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Pharmacy Regulation in Thailand: Roles and Reflections of Inspectors

By

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**Thesis submitted in partial fulfilment of the requirements for
the Degree of Doctorate in Public Health**

**Health Policy Unit
London School of Hygiene and Tropical Medicine
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DOCTORATE IN PUBLIC HEALTH SUMMARY STATEMENT

The DrPH degree aims to equip those who expect their careers to be in the practice of public health rather than in research to be able to understand and adapt scientific knowledge in order to achieve health gain, and was therefore highly relevant for my situation. I have been working as an inspector in the Thai Food and Drug Administration since 1980 and had encountered problems in enforcement. I felt fresh ideas and greater expertise would be the needed if I was to understand better why there were difficulties in pharmacy enforcement in particular, and I wanted to be able to contribute to changes in regulation policy. The three components designed for the DrPH programme appeared to offer access to a wide range of skills and insights from a range of pertinent disciplines, which could complement my own field experience.

The first, taught component, widened my perspectives and gave me better understanding of scientific knowledge. The compulsory courses - *Communication Skills, Management*, and *Social Science Research Methods and Paradigms* combined well to provide skills as well as basic knowledge needed for pursuing effective management and research. The content of the *Management* course exposed me to organisation and management problems both in U.K. health care settings as well as in other countries. The course on *Social Science Research Methods and Paradigms* was exceptionally significant for me, as I came from a pharmacy background and had little knowledge regarding different social science research methodologies. I learned a great deal about qualitative research approaches, and how they could complement quantitative methods, helping to understand the underlying reasons for certain behaviours. In particular, the Qualitative Workshop in the second term provided academic as well as practical knowledge regarding qualitative research design and methods. During the Workshop I practised developing questionnaires, interviewing, analysing data and writing-up. I found that qualitative methods were both relevant and appropriate for gaining an understanding of why things go wrong in enforcement policies. Discussion during the workshop period laid an important foundation for my selection of appropriate research methods for my study. Besides, I learned a great deal from the exchange of experiences with other DrPH students.

I also took advantage of other courses, which I considered to be useful for my career development. *Medical Anthropology in Public Health* and *Population and Development* courses were good examples, deepening my understanding of how to relate enforcement problems into a broader context of health behavioural problems, which are relevant to my

work. The courses *Health Policy: Process and Power*, and *Epidemiology for Policy Making* significantly gave me a more systematic and scientific understanding of what happens in the real world of policy-making, and helped me to understand better how the processes of policy formulation and implementation impact on the effectiveness of policy. Concepts from these courses were particularly useful in both my professional attachment and my research thesis. Finally, I also audited a course on *Comparative Health Care Systems* at the London School of Economics, which, although it focussed on European health care systems, enhanced my views of different health systems which was helpful given Thailand's current health reforms.

I chose to do my professional attachment – the second component of the DrPH degree – with the Drug Control Division in the Thai Food and Drug Administration (TFDA), Ministry of Public Health. The Drug Control Division is the main part of the TFDA responsible for enforcement for health consumer protection regarding medicinal drugs. My own work in the TFDA, has always been in another division, the Inspection Division, currently is responsible for import and export inspection. Working in the Drug Control Division gave me an insight into a different part of the TFDA, and I paid particular attention to the implementation of policies regarding consumer protection. In my professional attachment report, I used Hogwood and Gunn's framework to test how far the Drug Control Division was able to meet the ten pre-requisites for successful implementation. The attachment provided me the rare opportunity to step back and observe closely the working of my organisation from a more objective and relatively 'outsiders' view, within a scientific academic framework. For this part of the study I used research techniques of participant observation and document analysis. This was a valuable experience, and by the end of the four months, I had a more in-depth and systematic understanding of some of the constraints and management problems affecting the effectiveness of health consumer protection. This understanding was useful in approaching my research study on the role of inspectors because it made me aware of the nature of the policy-making process and the important role of management in reaching the organisation's goals.

The research study, the third element of DrPH degree, gave me the opportunity to explore in-depth one specific problem in my organisation – the one which I had experience of, and was interest in - the issue of regulation of pharmacies as conducted by inspectors. I was concerned about the gap between policy intent, as embodied in the 1967 Drugs Act, and policy implementation. For this research, I used a broad policy analysis approach to explore this gap, based on Walt and Gilson's framework of actors, process, context and content. Doing the research allowed me to have a first-hand experience in conducting qualitative

research from scratch – the interviews and documentary research were an important part of the research. The conceptual framework for the study was developed with the aim of exploring existing problems in the TFDA within the system of management, and the role of inspectors in enforcement. I hoped that the insights gained from the research would contribute to future policies or solutions for better enforcement practice.

This study is the first in Thailand to provide an in-depth analysis showing implementation deficits in the area of enforcement in pharmacies, by looking at the attitudes and roles of inspectors, and the way the management system of the TFDA affects their roles and attitudes. The research points to many factors, which adversely affect enforcement but, have been taken for granted. It fills a gap in the understanding of the role of pharmacy inspection, the problems inspectors encounter in their work, and their attitudes to those problems. Given the high level of interest in this study of policy-makers in the TFDA, I believe that the difficulties detected in the study will attract sufficient attention so that at least some will be addressed. The findings should help to design and implement more appropriate and more accepted strategies for enforcing regulations.

What I have learnt from the taught courses, my professional attachment and research emphasise the importance and possibilities for using and adapting scientific knowledge to do research for health gain and effective management. Together the range of skills, experience and knowledge from the three elements of the DrPH degree, have helped me to bridge the academic and practice arenas.

ABSTRACT

The Thai Drug Act 1967 regulates private pharmacies in Thailand, but violations are common. Effective enforcement is vital because pharmacies are the main drug distribution channel and have direct contact with consumers. However, independent studies suggest that there are wide discrepancies in regulation – and that the number of prosecuted cases does not reflect the number of violations that actually occur.

It seems that the reason for this discrepancy is that the Thai Food and Drug Administration (TFDA) inspectors do not fully exercise their authority in enforcing the Thai Drug Act 1967. This study aimed to seek out the reasons for this discrepancy by exploring the Act, the regulatory management system and TFDA inspectors' views and attitudes. Documentary analysis and semi-structured interviews were the two main methods used to collect data. Interviewees were recruited from current and former inspectors and policy makers in the TFDA.

There were three main findings. First, there is friction between the principle of a formal legalistic approach and the practice of the flexible approach used by the TFDA in enforcement. Second, interviews suggest that inspectors do not wholeheartedly enforce the Drug Act 1967 because the majority view the Act as unrealistic and impractical, and perceive that sanctions are not proportional to the harms caused. In other words, they feel that most of the sanctions are too severe. Third, inspectors described a number of obstacles to the exercise of their authority, resulting from business pressures, professionalism and the working process in the TFDA enforcement system. These constraints result in inspectors using unofficial methods (such as verbal warning) rather than fully using the sanctions available to them. This has led to under-enforcement and the erosion of the deterrence effect created by the Act.

