy-making.

Second, further analysis of the security frame is needed. As the security frame on SF medicines mainly emerged since 2012, my 2012 fieldwork (when the policy discourse just started) was only able to capture a glimpse of this discussion. My 2018 fieldwork at the provincial level did not seem to generate many useful insights. To understand the security discourse, this research relied heavily on discussions from media, academic literature and policy documents. Thus, more can be done to update and deepen our understanding of the security frame through fieldwork research in Beijing. However, given the sensitivity of the security frame and the policy discussions involved, interviews should be conducted with greater care.

Third, the disconnection between policy adoption and implementation in China deserves further investigation. Although not explored in-depth due to the scope of thesis, this research finds that the central-local disconnection in interpreting and delivering policy goals in China is likely to impact policy effectiveness. Bridging the disconnect between policy adoption and implementation is key to strengthen China's policy responses on SF medicines, such as issues related to production quality management, pricing, supply chain security, procurement practice, etc. Framing analysis may be of further use for this purpose by determining, for example, if frames resonate sufficiently within implementing agencies. To address this question on central-local disconnection, might require both a new theoretical approach and more in-depth empirical investigations.

Fourth, more research is needed to investigate the privileged access and policy influence of MPCs in Chinese pharmaceutical policy and regulation, a subject that has attracted much speculation but limited scholarship. More broadly, the pharmaceutical industry's influence in shaping the health system and policy-making in China warrants closer scrutiny. For example, the extent to which China's irrational use and over consumption of antibiotics (particularly between 1980s and 1990s) was driven by the need to promote the industry. Inspired from personal experience, research and practice into human body and mind, I also seek to explore the economics and politics behind the pharmaceutical industry which has shaped modern medicine and how people perceive diseases, treatment, and healing. Research is needed to investigate how modern medicines have become the mainstream paradigm for healing and treatment, while traditional medicines, such as homeopathy in the West and acupuncture in China which are more cost-effective and environmentally friendly, have been increasingly side lined over the last two centuries (being framed as "alternative medicines"). Pharmaceuticals focus on treating the physical symptoms by perceiving the human body as a machine, but not the cause of the problem (Myhill, 2018). Whereas natural medicines such as homeopathy and acupuncture perceive the human body as a universe, a holistic energy field with body-mind-soul connection. These operate on two different paradigms. Pharmaceuticals are now a widespread source of chemical pollution

(Britton, 2012) and to tackle acute global problems such as AMR we require the return of other forms of sustainable health care.

Fifth, more systematic research and thinking is required to examine global governance (if there is one) on SF medicines, a fragmented and under researched field. Mackey and Liang (2013) has done some preliminary research on international actors responding to SF medicines, including WHO, UNODC, Interpol, World Customs Organization. Lamy (2017) explored governance and issue framing at a regional level (Southeast Asia). So much remains unknown about how actors, institutions, politics, science, technology, and ideas work together globally to respond to SF medicines, and how global responses to SF medicines have transformed after 2017, when the dispute over definitions began to settle. In addition to quantitative studies focused on understanding the prevalence of SF medicines, effort is also needed to incorporate social and political sciences research into policy responses and to understand how to facilitate more effective cooperation globally.

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List of Appendixes

Appendix A: A glossary of Chinese and English names

Bai Wusong	白武松
Bi Jingquan	毕井泉
Bo Qicheng	卜绮成
Cao Wenzhuang	曹文庄
Hao Heping	郝和平
Hu Jintao	胡锦涛
Hu Ximing	胡熙明
Hu Yinglian	胡颖廉
Huang Dehui	黄得惠
Jiang Zemin	江泽民
Jin Shaohong	金少鸿
Jin Tongzhen	金同珍
Li Tieying	李铁映
Liu Peng	刘鹏
Liu Yandong	刘延东
Lu Yong	陆勇
Ma Huaide	马怀德
Ma Kai	马凯
Peng Peiyun	彭佩云
Qi Moujia	齐谋甲

Qian Xinzhong	钱信忠
Shan Chunchang	闪淳昌
Shao Mingli	邵明立
Shen Dengle	沈登乐
Shi Huan	石峘
Song Hualin	宋华琳
Wang Shaoguang	王绍光
Wang Yang	汪洋
Wen Jiabao	温家宝
Wu Bangguo	吴邦国
Wu Yi	吴仪
Xi Jinping	习近平
Xu Zhijian	徐志坚
Zhao Peng	赵鹏
Zheng Xiaoyu	郑筱萸
Zhu Rongji	朱镕基

Appendix B: Chinese policy documents referenced in the main text

Year	Issuer	Name
1978	国务院、卫生部 State Council, Ministry of Health	《药政管理条例》（试行） Drug Administration Regulation (Trial)
1978	国务院 State Council	国务院同意卫生部《关于建议成立国家医药管理总局的报告》 Notification of the State Council for the Approval of the Ministry of Health's Report on the Recommendation of the Establishment of the State Pharmaceutical Administration
1979	全国人民代表大会 National People's Congress	《中华人民共和国刑法》 Criminal Law of the People's Republic of China
1979	卫生部、国家计委、国家经济贸易委员会、化工部、农业部、商业部、总后勤部、国家医药管理总局 Ministry of Health, State Development Planning Commission, State Economic and Trade Commission, Ministry of Chemical Industry, Ministry of Agriculture, Minister of Commerce, PLA General Logistics Department; State Pharmaceutical Administration	《卫生部、国家计委、国家经委、化工部、农业部、商业部、总后勤部、国家医药管理总局关于在全国开展整顿药厂工作的报告》 Report of the Ministry of Health, the State Development Planning Commission, the State Economic and Trade Commission, the Ministry of Chemical Industry, the Ministry of Agriculture, the Ministry of Commerce, the PLA General Logistics Department, and the State Pharmaceutical Administration on Carrying out Nationwide Campaign to Rectify the Pharmaceutical Manufacturers
1980	卫生部 Ministry of Health	《卫生部关于在全国开展整顿药厂工作的报告的实施细则》 Detailed Implementing Rules of the Ministry of Health on Carrying out the Nationwide Campaign to Rectify the Pharmaceutical Manufacturers
1980	国务院 State Council	《国务院批转卫生部等单位关于加强药政管理禁止制售伪劣药品的报告的通知》 Circular of the State Council on Approving and Forwarding the Report of the Ministry of Health and Other Agencies on Strengthening the Administration of Pharmaceutical Affairs and Prohibiting the Production and Sales of Falsified and Substandard Medicines
1981	国务院 (87 号) State Council (No. 87)	《国务院关于加强医药管理的决定》 Decision of the State Council on Strengthening Pharmaceutical Administration
1982	中国医药工业公司 China National Pharmaceutical Industry Corporation	《药品生产管理规范》 Drug Manufacturing Management Standards (Trial implementation)