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A LIST OF ACRONYMS

| | |
|------|---------------------------------------------|
| DCD | THE DRUG CONTROL DIVISION, TFDA, MOPH |
| MOPH | THE MINISTRY OF PUBLIC HEALTH, THAILAND |
| NDC | THE NATIONAL DRUG COMMISSION |
| RAU | THE REGULATORY AFFAIRS UNIT, TFDA |
| RPA | THE RETAIL PHARMACY ASSOCIATION |
| TFDA | THE THAI FOOD AND DRUG ADMINISTRATION, MOPH |

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Chapter 1 - Regulating Medicines, Regulating Pharmacies

The Thai Drug Act 1967 regulates private pharmacies in Thailand, but violations are common. This thesis focussed specifically on inspectors' points of view in expressing what they perceived as problems preventing them from using their legal authority. The thesis is arranged in six chapters. Chapter 1 provides general information, the rationale of this study, the context of the medicinal drug system focusing on pharmacies, problems or violations in pharmacies and the three groups of actors in pharmacy. It is narrowed down to the specific situation in Thailand. Chapter 2 reviews the general literature regarding enforcement, inspectors, how inspectors perform their job and what affects their decisions. Chapter 3 describes the objectives of the study, choice of methods, data collection and analysis. Chapters 4 and 5 are the result chapters, and present data revealed from interviews and documentary research demonstrating the underlying reasons why inspectors fail to fully use their authority. Chapter 6 presents the study's discussion, conclusion and recommendations.

1.1 Introduction

Enforcement is a main component to assure public safety concerning medicinal drugs (WHO 1988), referred to hereafter as 'drugs'. In view of their life saving and life threatening effects, drugs are a highly regulated commodity (Davis 1997), and following the catastrophe of Thalidomide¹ in 1960s, are registered with more stringent criteria regarding safety, quality and efficacy before being marketed (Jasanoff 1994). Regulating manufacturers helps to ensure that drugs are produced in compliance with required standards. Drugs are then distributed to hospitals, clinics, health facilities, pharmacies or grocery stores depending on the types of drugs and regulations in each country.

Pharmacies are the main drug distribution channel in most countries. In 1994, medicinal drugs distributed globally via pharmacies had a value of £136 billion (Anon.1995). In many developing countries, 70-80% of all drugs are distributed through pharmacies (Malek 1994, WHO 1994, Bapna 1996, Stenson et al 1997).

¹ A medicine for morning sickness found out later that it caused infant malformity.

Pharmacies, though a part of the health care system, are mostly in the private sector, and driven by the need to make profits. They are usually regulated. Pharmacies have direct contact with consumers; the quality of care provided at this level is, thus, critical since drugs are provided directly to consumers who are not usually knowledgeable about them. A licence is usually required to assign responsibility to those who dispense medicines. Restrictions, which vary from country to country, normally cover conditions for licensing, quality and types of drugs sold, and who is allowed to dispense drugs. At pharmacies, it is mainly qualified pharmacists who are assigned as the responsible professional to provide appropriate services to the public (Angorn and Thomison 1989). They are commonly referred to as the professionals-in-charge.

1.2 Drug regulatory administration

Most countries have Drug Regulatory Authorities appointing their enforcers – inspectors – to visit premises to ensure that regulations are observed (Barnett 1990, Allsop and Mulcahy 1996). Therefore, inspectors are the enforcement arms or policy implementation tool of the agencies. Inspectors normally have a professional pharmacy qualification (WHO 1994). Most countries rely on their governments to implement regulations (Kamat and Nichter 1998), although in many developing countries the state's role regarding the implementation of regulations is generally passive (Bhat 1996, Kumaranayake 1997). Implementation is left to the inspectors. In contrast, in many developed countries, professional organisations play a significant role in regulatory control as well as promoting an ethical code of practice, which increases law adherence. For example, in the Great Britain the Code of Ethics 1992 is used in parallel with the Medicines Act 1968 (Appelbe and Wingfield 1998).

Although regulations exist in most countries, the degree to which they are enforced and effective is varied. Most developing countries have problems related to irrational and illegal dispensing practices. Malpractice is mainly through overuse of antibiotics, injections, poly-pharmacy, dispensing prescription drugs without prescription and dispensing withdrawn and unqualified drugs (Sterky et al 1991, Paphassarang et al 1995, Goel et al 1996, Stenson et al 1997, Kamat and Nichter 1998). Small countries tend to have problems of counterfeit medicinal drugs (WHO 1994). Where enforcement seems weak, often lack of budget, manpower and other resources are considered – with rare empirical data – to be causes (Asiimwe and Lule 1993, Yesudian 1993, Mujinja et al 1993, WHO 1994, Kumaranayake 1997, Tonteerawongs et al 1997). Violations in pharmacies can be varied in terms of nature and magnitude. Common transgressions found in pharmacies include (Roemer 1991,

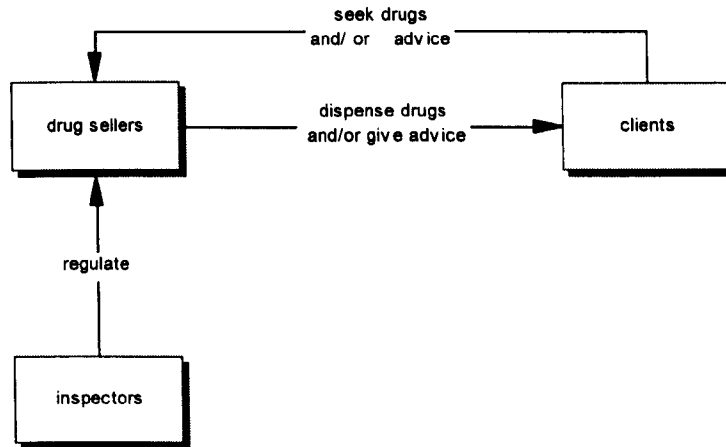
Wieringa et al 1992, RPSGB Annual Reports 1993-2000, TFDA Annual Reports 1994-2000, Davis 1997, Stenson et al 1997):

- Sale or supply of substandard drugs
- Sale or supply of prescription drugs without prescriptions
- Sale or supply of expired drugs
- Sale of unlicensed or withdrawn drugs
- Unsupervised sales
- Incorrect labelling
- Sale without premise licences
- Sale or supply of incorrect medicines
- Sale of excessive quantities of substances liable to misuse
- Inappropriate advertisement
- Unprofessional conduct

Violations in pharmacies mean that consumers are exposed to health hazards caused by sub-standard or inappropriate drugs, unnecessary side effects or drug resistance due to irrational drug dispensing. As a result, both individuals and countries may experience economic loss. However, enforcing regulations in pharmacies is difficult. There is a profession-profit tension – the need for profit as well as maintaining ethical practices (Cunningham-Burley and Maclean 1987, Cederlof and Tomson 1995, Goel et al 1996). Unfortunately, research to date has rarely gone beyond describing malpractice to understand the underlying causes of problems in pharmacies (Ross-Degnan et al 1992, Goel et al 1996).

1.3 The three groups of actors at pharmacies

To demonstrate problems in pharmacies, three groups of actors can be distinguished. They are drug sellers, clients and inspectors. Their interactions are illustrated in Figure 1.1.

Figure 1.1: Interactions among drug sellers, clients and inspectors

The term '*drug seller*' includes many groups of people who contact consumers in selling drugs. They can be professionally qualified pharmacists or other health professionals such as nurses; some may own pharmacies, others may work in pharmacies owned by businessmen as employees. They can be businessmen who own pharmacies and hire staff to sell drugs professionally or unprofessionally with informal training, or sell drugs by themselves. The informal training can be learning from drug labels, from their former employers and/or from medical representatives. Drug sellers also include those who sell drugs in unlicensed pharmacies such as grocery stores. This group of sellers is relatively uneducated and commonly referred to as '*grocer*' in Thailand.

A number of studies have looked at drug sellers and found that few are professionally qualified, and that they often make poor decisions on medicines (Kafle et al 1992, Muschell 1995, Goel et al 1996, Kumaranayake 1997, Stenson et al 1997). Their practices often seem to be profit driven. They perform illegal practices despite knowing that they are violating the law (Bhutta and Balchin 1996). However, the effect of such practice has not been studied much, although it is suspected to be an important issue (Cederlof and Tomson 1995, Ross-Degnan et al 1992).

Contextual factors such as cultural or socio-economic, accessibility to public health care facilities as well as sellers' attempts to protect their profit have also been suggested as influencing sellers' behaviour, possibly more than the effect of regulations (Cederlof and

Tomson 1995, Kumaranayake 1997, Stenson et al 1997). But there has been little research on how much such factors matter (Cederlof and Tomson 1995).

In many developing countries drugs are frequently bought on the customers' own initiatives, which can cause violations because of their demands (Goel et al 1996). Most customer demands are influenced by traditional beliefs and/or commercial pharmaceutical advertisements (Ross-Degnan et al 1992, Wieringa et al 1992, Dingelstad et al 1996). Pharmaceutical advertising is a big business, though it is regulated in most countries. In the US, it was estimated that in 1999 £1.3 billion was spent on direct-to-consumer prescription drugs advertising alone (Anon. 2001). The President of PT Warner-Lambert Indonesia, a large pharmaceutical company, said that medicinal drug advertisements on TV, radio and in print ranked first among the total advertising in Indonesia (Latchem 1995).

Contrary to the first two actor groups, studies regarding the effects of regulation on pharmacy have been rare (Goel et al 1996). While interventions to improve sellers' and consumers' behaviour have been implemented and evaluated, none has been found related to drug inspectors (Murray 1997). Drawing on research undertaken in the areas of pollution and occupational health and safety control, several potential research issues can be identified. These studies reveal that enforcement weakness is not simply an issue of corruption or ignorance or lack of staff, as often claimed, but in fact is due to a complex series of factors (Richardson et al 1982, Hutter 1988, Baldwin 1995, Yeager 1993, Black 1997). To have a healthy regulating mechanism, these studies suggested that many interrelated factors have to be implanted in enforcement systems; for example, the design, scope and form of regulation, the attitude of officers towards offences and offenders, the legal proceeding and penalties, the prosecution process, the background and training of officers, the policy conflict, the implementation process and administration in general. Support from a suitable and appropriate social and health infrastructure as well as administration are also recognised as important (WHO 1988, Kumaranayake 1997).

1.4 The situation in Thailand regarding private pharmacies

Thailand is a developing country situated in Southeast Asia with a population of about 59 million, of whom 31.5% are urban. The per capita income decreased from £1,524 in 1996 to £942 in 1997 due to the devaluation of the Thai currency (MOPH 1997).

The country is known as having a relatively non-conflict culture and strong hierarchical system (Klausner 1997, Kiatying-Angsulee 2000). Although Thailand has been under a democratic political system for many decades, vote buying is common (Economist 2002). Consequently, most politicians have close relationships with businessmen for financial support (Economist 2002), and political influence over government civil servants is felt to be increasing (Green 2000). Regulation enforcement, in general, is not perceived to be strong (Klausner 1997, Kiatying-Angsulee 2000, Economist 2002).

Private pharmacies are a significant drug distribution channel, distributing 50–60% of the total value (Working Group on Thai Drug System Analysis 1994). In rural areas, pharmacies are a significant source for self-medication because only 47.3% of the population has access to health facilities with physicians, compared to 81% in urban areas (Wibulpolprasert 1999). Studies suggest that 40–74% of people with minor illness seek first care from nearby pharmacies (Chuengsatiansup et al 2000). Drugs are distributed through 14,664 licensed pharmacies nationwide (see Table 1.1). In addition, it is estimated that 100,000 grocery stores in remote areas sell drugs without licence all over the country (Sringernyung and le Grand 1990). The number of grocery stores selling drugs without licence in Bangkok is not known, but there are many grocery stores selling drugs without licences.

1.4.1 The Drug Act 1967 and its control of pharmacies

The first Thai Drug Act appeared in 1936 but has since changed. Currently drugs are subject to three Acts according to how they are classified. The Psychotropic Substance Control Act 1975 covers drugs that are classified as psychotropic substances, mostly sedatives, anti-anxiety and hypnotic drugs. The Narcotic Substance Control Act 1979 covers chemicals such as morphine, ecstasy and codeine. The remainders fall under the responsibility of the Drug Act 1967. Each Act covers both modern and traditional medicines. This study focuses only on the Drug Act 1967, and on modern drugs.

The current Drug Act 1967 regulates the quality of drug products and the manner in which drugs are manufactured, imported and sold. The Act covers premise licensing, product registration, advertisement control, and inspection. In pharmacies, there are two main responsible groups: the professionals-in-charge and the licensees. Different duties and responsibilities are imposed accordingly. Consumer safety lies heavily upon the professionals-in-charge who are pharmacists, nurses, physicians, veterinarians or the Ministry of Public Health (MOPH) trainees depending on type of pharmacies they are

employed by. Owners or licensees of pharmacies are not required to have minimal professional or educational qualification, but must meet the specified standards, which are mostly about the capability to run a business. They must employ professionals-in-charge as specified by the law.

Most pharmacies in Thailand fall into two categories – type A and type B. The two main differences are types of drug they can sell and types of professionals-in-charge. Type B pharmacies can sell only specified items, while type A can sell all legitimate drugs. Professionals-in-charge of type A pharmacies are pharmacists, while those of type B pharmacies are MOPH trainees or nurses. Type A pharmacies are more common in Bangkok, the capital, and its vicinity, whereas type B are more common across the country (see Table 1.1). Most pharmacies are also residences, except those in department stores or in supermarkets.