1984	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中国人民共和国药品管理法》 Drug Administration Law of the People's Republic of China
1984	国家医药管理局 State Pharmaceutical Administration	《药品生产质量规范》 Drug Manufacturing Management Standards (Revision of the 1982 GMP)
1988	卫生部 Ministry of Health	《药品生产质量管理规范》 Drug Manufacturing Quality Management Standards
1989	国务院 (10 号) State Council (No. 10)	《关于扩大医疗卫生服务有关问题的意见》 Opinions on Several Issues Related to Expanding Health Services
1992	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中华人民共和国专利法》(1992 年修正) Patent Law of the People's Republic of China (1992 Amendment)
1992	国家医药管理局 State Pharmaceutical Administration	《药品行政保护条例》 Regulations on Drug Administrative Protection
1992	卫生部 Ministry of Health	《卫生部关于进一步深入开展查处制售假药劣药违法犯罪活动的通知》 Circular of the Ministry of Health on Further Carrying out the Investigation and Punishment of the Illegal and Criminal Activities of Manufacturing and Sales of Falsified and Substandard Medicines
1992	卫生部 Ministry of Health	药品生产质量管理规范 (修订 1) Drug Manufacturing Quality Management Standards (1st Amendment)
1993	中共十四届中央委员会 The 14th Central Committee of CCP	《中共中央关于建立社会主义市场经济体制若干问题的决定》 1993 Decision of the Central Committee of the Chinese Communist Party on Some Issues Concerning the Establishment of a Socialist Market Economic Structure
1994	国务院 (53 号) State Council (No. 53)	《国务院关于进一步加强药品管理工作的紧急通知》 Urgent Circular of the State Council on Further Strengthening Drug Administration
1996	国务院办公厅 (14 号) General Office of the State Council (No. 14)	《国务院办公厅关于继续整顿和规范药品生产经营秩序加强药品管理工作的通知》 Circular of the General Office of the State Council on Continuing to Rectify and Standardise the Market Order in Pharmaceutical Manufacturing and Business Operation and Strengthening the Work of Drug Administration
1997	中共中央、国务院 Central Committee of the CCP, State Council	《中共中央、国务院关于卫生改革与发展的决定》

		Decision of the Central Committee of the Chinese Communist Party and the State Council on Health Reform and Development
1997	全国人民代表大会 National People's Congress	《中华人民共和国刑法》(1997 年修订) Criminal Law of the People's Republic of China (1997 Amendment)
1998	国家药品监督管理局 State Drug Administration	《药品生产质量管理规范》(修订 2) Good Manufacturing Practice (GMP) Guidelines for Pharmaceutical Products (2nd Amendment)
1998	国家药品监督管理局、国家工商行政管理局 State Drug Administration, State Administration for Industry and Commerce	《国家药品监督管理局、国家工商行政管理局关于严厉查处制售假药违法行为的紧急通知》 Urgent Circular of the State Drug Administration Bureau and State Administration for Industry and Commerce on Seriously Investigating and Severely Punishing the Illegal Acts of Manufacturing and Sales of Falsified Drugs
2000	国家计划委员会 State Planning Commission	《药品政府定价办法》 Measures related to the Government Fixed Pricing for Pharmaceuticals
2000	国务院 (32 号) State Council (No. 32)	《国务院关于开展严厉打击制售假冒伪劣商品违法犯罪活动联合行动的通知》 Circular of the State Council on Carrying out Joint Actions to Severe Crackdown on Manufacturing and Sales of Spurious, Counterfeit, Falsified and Substandard Goods
2001	国务院 (11 号) State Council (No. 11)	《国务院关于整顿和规范市场经济秩序的决定》 Decision of the State Council on Rectifying and Standardising Market Economic Order
2001	国家药品监督管理局，卫生部，国家工商行政管理总局 State Drug Administration, Ministry of Health, State Administration for Industry and Commerce	《关于进一步整顿和规范药品市场秩序，严厉打击制售假劣药品医疗器械违法犯罪活动的通知》 Circular on Further Severely Cracking Down on the Illegal and Criminal Activities of Manufacturing and Sales of Falsified and Substandard Drugs and Medical Devices
2001	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中华人民共和国药品管理法》(2001 年修订) Drug Administration Law of the People's Republic of China (2001 Amendment)
2004	国务院办公厅 (43 号) General Office of the State Council (No. 43)	《国务院办公厅关于印发食品安全专项整治工作方案的通知》 Notice of the General Office of the State Council on Printing and Issuing the Work Plan for Special Rectification on Food Safety
2006	国务院办公厅 (51 号) General Office of the State Council (No. 51)	《国务院办公厅关于印发全国整顿和规范药品市场秩序专项行动方案的通知》 Circular of the General Office of the State Council on Printing and Issuing the Plan for the Nationwide Special Campaign of Rectifying and Standardising the Pharmaceutical Market Order