Table 1.1: Number of licences in Thailand

| Type | Bangkok | Up-country (75 provinces) |
|--------------------------------|---------|------------------------------|
| Modern drug manufacturers | 120 | 54 |
| Traditional drug manufacturers | 273 | 451 |
| Modern drug importers | 479 | 31 |
| Traditional drug importers | 144 | 7 |
| Modern drug pharmacies | 3,611 | 7,483 |
| -type A pharmacies | (2,973) | (3,197) |
| -type B pharmacies | (638) | (4,286) |
| Traditional pharmacies | 411 | 1,600 |
| Total | 5,038 | 9,626 |

Source: DCD, TFDA, 2000.

All professionals-in-charge are required by the 1967 Act to register their duty hours. The Act allows professionals-in-charge to register their duty hours during specific periods, mostly 5.00 – 8.00 p.m. By this interpretation one pharmacist can work full time at one place, for example in governmental offices, and work part-time at pharmacies (for more detail see Box 1, Chapter 4). In practice, most professionals-in-charge do not usually work in their pharmacies during their registered hours; pharmacy owners, who are businessmen and hire professionals-in-charge, sell drugs outside the registered duty hours as well as during the registered duty hours without supervision of professionals-in-charge. Currently it is hoped that these problems are declining due to the increased number of pharmacists who own and work in their own pharmacies, which account for about 30% of type A pharmacies. Figure 1.2 shows pharmacy services in type A pharmacies.

Figure 1.2: Pharmacy services in type A pharmacies in Bangkok

Modern drug classification according to the Drug Act 1967 in Thailand is more detailed than the general classification in many countries. There are four groups of drugs sold under different conditions (see Table 1.2). First, the *Household Remedy Group*, which aims for self-medication. These drugs can be sold anywhere, as in the UK General-sale list or the US over-the-counter list. The List is restricted by the nine criteria² set by the National Committee of Household Remedy Selection. Although they are extremely safe, they are not popular as people perceive them as '*weak drugs*' (Sringernyung and le Grand 1990, Jaiwithi 1993). Promotion from government is weak (Chuengsatiansup et al 2000). The Government Pharmaceutical Organisation is the main producer, but production is limited, as it does not earn much profit (Chuengsatiansup et al 2000). Private pharmaceutical companies are not interested in this market.

Second, the *Ready-packed medicines not categorised as dangerous or special controlled drugs*, the so-called the Ready-packed drugs, are relatively limited too. These are usually drugs for common illness such as cold remedies, antacid and vitamins. The drug items in this group would be classified as in the UK's General-sale list or the US's over-the-counter drugs. This is the only group of drugs that type B pharmacies can sell in addition to the Household Remedy group.

² The selection criteria are 1) Commonly used and/or relevant to the national health problem, 2) For common illness treatment or palliation that fits for self-care, 3) High safety and low possibility of misuse or abuse, 4) High stability, 5) Easy to use, 6) Not expensive – with consideration to consumers, 7) Suitable package size, 8) Necessity and popularity, 9) Do not contain parts of legally protected animals (The Drug Committee Minute Report 1/2541).

Third, the *Dangerous Drug Group* is the biggest group. It comprises many drugs that are classified as prescription drugs in other countries, such as antibiotics, anti-hypertensive drugs, anti-diabetic drugs and the like. In Thailand, drugs in this group do not require prescriptions, but do need to be sold under the supervision of professionally qualified pharmacists. This group of drugs will be referred to as *pharmacy drugs*.

Fourth, the *Special Controlled Drug Group* is equivalent to the widely known prescription drugs. They require both prescriptions and pharmacist supervision before dispensing. This group will be referred to as *prescription drugs*.

Table 1.2: Drug classification and eligible types of pharmacies

| Drug classification | Eligibility to be sold | No of registered items * (1993) |
|---------------------|----------------------------------|----------------------------------|
| Household remedies | Anywhere, no licence is required | 148 |
| Ready-packed drugs | Type A and Type B pharmacy | 4,604 |
| Pharmacy drugs | Type A pharmacy | 12,367 |
| Prescription drugs | Type A pharmacy | 1,533 |

* Kiatying-Angsulee, 2000; 13.

1.4.2 Common violations in pharmacies in Thailand

In Thailand, commercial advertising to consumers is allowed for the Household Remedy drugs and the Ready-packed drugs only. Yet drug advertisement expenditure, excluding radio, is ranked among the top five highest in 1993 at a cost of 600 million baht (Working Group on Thai Drug System 1994). Advertising is believed to have a strong impact on drug utilisation, as well as 'word-of-mouth' (Chartbunchachai et al 1990). Studies show that the majority of clients come to pharmacies in Thailand with pre-decision; they specify drug names, shape or colours of drugs which they had used themselves, been told of by friends or relatives or seen in advertisements (Chartbunchachai et al 1990, Sringermyuang and le Grand 1990, Khwanlertmongkol 1994). These incidents cause problems in both professional practices and regulatory control because a number of demands are based on misbeliefs such as the more items the more effectiveness the drugs are (Chartbunchachai et al 1990, Sringermyuang and le Grand 1990, Khwanlertmongkol 1994).

Studies in rural areas have shown that villagers have positive attitudes towards modern medicines. They believe that the drugs on the market must be safe otherwise the government would not allow their sale or advertisement (Limdool 1991, Chuengsatiansup et

al 2000). They also believe that modern medicines are more potent than traditional medicines especially for acute sickness (Sringeranyuang and le Grand 1990, Pradabmook 1990), and that drugs from grocery stores are more potent than those from health centres and the Household Remedy Drugs (Sringeranyuang and le Grand 1990, Jaiwithi 1993). Consequently, most grocery stores, especially those in remote areas, illegally sell various kinds of drugs. Although common drugs sold are for minor illness such as common cold, headache, fever, cough, stomachache, peptic ulcer and malaise (Chartbunchachai 1990, Kornkasem et al 1995, Sringeranyuang and le Grand 1990), about 10% of drugs sought for self-medication are prescription drugs (Sringeranyuang and le Grand 1990).

Not only grocery stores, but also licensed pharmacies are found violating the Drug Act 1967. Type B pharmacies are regularly found selling drugs other than the permitted Ready-packed drugs (Tonteerawongs et al 1997, Hongsamoot et al 1999, Saorumnee and Bunyarat 2001). Most type A pharmacies sell drugs outside the registered period and sell drugs without pharmacist supervision, as mentioned in section 1.4.1. In terms of drug items, one common problem found in most pharmacies is selling prescription drugs without prescriptions. A study showed that in Bangkok requests for steroid tablets, which are prescription drugs, were met in 65.4% and 21.2% in type A and type B pharmacies, respectively (Hongsamoot et al 1999). The percentages were higher up-country (Tonteerawongs et al 1997, Hongsamoot et al 1999, Saorumnee and Bunyarat 2001). The illegal and irrational supply of pharmacy drugs such as antibiotics and non-steroidal anti-inflammatory drugs is also rampant (Podhipak et al 1993, Tonteerawongs et al 1997, Thamlikitkul 1988, Saorumnee and Bunyarat 2001). The TFDA 2001 survey showed that 23.8% and 21.7% of tetracycline dispensed in type A and type B pharmacies, respectively, had expired (Saorumnee and Bunyarat 2001).

1.4.3 Inspectors and their jobs

Before 1984, the Thai Food and Drug Administration (TFDA) was exclusively responsible for regulating pharmacies across the country. Since then the authority has been decentralised and its responsibilities delegated to the Provincial Health Offices (PHO) which belong to another MOPH department, but the TFDA still holds the authority to inspect wherever there are suspected problems. In the TFDA, responsibilities used to lie with the Inspection Division to monitor the 1967 Act and the Drug Control Division to register products. However, in 1997, the inspectorate was amalgamated under the Drug Control Division (see Annex 1 for the staff). Inspectors, all of whom are pharmacists, are the main enforcers authorised by the Drug Act 1967 who carry out routine enforcement (MOPH Ministerial Order 1984). Inspectors

carry out inspection at all licensed drug manufacturers, drug importers and pharmacies including those who are unlicensed but perform activities related to the 1967 Act.

Currently, there are 12 TFDA drug inspectors inspecting mainly in Bangkok and about 800 PHO inspecting in the 75 provinces (see detail in Table 1.3). However, PHO inspectors spend no more than 10% of their total time on drug inspection due to the burden from other responsibilities (Interviews 2000).

Data, though not perfectly matched, from inspection reports showed low frequency of reported violation, which contrasts with the results from independent studies (see Table 1.3 for details). The discrepancy between violations and those reported is puzzling, and suggests that the policy of regulation is failing. Without thorough understanding it is difficult to improve the situation. As the three groups of actors interrelate, understanding the actions of each group would be helpful for improving enforcement. In this particular study, a better understanding of the inspector's role was the focus in order to maximise quality of work in the government within the limited resources. In the absence of studies as to why inspectors fail to implement the law fully, material from other spheres may help. This is explored in chapter 2.

This study sets out to explore enforcement conducted by the TFDA inspectors, and to ask why inspectors fail to implement their authority, as indicated by the discrepancies between the inspection reports and independent studies. Clearly, the implementation of regulations is not the only factor involved in the correct supply and use of drugs in the community in Thailand. It is a multi-component problem. Consumer knowledge, control of advertising, the attitudes of drug sellers, the health care system, and other factors are likely to be important as well. Nevertheless, within the resources of the current study, only one issue can be addressed - the implementation of regulation by inspectors. The results that emerge will, therefore, only address one part of the quality supply and use of medicines.

Table 1.3: The discrepancies in violation data between the TFDA inspection reports and independent research studies

| Source of data, year, type of pharmacies , number of pharmacies inspected , offences | Inspection data | | | | | | | | | | Study 1 | | Study 2 | | Study 3 | |
|--------------------------------------------------------------------------------------------------------|-----------------|----------|-------------|------------|-----------|----------|-----------|------------|----------|-----------|------------------------------------|-------------|------------------------|---------------|------------------------------|-------------|
| | 2000 | | 1999 | | 1996 | | 1995 | | 1994 | | (Saorumnee and Bunyarat 2001) | | (Oonhalekaka 1999) | | (Tonteerawong et al 1997) | |
| | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B |
| | 310 | 62 | 718 | 61 | 320 | 215 | 1,069 | 659 | 364 | 41 | 260 | 198 | 1,995 | 2,134 | 1032 | 731 |
| Sell non- registered drugs | 12 3.9 | 0 0.0 | 108 15.1 | 0 0.0 | 10 3.1 | 2 0.9 | 12 0.9 | 4 0.6 | 4 1.1 | 3 7.3 | N/a | N/a | 2 1.0 | 25 1.2 | N/a | N/a |
| Sell expired drugs | 1 0.3 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 4 1.1 | 0 0.0 | 62 23.8 | 43 21.7 | 133 6.7 | 304 14.2 | N/a | N/a |
| Sell drug other than permitted | N/a | 0 0.0 | N/a | 24 39.3 | N/a | 2 0.9 | 0 0.0 | 87 13.2 | 0 0.0 | 6 14.6 | N/a | 171 86.2 | N/a | 1,229 57.6 | N/a | 299 40.9 |
| Sell withdrawn drugs | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 2 0.3 | 0 0.0 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| Sell fake drugs | 3 0.9 | 0 0.0 | 2 0.3 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| Sell without prescriptions | 6 1.9 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | N/a | N/a | 1,492 74.8 | N/a | 178 17.3 | N/a |
| Sell out of the duty hour | 1 0.3 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| Absence of professionals-in- charge | 6 1.9 | 0 0.0 | 4 0.6 | 0 0.0 | 0 0.0 | 0 0.0 | 24 2.2 | 0 0.0 | 0 0.0 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| Incorrect labelling | 5 1.6 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 6 0.6 | 0 0.0 | 2 0.5 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| False advertisemet | 0 0.0 | 0 0.0 | 0 0.0 | 0 0.0 | 1 0.3 | 0 0.0 | 0 0.0 | 0 0.0 | 4 1.1 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |
| Incorrect entry record | 3 0.9 | 0 0.0 | 0 0.0 | 0 0.0 | 1 0.3 | 0 0.0 | 4 0.4 | 0 0.0 | 2 0.5 | 0 0.0 | N/a | N/a | N/a | N/a | N/a | N/a |

A = type A pharmacy

B = type B pharmacy

Chapter 2 - Inspectors: an Enforcement Arm of the Regulatory Agency

Laws are recognised as government mechanisms or state power, or embodiments of policy decisions, to affect behaviour of certain groups in order to maintain good social order (Rhodes 1981, Cotterell 1992, Black 1997). After promulgation, enforcers are those who ensure law adherence. This chapter provides a general overview about regulatory enforcement by inspectors.

2.1 Enforcement, discretion and compliance

Enforcement is a way of social control with the ultimate goal of bringing compliance into effect to protect public safety (Rhodes 1981, Bardach and Kagan 1982). Enforcement can be carried out by various measures but generally there are two approaches, compliance and deterrence, both of which aim to prevent violations but differ in the means of securing that goal (Kelman 1981, Bardach and Kagan 1982, Hawkins and Thomas 1984, Cotterrell 1992). Firstly, the *compliance or rewarding approach* secures conformity with law by acting to prevent potential violations and remedy underlying problems without the necessity to detect and penalise violators. Giving incentives is the main strategy such as granting registration codes, licences or certificates. One example is the registration codes issued to pharmaceutical products that meet the specified standards, which allow them to be marketed. Secondly, in the *deterrence or punitive approach* law adherence is assured by penalising violators in order to deter violations in the future. Enforcement, thus, does not use only punishment or coercion to gain compliance. In fact, where violation is high, the use of the compliance approach in supplement to the deterrence approach is essential due to the limits of the deterrence approach (Packer 1968, Kelman 1981, Rhodes 1981, Kagan 1994).