2007	国务院办公厅 (24 号) General Office of the State Council (No. 24)	《国家食品药品安全“十一五”规划》 11th Five-year Plan on National Food and Drug Safety
2012	国务院 (5 号) State Council (No. 5)	《国家药品安全“十二五”规划》 12th Five-year Plan on National Drug Safety
2012	全国人民代表大会 National People’s Congress	《中华人民共和国国民经济和社会发展第十二个五年规划纲要》 12th Five-Year Plan for National Economic and Social Development
2012	工业和信息化部 Ministry of Industry and Information Technology	《医药工业“十二五”发展规划》 12th Five-year Development Plan of the Pharmaceutical Industry
2012	国家食品药品监督管理局 State Food and Drug Administration	《国家食品药品监督管理局关于印发药品安全“黑名单”管理规定（试行）的通知》 The Provisions for the Administration of a Drug Safety Blacklist (for Trial Implementation)
2012	国家食品药品监督管理局 State Food and Drug Administration	《仿制药质量一致性评价工作方案》 The Work Plan for Quality Consistency Evaluation for Generic Medicines
2013	中共中央委员会 Central Committee of the CCP	《中共中央关于全面深化改革若干重大问题的决定》 Decision of the Central Committee of the Chinese Communist Party on Some Major Issues Concerning Comprehensively Deepening the Reform
2015	国务院 (28 号) State Council (No. 28)	《中国制造 2025》 Made in China 2025
2015	国家食品药品监督管理局 China Food and Drug Administration	《关于开展药物临床试验数据自查核查工作的公告》 Announcement on Carrying out Self-inspection and Verification on Drug Clinical Trial Data
2015	国务院 (44 号) State Council (No. 44)	《国务院关于改革药品医疗器械审评审批制度的意见》 Opinions of the State Council on the Reform of the Evaluation and Approval System on Medicines and Medical Devices
2016	国务院 (67 号) State Council (No. 67)	《“十三五”国家战略性新兴产业发展规划》 13th Five-year National Development Plan for Strategic Emerging Industries
2016	中共中央委员会、国务院 Central Committee of the CCP and State Council	《“健康中国 2030”规划纲要》 "Healthy China 2030" blueprint
2017	国务院 (12 号) State Council (No. 12)	《国家药品安全“十三五”规划》 13th Five-year Plan on National Drug Safety
2017	中共中央委员会、务院办公厅 (42 号) Central Committee of the CCP and General Office of the State Council (No. 42)	《中共中央办公厅国务院办公厅关于深化审评审批制度改革鼓励药品医疗器械创新的意见》 Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging the Innovation of Medicines and Medical Devices
2017	工信部、发改委、科技部、商务部、卫计委、食药总局	《医药工业“十三五”发展规划》 The 13th Five-year Development Plan of the Pharmaceutical Industry

	MIIT, NDRC, Ministry of Science and Technology, Ministry of Commerce, National Health Commission, CFDA	
2019	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中华人民共和国疫苗管理法》 Vaccine Administration Law of the People's Republic of China
2019	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中华人民共和国药品管理法》(2019 年修订) Drug Administration Law of the People's Republic of China (2019 Amendment)
2020	全国人民代表大会常务委员会 Standing Committee of the National People's Congress	《中华人民共和国生物安法》 Biosecurity Law of the People's Republic of China
2021	中共中央委员会 Central Committee of the CCP	《中共中央关于党的百年奋斗重大成就和历史经验的决议》 Resolution of the Central Committee of the Chinese Communist Party on the Major Achievements and Historical Experience of the Party over the Past Century

Appendix C: WHO definitions of substandard and counterfeit medicines since 1992

Year	Term	Issuer	Definition
1992	Counterfeit Medicine	WHO	A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredient or with fake packaging.
2003	Substandard Medicine	WHO	A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredient or with fake packaging.
2007	Counterfeit Medicine	IMPACT [39]	A medical product is counterfeit when there is a false representation in relation to its identity, history or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.
2008	Counterfeit Medicine	IMPACT	A medical product is counterfeit when there is a false representation[1] in relation to its identity[2] and/or source[3]. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components[4], without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products.

[39] IMPACT was International Medical Products Anti-counterfeiting Taskforce launched by the WHO in 2006, but because of its lack of transparency and relationship with the private sector and participation in IPR enforcement, the taskforce was no longer in operation after 2010.

			Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices in legitimate and medical products should not be confused with counterfeiting. Notes: 1 Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed. 2 This includes any misleading statement with respect to name, composition, strength or other elements. 3 This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution. 4 This refers to all components of a medical product.
2009	Substandard Medicine	WHO	Substandard medicines (also called out of specification products) are genuine medicines produced by manufacturers authorized by the NMRA [National Medical Regulatory Authority] which do not meet quality specifications set for them by national standards.
2010	Substandard Medicine	WHO	Each pharmaceutical product that a manufacturer produces has to comply with quality standards and specifications at release and throughout the product shelf-life required by the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable National Medicines Regulatory Authority before the product is authorized for marketing. Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.
2017	Substandard medical products	WHO	Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
2017	Unregistered /unlicensed medical products	WHO	Medical products that have not undergone evaluation and/or approval by the NMRA for the market in which

			they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
2017	Falsified medical products	WHO	Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Appendix D: China's legal definitions of SF medicines

Drug Administration Law of the People's Republic of China (1984)

[*translated from Chinese by the author based on the official translation of the revised Drug Administration Law in 2001*]

Article 33-34 under Chapter V: Control over drugs

Article 33 Production and distribution of counterfeit drugs are prohibited.