However, within the deterrence approach, laws can be enforced differently. Generally, there are two styles or strategies: legalistic strategy or 'going by the book'¹ and flexible strategy ²

¹ All offences have the same priority. They are charged whenever detected with the sanctions provided by laws.

² Regulatory requirements and sanctions are applied flexibly depending on situations. Bargaining, persuasion or education is often used in place of legal actions.

(Bardach and Kagan 1982, Hutter 1986, Baldwin 1990). Both have advantages and disadvantages, and there has been no evidence showing which style works better (Hawkins and Thomas 1984, Aoki 2000, Kagan 2000).

There are a number of advantages in legalistic enforcement. First, it pursues one of the principles of enforcement, uniformity and sense of fairness (Baldwin 1990, Schwartz 1994). Decisions at both site-level or in prosecution process are easier and faster because they are based on standards specified in laws (Bardach and Kagan 1982). This ought to bring regulatory authorities efficiency. Second, highly experienced enforcers are not necessary and less training can be expected because judgements are made based on the rules. Regulatory authorities therefore do not have to pay high salaries or spend resources on training programmes (Rhodes 1981). Finally, regulatory authorities are less likely to be accused of being biased against the regulated (Bardach and Kagan 1982).

However, the fact that most laws are not perfect (see section 2.4) is one of major constraints against legalistic enforcement. In the case of imperfect laws, rigidly following the laws can produce resentment, legal resistance or increase political tension because of the close ties between business and politicians (Schwartz 1994). In addition, it can create an atmosphere that works against voluntary compliance, which is an important part of the enforcement system, or create greater inducements to corruption (Aoki 2000, Kagan 2000).

Resources have a major implication on deterrent enforcement as the job is labour-intensive (Anderson 1975, Baldwin 1990, Cotterrell 1992). First, lack of resources makes it impossible to inspect frequently enough to ensure that statutory requirements are being observed (Rhodes 1981). Second, laws often do not prioritise offences. However, the lack of resources, especially staff, is a driving force for regulatory authorities to prioritise seriousness of offence to gear their efforts towards the more serious ones (Bardach and Kagan 1982, Scholz 1994). It has been estimated that it takes three person-days per one prosecution to compile evidence and prepare cases to proceed for full prosecution (Baldwin 1995).

Consequently, flexible enforcement strategy is often the preferred approach (Rhodes 1981, Black 1998, Gunningham and Sinclair 1999, May and Winter 2000). It is argued that flexible enforcement by inspectors can be effective in bringing compliance, because inspectors possess authority which is a threat to the regulated (Rhodes 1981, Hawkins and Thomas 1984). Regulated businesses are not certain what enforcers can or will do, so most of them

are ready to co-operate (Rhodes 1981, Bardach and Kagan 1982). In most cases inspectors bargain for prompt correction of certain violations in return for dropping prosecution, which is generally perceived by inspectors as providing the same public protection but costing less in terms of time and resources spent on official prosecution processes (Hawkins and Thomas 1984, Kagan 1994).

Discretion³ is key to effective flexible enforcement (Hawkins and Thomas 1984, Davis 1996, Baldwin 1997). But there are positive and negative sides to discretion. Discretion provides power to officers and uncertainties to the regulated (Bardach and Kagan 1982, Baldwin 1997). This causes negative psychological effects to both the public and business as decisions are entirely dependent on officers, who may be biased, corrupted or influenced by powerful figures to be stricter or turn a blind eye to offences, leading to feelings of unfairness among the regulated (Bardach and Kagan 1982, Silveria 1997).

Despite these drawbacks, there are benefits. Discretion is *'perceived as a technical tool or instrument used when lack of factual data or technical knowledge, or on account of the unavailability of sufficient information on all the interests and assessment factors to be weighed'* (Silveria 1997; 51). It allows enforcers to play roles as bargainer, persuader, adviser, educator or negotiator along with the role of punisher, as fits the situation (Bardach and Kagan 1982, Baldwin 1990). With more flexibility, enforcers can better distinguish serious from non-serious violation and invest effort in the former (Bardach and Kagan 1982). This would increase enforcement efficiency.

Discretion can quickly curtail loopholes in regulations (Bardach and Kagan 1982, Aoki 2000). For example, in Kelman's (1981) study, when the relationship between increased noise and hearing loss had not been established, the US government set up a study to seek the answer and took a long time before establishing the fixed limit. In contrast, the Swedish government adopted a limit that was considered safe and gave discretion to inspectors to deal with the cases where noise was higher. In this way the Swedish government saved money and time and achieved the same result as the US.

Realising the problems and limits of the legalistic strategy, many regulatory authorities allow various forms of official discretion exercising by inspectors (Kelman 1981, Bardach and Kagan 1982, Scholz 1991); for example, giving discretion to judge the severity of offences

³ In this study 'discretion' means freedom of judgement not bound by regulations inspectors are enforcing. Options can be inspectors' own decisions or pre-specified by regulatory agencies.

and act accordingly, to issue a warning in cases considered not serious, to fine at an amount considered appropriate, to issue a warning with no further action unless remedial measures are not in place in the next inspection or on-the-spot agreement on corrective actions.

An effective management system should be able to check and prevent the misuse of discretion by using methods such as re-inspection, rotation, establishing special complaints channels, continuous training and discussion programmes, monitoring personal prosecution records, repeated stress on the organisation's purpose or through third party participation (Kelman 1981, Bardach and Kagan 1982). Openness of regulatory authorities, which includes availability of reasons or information on decisions or how laws are considered or interpreted, is another key way to maximise the appropriate use of discretion and demonstrate justice to the public (Silveria 1997). Nevertheless, the effective use of discretion requires enforcers' capacity to be reasonable, technically competent, possess good communication skills and good judgement (Bardach and Kagan 1982).

Given the advantages and disadvantages of each enforcement approach and strategies including limits of punishment in changing behaviours, empirical studies suggested that '*a mix of strategies*' according to the situation would be most effective (Katz and Kahn 1978, Braithwaite et al 1987, Scholz 1991, Kagan 1994, Gunningham and Sinclair 1999). The mixed strategy conveys the meaning of using bargaining, compromising, negotiating, persuading, rewarding, and educating techniques to bring compliance in addition to punishment strategy (Braithwaite et al 1987, Baldwin 1990, Scholz 1991). Meanwhile, other conditions are simultaneously and actively required to promote effective enforcement. For example, punishment should be timely, the possibility for arrest must be high, the desired behaviour is known and understood, and offenders are a minority (Elliot 1992, Cotterrell 1992, Scholz 1994, Suriyawongpaisal 1996). A combined package comprising criminal and administrative sanctions as well as the simultaneous use of positive with negative sanctions is suggested as essential for success (Baldwin 1990, Cotterrell 1992). In terms of the behavioural aspect, negative sanctions are not sustainable unless they are accompanied by rewards (Bandura 1969). Consequently, having effective enforcement is complicated.