A drug is a counterfeit drug in any of the following cases:

(1) the ingredients in the drug are different from those specified by the national drug standards; or

(2) a non-drug substance is simulated as a drug or one drug is simulated as another.

A drug shall be treated as a counterfeit drug in any of the following cases:

(1) its use is prohibited by the regulations of the drug regulatory department under the State Council administration of health departments;

(2) it is produced without approval;

(3) it is deteriorated;

(4) it is contaminated;

Article 34 Production and distribution of substandard drugs are prohibited.

A drug shall be treated as a substandard drug in any of the following cases;

(1) its content not up to the national drug standards or drug standards under provinces, autonomous regions and municipalities directly under the central government;

(2) it is beyond the date of expiry;

(3) other cases where the drug standard are not conformed.

Drug Administration Law of the People's Republic of China (2001 Amendment)

[official translation]

Articles 48-50 under Chapter V: Control over drugs

Article 48 Production (including dispensing, the same below) and distribution of counterfeit drugs are prohibited.

A drug is a counterfeit drug in any of the following cases:

(1) the ingredients in the drug are different from those specified by the national drug standards; or

(2) a non-drug substance is simulated as a drug or one drug is simulated as another.

A drug shall be treated as a counterfeit drug in any of the following cases:

(1) its use is prohibited by the regulations of the drug regulatory department under the State Council;

(2) it is produced or imported without approval, or marketed without being tested, as required by this Law;

(3) it is deteriorated;

(4) it is contaminated;

(5) it is produced by using drug substances without approval number as required by this Law; or

(6) the indications or functions indicated are beyond the specified scope.

Article 49 Production and distribution of substandard drugs are prohibited.

A drug with content not up to the national drug standards is a substandard drug.

A drug shall be treated as a substandard drug in any of the following cases;

(1) the date of expiry is not indicated or is altered;

(2) the batch number is not indicated or is altered;

(3) it is beyond the date of expiry;

(4) no approval is obtained for the immediate packaging material or container;

(5) colorants, preservatives, spices, flavorings or other excipients are added without authorization; or

(6) other cases where the drug standard are not conformed.

Drug Administration Law of the People's Republic of China (2019 Amendment)

[*official translation*]

Article 98 The manufacture (including preparation, same hereinafter), sale, or use of counterfeit or inferior drugs is prohibited.

A drug shall be deemed a counterfeit drug in any of the following circumstances:

(1) the ingredients in the drug are not compliant with the ingredients stipulated in the national drug standards;

(2) a non-drug substance is substituted for a drug or one drug is substituted for another;

(3) a deteriorated drug; or

(4) the indications or functions indicated are beyond the specified scope.

A drug shall be deemed as an inferior drug in any of the following circumstances:

(1) the ingredients of the drug are not compliant with the national drug standards;

(2) a contaminated drug;

(3) the validity period is not indicated or is altered;

(4) the product batch number is not indicated or is altered;

(5) it is beyond the date of expiration;

(6) preservatives or excipients are added without authorization; or

(7) any other cases that do not conform to the national drug standards.

The manufacture or importation of drugs without a drug approval license is prohibited. The use of active drug ingredients, packaging materials, or containers for drug manufacturing, which have not been reviewed and approved in accordance with the provisions, is prohibited.

Appendix E: Consent form for interviews (2012)

London School of Hygiene & Tropical Medicine
Keppel Street, London,
WC1E 7HT, UK

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

China's Policy on Counterfeit Medicines:
Navigating between Economic and Public Health Concerns

I, Xu Jingying, am a second-year PhD student in the Department of Global Health and Development of the London School of Hygiene and Tropical Medicine in the United Kingdom. The aim of my PhD thesis is to understand China's policy on counterfeit medicines since the late 1970s.

The purpose of my trip to China this time is to carry out key informant interviews, including academics, government officials and industry representatives. Interview is a useful tool in academic research to generate important primary data. In my research, I expect interviews to help provide valuable information about how a broad range of economic, political, social and historical factors might have influenced China's policy on substandard and falsified medicines.

Consent and confidentiality of interviews

This project has been reviewed and approved by the ethics committee at London School of Hygiene and Tropical Medicine as required for all PhD projects.

Your participation in this interview is completely voluntary and you can opt to answer or not answer any of the questions posed at any point during the interview process. I would like to record our interview for the purpose of data accuracy. But formal permission will need to be obtained before recording. If the informant wishes not to be recorded, the student will take notes during the interview. Your consent to be interviewed, and how it will be recorded, can be indicated on the consent form attached to this sheet. You may also choose to provide your consent orally to the student.

Interview data will be transcribed and analysed by the student. Only my PhD supervisors, Professor Kelley Lee and Dr Anne Roemer-Mahler, will have the opportunity to look at data collected from the field. Data will not be quoted, either directly or anonymously, without the interviewee's formal consent. If interview data are used for other research purposes than the PhD thesis or subsequent publications deriving from it, written consent from key informants will be obtained beforehand.

Follow up

Please do not hesitate to ask any questions you may have about this research project and process. If you wish, I can provide you with a synopsis of the research findings once the analyses and dissertation is completed. Kindly provide me with your full email or address on the consent sheet for this purpose.

Xu Jingying's contact information:

Email: xujy8825@gmail.com; jingying.xu@lshtm.ac.uk
Mobile: +86 139-5715-2268 (China); +44 787-7111-953 (UK)

THANK YOU!

Consent Form

Project title (tentative):

China's Policy on Counterfeit Medicines:
Navigating between economic and public health concerns

Interviewer's name and contact details:

XU Jingying
Phone: +86 139-5715-2268 (China); +44 78-7711-1953 (U.K.)
Email: xujy8825@gmail.com; jingying.xu@lshtm.ac.uk

I have read the information above and understand what is required of me to take part in the interview. My questions concerning this study have been addressed by the researcher identified above.