The constraints of using only enforcers to obtain compliance are recognised. The approaches of enforcement itself have changed over time towards including participation from other parts of society in the cycle of enforcement in order to better tackle the cause of violation not the violations per se (Cotterrell 1992, Klausner 1997, Braithwaite 2000, Hutter

2001). Given the different motivations for law-breaking behaviour, various types of measures are necessary for better compliance (La Fave 1962b, Bardach and Kagan 1982).

Examples of broad participation include the concepts of self-regulation and empowering communities such as school, communities, workplaces or families (Bardach and Kagan 1982, McGary 1996). The police, for example, use community relations as an essential element of effective crime control (Kleinig 1997). Studies in the US and UK also suggest close links between the capacity of state agencies to enforce the law and the willingness of citizens to play a role, as essential for effective enforcement (Blackie 1970, Cranston 1979, Hutter 1986, Cotterrell 1992, Morgan 1997).

Sensitising the public about the health rationale or socio-economic justifications underlying the laws could bring congruency to behaviours that are not conforming to existing laws (Klausner 1997). Education is, thus, one measure used to alter deep-rooted problems, which enforcement alone may fail to do. The US alcohol prohibition in 1920-1930 is a good example where the number of convictions rose six times but there was no change in consumption (Cotterrell 1992; 55). Raising awareness of self-protection through health promotion activities or having special channels for consumer complaints are also used to create public pressure on the regulated (Scholz 1991, Schwartz 1994).

Expanding citizen-group rights to participate in regulatory policy-making process is another way to break up informal relationships between regulators and regulated (Bardach and Kagan 1982). Making the enforcement process more visible, and accountable to monitoring and influence by advocacy groups and individual complainants, can also strengthen enforcement (Bardach and Kagan 1982).

2.2 Inspectors and their implementation of regulations

Crime is divided broadly into two types (Sutherland 1949, Cotterrell 1992): first, real crime, which is dealt with by the police who usually use criminal sanctions as their punishment tools; and second, white-collar crime or technical crime, in which victims usually cannot clearly recognise the hazards and which is committed by a person of respectability and high social status in the course of his/her occupation. Violations in the area of medicinal drugs are good examples of 'white-collar' crime. Clients would not normally know whether the drugs they are consuming are of good quality or dispensed to them correctly or rationally. Negative consequences are seldom identified, especially at the time violation is committed.

Regulatory authorities that deal with technical crime are usually separate from the police. They have various punishments ranging from using administrative sanctions, such as giving notice requiring compliance with the law, using court enforceable orders, to actual prosecution (Cotterrell 1992). The administrative measures usually affect the productivity of the sanctioned business, by suspension or revocation of licence, product recall, issuing improvement or prohibition notices, or public advertisements (Rhodes 1981).

Regulatory authorities have their enforcers known as inspectors. Inspectors work in private places where the police would not normally go (Rhodes 1981, Bardach and Kagan 1982, Hawkins and Thomas 1984). Examples of inspectors' work areas include occupational health and safety; teaching; pollution generated by factories; medicinal drugs manufactured, distributed and sold; food safety; transportation; building; nursing home and so on. Each of these requires different kinds of expertise, for example engineers, pharmacists, teachers, managers, health personnel or food scientists. Inspectors can be called an enforcement arm of the regulatory authorities. They are equipped with authority to enter private property, examine and copy books and records, take samples, and interrogate executives and workers in order to uncover evidence of non-compliance with the law.

Although possessing authority to monitor law adherence, inspectors do not work like police. Most inspectors have specialised knowledge related to the areas they are enforcing, in which they are assigned roles other than merely detecting crime for prosecution (Blackie 1970, Kelman 1981, Rhodes 1981, Bardach and Kagan 1982). Many studies suggest that inspectors should be flexible, use discretion as central to sound professional decisions, and have wider promotional and advisory roles in seeking compliance and furthering the underlying purposes of the legislation rather than being bound by rules (Schuck 1972, Rhodes 1981, Bardach and Kagan 1982, Kleinig 1997).

Inspectors are viewed as a bridging mechanism between legislative intention and the realities in order to minimise drawbacks which laws or enforcement processes may possess (Rhodes 1981, Bardach and Kagan 1982, Hawkins and Thomas 1984). Their discretion is expected to decrease enforcement limitations or constraints due to the lack of staff and resources (Kadish and Kadish 1973, Anderson 1975, Lloyd-Bostock 1987). In many instances they can variably deal with offences detected by issuing prosecutions on infringements to issuing verbal warning (Rhodes 1981, Hawkins and Thomas 1984).

To pursue their mixed role effectively, inspectors' capabilities are essential, as Blackie (1970; 71) has said '*the quality of the inspector cannot be too high*'. They initiate decisions, interpret regulations, make on-the-spot assessment, decide how to proceed with breaches detected and act on behalf of organisations they work with (Rhodes 1981, Hawkins and Thomas 1984, Black 1997). Their technical knowledge is important to ensure they can detect problems and provide advice (Rhodes 1981, Bardach and Kagan 1982, Cotterrell 1992). Their experience is likewise indispensable. Together, their knowledge and experience enable inspectors to make independent decisions; otherwise they would need to depend upon information provided by the business. It also helps inspectors to spot problems, understand and think through the problems, see through unjustified excuses, make decisions intelligently and elicit co-operation by giving useful advice (Bardach and Kagan 1982).

In many countries, recruitment of inspectors is based on experience, personality and attitude (Blackie 1970, Kelman 1981). The job is generally competitive and considered prestigious, with a high salary (Blackie 1970). The the US pharmacy inspector's minimum salary is set at the same level as the pharmacy manager (personal communication). Given the fact that inspectors are the professionals with first-hand experience in the field, they are always perceived as a major component in the enforcement system. High participation in policy making to provide their field experience is recognised as important (Rhodes 1981). Inspectors in many regulatory authorities are pioneers in reform or consultants to Ministers (Blackie 1970).

Despite being a professional job, inspection can be daunting. Inspectors work in the field, make decisions in face-to-face contact, and sometimes are directly exposed to offenders' reactions of outrage, pleas of mercy, and on occasion, threats or bribes (Hawkins and Thomas 1984). The confrontational environment and risky nature of the job can demotivate inspectors (Fincham and Rhodes 1999).