I understand that I can withdraw from the interview process at any time I wish without having to provide any explanation.

I agree to be interviewed and the interview to be recorded.

☐ Yes ☐

I agree to be interviewed and the interviewer takes notes only, without recording.

☐ Yes ☐ No ☐ pplicable

I give consent that my responses may be quoted in the research described above.

☐ Yes ☐

I give my consent that my responses may be quoted anonymously.

☐ Yes ☐

I would like to receive a synopsis of the research findings from the researcher.

☐ Yes ☐

Name:

Email:

Phone:

Signed: Dated:

London School of Hygiene & Tropical Medicine

Keppel Street, London,
WC1E 7HT, UK

中国的假劣药对策: 探求经济发展与公共健康的平衡

本人许静颖（中国国籍，浙江杭州人）是二年级的博士生，现于英国伦敦大学卫生和热带医学学院，研读全球健康与发展专业。我的博士论文主要关注中国的药品安全问题和政府的相关对策，尤其是近三十年伴随着我国经济高速增长和产业迅猛发展而变得尤为突出的假劣药问题。

我本学年的学术调研计划主要以中国北京、上海、南京、和杭州为主。学术访谈是一个对收集原始数据的极为重要的学术研究方法。我希望通过此行采访相关政府官员，学者以及行业协会人员，搜集对完成博士论文有帮助和价值的信息。

访谈同意书和保密规定

该研究课题，如同所有其他博士课题，已经通过伦敦大学卫生和热带医学学院伦理委员会的审查和批准。

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跟进

如果您对这一研究课题和过程有任何的疑问或者建议，请随时提出。如果您愿意，本人可以在完成论文后向您提供论文摘要和研究结论。请在附表提供您完整的电子邮件地址表同意这一目的。

本人联系方式:

邮件: xujy8825@gmail.com; jingying.xu@lshtm.ac.uk
手机: +86 139-5715-2268 (中国); +44 78-7711-1953 (英国)

衷心感谢您的参与和支持!

访谈同意书

论文题目（暂定）：

中国的假药对策: 探求经济发展与公共健康的平衡
China's Policy on Counterfeit Medicines:
Navigating between economic and public health concerns

采访者姓名和联系方式：

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我已阅读以上信息并且了解我此次接受学术访问的原因和目的。我关于这次受访的疑问采访者已予以解答。我知道我可以在访谈进行中的任何时间选择退出，并且不需要提供任何解释。

我同意接受采访并且允许录音。

☐ 是 ☐否

我同意接受采访，采访者只能做笔录，不允许录音。

☐ 是 ☐否 不适用☐

我同意我的回答可以被上述研究课题直接引用。

☐ 是 ☐否

我同意我的回答可以被上述研究课题匿名引用。

☐ 是 ☐否

我希望收到上述研究课题的摘要。

☐ 是 ☐否

您的姓名:

邮件:

电话:

签字: 日期:

Appendix F: Sample of interview guide (2012)

I developed two sets of questions prior to my fieldwork in China, one contains more general questions, while the other more specific questions on policy actors and processes. Depending on the occupation or area of expertise of each individual interviewee, interview questions can be a combination of general and specific.

A) General questions

1. Could you please tell me a little bit about how you arrived at your current position and what your main duty is at the moment?
2. To the best of your knowledge, when do you think the problem of falsified/substandard/counterfeit medicines began to emerge in China?
3. Drug safety in recent years is a big issue in China, what do you think are the major causes of the SF medicines problem in China?
4. To the best of your knowledge, what types of medicines do you think are falsified/substandard/counterfeit in the Chinese context? What types of falsified/substandard/counterfeit medicines are most prevalent?
5. Which are the challenges that you think the government faces in eliminating counterfeit medicines? And for strengthening medicine quality in general?
6. Given my research focuses on the government responses to counterfeit medicines, are there any documents or information that you think are important for me to look at?
7. Are there any other key informants you can recommend for this research project?

B) Specific questions

1. When do you think the urgency to combat counterfeit medicines attracted the government's attention and came into the policy agenda?
2. What are the major policies and enforcement mechanisms in China for combating counterfeit medicines?
3. Do you think the problem is clearly defined in Chinese legislations (for example the definitions on counterfeit and substandard medicines)?
4. Which actors do you think are influential in defining the problem, policy formulation and enforcement? And why?
5. Which government agency (or agencies) is leading policy-making and/or enforcement?
6. To what extent do you think the government has a clear objective and strategy on SF medicines?
7. How does the regulatory system work in China for ensuring quality of medicines? And for medicine import and export?

8. What role do multinational pharmaceutical corporations play in combating counterfeit medicines in China? How about domestic Chinese pharmaceutical companies?
9. Do you think there has been a changing attitude/response from the Chinese government to tackle the problem? If yes, when was this shift occurred? What do you think are the main driving forces behind the policy change?
10. Do you think other actors such as media, medical professionals, and civil society groups have been active and effective in combating counterfeit medicines?
11. What is your view on the level of cooperativeness and openness of the Chinese government in handling counterfeit medicines internationally? What do you suggest they can do to improve?

Appendix G: List of interviews (2012)

No.	Date	Time	Taped	Detail
Beijing				
1	3.12	9am-10:10am	Yes	01BJ120312, Deputy Director of Pricing and Reimbursement, R&D-based Pharmaceutical Association Committee (RDPAC)
2	3.12	6:30pm-8pm	Yes	02BJ120312 Liu Peng, Assistant Professor in Public Administration, Renmin University of China.
3	3.14	10am-10:50am	Yes	03BJ140312, National Programmer Officer – pharmaceuticals, Health System Development Team, WHO China Country Office
4	3.19	10am-12pm	Yes	04BJ190312, independent (retired) researcher, China Academy of Social Sciences (CASS)
5	3.19	3pm-4pm	Yes	05BJ190312 Hu Yinglian, Assistant Professor in Social and Cultural Studies, Chinese Academy of Governance
6	3.20	8:45 am-10am	Yes	06BJ200312 Jin Shaohong, Professor, Expert, SFDA Drug Evaluation Committee, National Institute for the Control of Pharmaceutical & Biological Products
7	3.20	2:50pm-3:40pm	Yes	07BJ200312 Song Ruilin, Executive President, China Pharmaceutical Industry Research and Development Association (Sino-PhIRDA), (former Deputy Director General of State Council Regulatory Affairs Office)
Tianjin				
8	3.25	1:40pm-4:10pm	Yes	08TJ250312 Song Hualin, Professor of Administration Law, Nankai University
Beijing				
9	3.27	2:40-4:40	Half	09BJ270312, Specialist, Government Affairs, Novartis China
10	3.28	10am-11am	Yes	10BJ280312, Director, Healthcare Cooperation Programme, The American Chamber of Commerce in China
11	4.01	10:30am-11:20	Yes	11BJ010412, Executive Deputy Secretary – General, Sino-PhIRDA; Deputy Director-General, Research Center for Medicinal Policy, Chinese Pharmaceutical Association
12	4.01	12pm-1:30pm	Yes	12BJ010412, Post-Doctoral Fellow, Research Center for Government by Law, China University of Political Science and Law
13	4.11	9:50-11:10am	No	13BJ110412, Director of Government Affairs, Nanjing Sanhome Pharmaceutical Ltd

14	4.14	4-6pm	No	14BJ140412, Inspector, Department of Policy and Regulations, SFDA
Nanjing				
15	4.19	9:30-10:25am	No	15NJ190412, Lawyer, Associate Professor in Pharmaceutical Administration, School of International Pharmaceutical Business, China Pharmaceutical University (CPU)
16	4.20	6:30-8:30pm	Yes	16NJ200412, Lecturer in Pharmaceutical Administration, School of International Pharmaceutical Business, CPU
17, 18	4.21	4:30-6:30pm	Yes	17NJ210412, Lecturer, School of International Pharmaceutical Business, CPU 18NJ210412, Senior Lecturer in Business Management, School of International Pharmaceutical Business, CPU
Hangzhou				
19	4.25	7:30-10pm	No	19HZ250412, Adviser, Zhejiang Provincial Food and Drug Administration Bureau; former Deputy Director General of Zhejiang Entry-Exit Inspection and Quarantine Bureau
Beijing				
20	5.05	9am-10:30	No	20BJ050512, Deputy Director, Institute for Global Health, Peking University
21	5.08	8:30-9:20am	Yes	21BJ080512 Yu Hui, Research Fellow, CASS; President and Director of Changce Think Tank; and Director for China Research Center for Public Policy, China Society of Economic Reform
22	5.08	1:30-3:10pm	No	22BJ080512, Secretariat, China Pharmaceutical Enterprises Association
23	5.15	10:40am-1pm	Yes	23BJ150512 Pan Xilong, Professor, School of Public Health, Peking University Health Science Centre
24	5.17	9:30am-1:10pm	Yes	24BJ170512 Zhu Hengpeng, Professor in Industrial Economics, CASS
25	5.22	10am-12:30pm	Yes	25BJ220512 Xi Shujing, Financial Channel Reporter, Sina Corporation
26	5.25	3pm-4:50pm	Yes	26BJ250512, Lawyer and Patent Attorney, Beijing Huake Alliance Patent Firm, works on pharmaceutical patents
27	5.28	10:40am-3pm	Some part	27BJ280512 Zhao Xiaoming, Vice President, China Pharmaceutical Enterprises Association; and Former Director, Drug Market Supervision Department, SFDA

28	5.28	9:20-10:30pm	Yes	28BJ280512 Song Hualin, second interview
29	5.29	3:30pm-4:50pm	Yes	29BJ290512 Shi Luwen, Professor and Director, School of Pharmaceutical Science, Peking University
30	5.30	2pm-3:50pm	Yes	30BJ300512 Yang Li, Associate Professor in Health Policy and Management, School of Public Health, Peking University
31	6.02	1pm-6pm	No	31BJ020612, Manger, International Trade Division, Gan & Lee Pharmaceuticals - Biopharmaceutical Industry person
32	6.04	2pm-3:20pm	No	32BJ040612 Hu Yinglian, second interview
33	6.07	9:40am-11:30am	Yes	33BJ070612 Chen Jin, Lecturer in Pharmaceutical Affairs and Intellectual Property Rights, School of Pharmacy, PKU
34, 35	6.08	10am-11:50am	No	34BJ080612 Anna Zhao, Trade & Investment Manager, Sector Lead for Healthcare & Life Sciences China, UK Trade & Investment, British Embassy Beijing 35BJ080612 Tom Duke, Senior Intellectual Property Liaison Officer, Economic & Trade Policy, Intellectual Property Office, British Embassy Beijing
36	6.08	2-4pm	No	36BJ080612, Associate Regulatory Affairs Manager, Regulatory Affairs, Hangzhou MSD Pharmaceutical Co., Ltd. Beijing Branch
37	6.09	4:40-5:10pm	No	37BJ090612, Director of Editorial Department, Chinese Pharmaceutical News
38	6.11	2pm-3:20pm	No	38BJ110612, Director, Division of General Affairs, The Pharmaceutical & Biological Invention Examination Department, The Patent Office of SIPO
39	6.12	4:30pm-5:20pm	No	39BJ120612, General Counsel and Director of Legal Affairs, RDPAC
40	6.14	10am-11:20	No	40BJ140612 Liu Peng, second interview
Shanghai				
41	6.27	9:30am-11am	No	41SH270612, Director of Center for Intellectual Property Study, School of Law, Fudan University
42	6.30	1:30pm-2:30pm	No	42SH300612, Lecturer, School of Intellectual Property, East China University of Political Science and Law
43	7.10	6-8pm	No	43SH100712, Manager, Marketing Department, China National Pharmaceutical Industry Information Center

44	7.11	11:30am-12:30pm	No	44SH110712, Associate Dean and Party Secretary, School of Public Health, Fudan University
45	7.11	2:30pm-4:30pm	Yes	44SH110712 Ye Hua, Associate Professor, School of Pharmacy, Fudan University
46	7.12	3pm-4:10pm	No	46SH120712, Manager of Worldwide Security, Johnson & Johnson; and Enforcement Committee Vice Chairman of Quality Brands Protection Committee (QBPC)
47, 48, 49	7.13	10:30am-1pm	No	47SH130712, Director and Chief Pharmacist, Shanghai FDA, Inspection Team 48SH130712, Section One, Shanghai FDA, Inspection Team 49SH130712, Chief, Section One, Shanghai FDA, Inspection Team
50	7.16	11:15am-12:00pm	No	50SH160712, Senior Legal Counsel, Eli Lilly
Hangzhou				
51	7.22	3:30-4:30pm	No	51HZ220712, Vice Chairman, Expatriate Supervisory Board of Zhejiang Province State-owned Enterprises; former Division Director of Zhejiang Province Drug Administration Bureau and Division Director of Zhejiang Province Economic and Trade Commission

Appendix H: Consent form for interviews (2018)

INFORMED CONSENT

知情同意书

Participation in Research on Medicine Quality

参与药品质量问题研究

Background Information

The global trade in substandard and falsified medicines appears to be rising. However, we don't have a clear understanding of why this is, or of how the market in these products really works. Researchers from the UK, Netherlands, Indonesia and Turkey are conducting a study that aims to increase our understanding of the factors that drive people to make, sell and consume poor quality medicines. We hope the information will eventually contribute to reducing the harm that these medicines do to individuals, communities and the economy.

This study is sponsored by Erasmus University and the Wellcome Trust, a global health charity based in the United Kingdom. It is overseen by an advisory committee that includes representatives from global health organisations and other universities and medical charities.

背景信息

全球假劣药品的贸易有抬头趋势。而药品质量问题这个领域的研究依然非常缺失。来自英国、荷兰、印度尼西亚和土耳其的研究人员共同组建了这个药品质量问题的研究小组，希望能进一步厘清全球药品质量问题背后的政治经济动因。我们希望研究成果能够影响国际组织和相关国家的政策过程，从而为进一步减少假劣药品带给公共健康和产业经济的危害做出一点贡献。

本研究课题是由英国惠康基金会（英国最大的生物医药研究赞助机构）资助，合作方包括世界卫生组织药品质量小组。课题的顾问团队有十余位成员，包括学者、国际组织官员、国际慈善机构医药专员。我们的初步研究成果报告会将于 2018 年 4 月 24 日在伦敦举行。最终研究成果报告将于 2018 年 9 月 23-28 日在英国牛津大学举办的第一届“药品质量与公共健康”全球学术论坛发表。

Your Participation in This Research

We'd like to interview you as part of this study. Our questions will vary according to your own role, but in general we will ask you to share your experience, opinion and knowledge about the way medical products are regulated, made, sold or consumed. We'll take notes on the conversation, and if you agree, we'll also tape the interview so that we can check that we have

understood you correctly. Your participation will be entirely voluntary -- we do not provide any pay or other compensation. You can refuse to answer any question, or just tell us if you want to stop the interview completely. Most interviews will take 60-90 minutes.

关于您参与此次研究

与您的访谈会成为我们实证研究的一部分。我们的问题会根据您所从事的工作性质不同而相应调整。大致来说，我们希望能够了解药品在监管、生产、流通与销售等方面的信息，并且期待您能分享您的知识、个人经历、和对问题的看法。研究人员将对整个访谈做笔录。如果您同意的话，我们会对访谈进行录音以便于后期整理和能准确地理解您所表达的意思。您的参与完全出于自愿，您可以拒绝回答任何问题，或者在需要的时候随时停止访谈。访谈时间大约会在 60-90 分钟。

Confidentiality

The study team recognises that poor quality medicines sometimes reach patients because of illicit or unethical behaviour somewhere in the production or supply chain. We are interested to learn the general mechanisms at work, both legal and illicit, but we understand that this will only be possible if we maintain absolute confidentiality. You will be asked to sign this form, which will be linked with an anonymous participant number, then stored separately from the study data. Only your participant number will be used on any study documentation, including in file names. Nobody outside the study team will be allowed to listen to interview tapes at any point.

When we are analysing and reporting the data, and when it is important to our understanding of the information, we may identify your observations by functional role (For example: "Pharmacist" or "Regulator").

保密性（对于受访者及信息的保护）

您的身份信息、访谈内容都将受到严格保密，这也是我们从事社会科学研究的学者所需要遵循的最基本的伦理要求。 所有受访者都将以匿名的形式出现，采访者会对受访者根据时间顺序进行编码。除采访者本人以外，没有任何人有机会聆听访谈录音。所有的笔记整理和转录工作（录音转成文字）都将由采访者本人进行。除本研究小组成员，没有任何人有机会看到后期整理出的访谈内容。

在报告写作过程中，如果有需要引用任何访谈信息，我们可能会将您的工作性质加以说明，比如：“药厂代表”、“监管者”、“医生”。

Use of the Information

We will use the information we collect to write a report for study sponsors, and will report our findings in medical journals. We also expect to discuss the findings with representatives of governments, funding agencies and global health organisations that are planning measures to increase access to affordable quality-assured medicines, and to reduce the supply and consumption of poor quality alternatives.

信息使用

采集的信息将用于学术报告/论文的写作，有一份成果报告将交予出资机构，另外我们也会在英文学术期刊上发表学术成果。研究小组也会与出资方、政府机构、全球卫生组织探讨我们的研究成果，为提高高质量药品的可及性，降低低质量药品的供应与消费提供新的政策建议。

For more information, questions or concerns: Please contact Jingying Xu, PhD Candidate of the London School of Hygiene and Tropical Medicine (jingying.xu@lshtm.ac.uk), or the lead research, Dr Elizabeth Pisani (pisani@ternyata.org).

如您想了解更多信息，或者有任何问题和疑虑：请联系伦敦卫生与热带医学院的博士生许静颖 (jingying.xu@lshtm.ac.uk)，或者我们的项目负责人 Dr Elizabeth Pisani (pisani@ternyata.org)。

Agreement:

The nature and purpose of this research have been sufficiently explained and I agree to participate in this study. I understand that I am free to withdraw at any time.

协议：

研究人员已将研究的初衷与目的详细解释。我同意参与此次研究。我了解我有权力在任何时候选择退出。

Signature 签字: _____ Date 日期: _____

Name (print) 姓名（印刷体）: _____

Appendix I: Sample of interview guide (2018)

A) Questions for medicine regulator, testing and detection agency

1. What are the current policies on medicine (including API) registration, production and regulation for the Chinese domestic market, import and export?
2. How big is the problem of substandard and falsified medicines in this area or from your work experience?
3. How is the Chinese medicine standard set? What are the types of medicine standard in China?
4. How does the central-provincial medicine regulatory system work in China?
5. Are there different regulators for API and other raw chemical materials for medicinal use? How does the regulation work?
6. The government pledged to improve medicine quality in recent years, why did it happen, what are the main policies and programme to make it happen?
7. How did the 2015 regulatory reform start and what's the impact on medicine quality and the pharmaceutical industry so far?
8. Is there a quality difference between medicines produced by R&D-based multinational pharmaceutical companies and domestic generic producers? Can you give examples?

B) Questions for pharmaceutical manufacturers and distributors

1. What are the main features of the Chinese domestic API market? For example: product range, production scale, comparative advantage vis-à-vis the Indian manufacturers, international competitiveness, etc.?
2. Which are the major import and export destination countries for China (and your company)?
3. How supportive is the local government of the pharmaceutical industry?
4. Regarding the recent closure of many API/chemical factories, what has happened? What would be the possible short-term and long-term impacts?
5. What are the procedures for exporting API and intermediates from China? If your company exports products to the US and the EU markets, is there any additional inspection required? How does your company work with foreign inspections?
6. Are there many quality standards? What is the regulation on quality compliance like?
7. Are there different quality requirements for different export markets (regulated markets vs. non-regulated markets)? What quality standard does your company follow?

Appendix J: List of interviews (2018)

No.	Date	Time	Taped	Detail
1	2.14	10am-12pm	No	01HZ140218, Retired Senior Official, Zhejiang Provincial Food and Drug Administration Bureau
2, 3	2.15	10:15-11:45am	No	02HZ150218, Chemicals and Minerals Identification Department, Hangzhou Entry-Exit Inspection & Quarantine Bureau
	2.23	2-2:50pm	No	06HZ230218, Second Interview
4, 5	2.16	3:30-5pm	No	03HZ160218, Deputy Director of the General Office, Zhejiang Entry-Exit Inspection & Quarantine Bureau
	2.21	3:40-5:10pm	No	05HZ210218, Second Interview
6	2.21	9-11am	Yes	04HZ210218, Government Affairs, Zhejiang CONBA Pharmaceutical Co. Ltd
7, 8	2.24	2:30-4pm	Yes, partially	07HZ240218, Deputy Head, Registration Department, Zhejiang Provincial Food and Drug Administration Bureau
	3.15	2:15-3:30pm	Yes	19HZ150318, Second Interview
I spent two mornings at Zhejiang Chemical Import & Export Corporation and conducted five interviews.				
9	2.28	9:45am-1:30pm (inc lunch)	Yes	08HZ280218, Manager, Risk Management Department, Zhejiang Chemical Import & Export Corporation
10, 11			Yes	09HZ280218, General Manager, Pharmaceutical Department, Zhejiang Chemical Import & Export Corporation
	3.14		Yes	17HZ140318, Second Interview
12, 13			No	10HZ280218, CEO and General Manager, Zhejiang Chemical Import & Export Corporation
			No	18HZ140318, Second Interview
14	3.1	10am-12:30pm (inc lunch)	No	11HZ010318, Director of Professional Office and Chief Pharmacist, Zhejiang Institute for Food and Drug Control
15			Yes	12HZ010318, Director, Chemical Drug Testing Department, Zhejiang Institute for Food and Drug Control
16	3.2	9:30am-11:15am	Yes	13HZ020318, CEO (retired), Zhejiang Huahai Pharmaceutical Co. Ltd

17	3.5	5pm-5:45pm	Yes	14TEL050318, Vice-president, China Chamber of Commerce for Import & Export of Medicines & Health Products
18	3.10	4:20-5:30pm	No	15HZ100318, Quality Control Specialist, Chiatai Qingchunbao Pharmaceutical Co. Ltd
19	3.12	3-3:50pm	Yes	16TEL120318, API Sales Manager, Zhejiang Hisun Pharmaceutical Co. Ltd