Studies suggest that enforcing regulation in the field is not as simple as it is written in law; there is an obvious paradox between the power given by statute and the use of those powers. Inspectors seem to be saying that it is neither desirable nor practicable to perform legalistic enforcement and use those powers except as a last resort; that flexible enforcement is likely to be the first-choice (Rhodes 1981, Cotterrell 1992, Baldwin 1995, Black 1995). They indicate that flexible enforcement enables them to cope better with the variety of situations in the field, to get their job done effectively with less conflict than the legalistic approach (Bardach and Kagan 1982, Gunningham and Sinclair 1999, May and

Winter 2000). Inspectors take many components into consideration before making decisions (Rhodes 1981, Hawkins 1984, May and Winter 2000).

Inspectors often claim that they are closest to the real situation, and given their professional background, they should not be slavish followers of regulations and administrative procedures, which are not responsive to the real situation (Allsop and Mulcahy 1996, Kleinig 1997). Consequently, in the field, inspectors commonly utilise a number of enforcement techniques rather than the heavy-hand of the law (Rhodes 1981, Baldwin 1990, May and Winter 2000). Dropping prosecutions for minor violations in return for prompt remedial action on more serious ones, though officially not permitted, is often found (Bardach and Kagan 1982).

The fact of having high qualifications and professional background may mean inspectors themselves prefer to use their education and professional skills in judgements, rather than acting to police those inspected (Rhodes 1981). These views and attitudes inspectors possess may make them try to ensure that licensees fully understand and fulfil their responsibilities under regulations before taking any legal action. Compromising would be a way to resolve conflicting interests, or they may prefer using negotiation to correct a problem (Hawkins and Thomas 1984). Flexible enforcement techniques are sometimes useful to get 'inside' information to trace back or further investigate serious cases (Bardach and Kagan 1982).

In the field, with a mixture of 'bad and good apples', inspectors tend to assess each offender independently as they realise that the regulated are different in capacity and intention to comply with law (Bardach and Kagan 1982, May and Winter 2000). Harm and risk caused by violation form a main factor taken into consideration before making a decision, in conjunction with other factors (Kadish and Kadish 1973, Rhodes 1981, Benson 2001). There are continuums of actions ranging from 'professionals talk to professionals' to heavy-handed actions depending on the situation (Braithwaite et al 1987, Baldwin 1990). Coercion or use of inspector's authority is likely to apply to those 'bad apples' who tend to be problematic or difficult to deal with (Baldwin 1990, Black 1998). Where improvement on the legal standards of performance is wanted, the advisory strategy is likely to be adopted; but advice tends to be confined to areas where compliance is considered unproblematic, where risks are low or where it is thought that formal legal enforcement is not feasible (Baldwin 1990).

Threat of punishment is viewed by inspectors as ineffective, especially in the case of widespread offences where inspectors would never inspect frequently enough to provide adequate deterrence (Katz and Kahn 1978). Prosecution is often undertaken after a second visit and where '*serious irregularities*' are found (Kagan 1994).

Inspectors are often inclined to patience and sympathetic consideration of the difficulties of those inspected, with sanctions remaining very much in the background (Rhodes 1981, May and Burby 1998). Inspectors' sympathetic attitudes on the regulated are sometimes suspected by the public to be because inspectors identify themselves too close to the regulated, or because they may expect to work with the regulated in the future (Kelman 1981, Bardach and Kagan 1982, Schwartz 1994). In order to prevent this allegation, some regulatory authorities regularly provide or remind inspectors of the worst cases so that the inspectors' knowledge of possible risks is broadened, whilst at the same time boosting their morale and motivation (Bardach and Kagan 1982).

In general, inspectors seem inclined to use their professional expertise and experience in flexible ways due to their perceptions on their roles and their jobs as mentioned earlier. Nevertheless, they are influenced by the context within which they work, the laws that direct their work, and the characteristics of the agency that employs them. These factors all affect the way inspectors implement regulations and how they use their authority.

2.3 Contextual factors

Independence of regulatory agencies is essential to inspection work but hardly exists (Blackie 1970, Anderson 1975). They fall between consumer protection and business and political pressure. Often, it is difficult for the agencies to work independently and this is true in both developed and developing countries (Dukes 1985, Cotterrell 1992, Kiatying – Angsulee 2000). Economically powerful actors (especially large business enterprises) have much greater control over the manner in which law is enforced than do other actors (Cotterrell 1992), because they are capable of arranging organised pressures or can sue regulatory authorities while consumers are seldom able to (Anderson 1975). In the US for example, businesses have exerted influence over the Congress in postponing or overriding state agencies' efforts in important areas such as pollution, food safety and pesticide safety (Dempsey 1994). The private-public co-operation, a strategy employed by many regulatory authorities, is another way that allows business to influence regulatory authorities' decisions through advisory groups or working groups (Anderson 1975, Jasanoff 1994).

A regulatory agency's enforcement style can be pressurised by politicians who may be influenced by businessmen. The aims and objectives sometimes change in accordance with policies from top-level executives leading to changes in enforcement practices (Blackie 1970, Rhodes 1981, Bardach and Kagan 1982, Cotterrell 1992). For example, when the US Congress criticised the Occupational Safety and Health Administration of being too relaxed, serious violation cases jumped from 2% of the total violation to 6% (Kelman 1981). Afterwards, with the new President, the organisation was claimed to be 'overregulated' (Kelman 1981).

Even in countries with relatively similar traditions, there can be marked differences in regulatory policies, because of varying national situations and the differing pressures exerted on policy makers (Dukes 1985). A number of studies (Cotterrell 1992, Dempsey 1994, Kagan 2000) conclude that business pressures have usually been extremely successful in limiting the scope of legal control, or the effectiveness with which control can be exercised. As these pressures affect managers' decisions, they would unavoidably affect inspectors' decisions in order to comply with their managers (Kelman 1981).

Public interest and social pressure, either for or against enforcement practice, is vital to regulatory authorities, which are usually politically sensitive. Positively they can counteract business pressure, such as in the case of non-governmental organisations countering the pharmaceutical business in South Africa to bring HIV drug prices down. Hawkins and Thomas (1984) illustrate that drunk driving enforcement was better achieved only when attitudes of the public changed through campaigns about loss of life from drunk driving and have led to greater social acceptance on drunk driving enforcement.

Criticisms, complaints or dissatisfaction with the result of inspection are obvious possible influences on an inspector's choice of methods (Rhodes 1981). The absence of effective and critical public opinion may result in failure to enforce the law especially when enforcement goals and objectives are largely set by inspectors themselves; or when inspectors are pursuing their own interests in reaching an accommodation with those they are set up to enforce, rather than acting in the public's interest (Lipsky 1980, Rhodes 1981, Hudson 1997).

2.4 Good laws

Laws are central to enforcement, and enforcement failure may result from inappropriate laws, which cause conflicts in enforcing regulation in the field (Baldwin 1990, Black 1995). Good laws must not appear utopian but practical, reasonable and responsive (Anderson 1975, Bardach and Kagan 1982, Cotterrell 1992, Elliot 1992). Nevertheless, most laws are imperfect; and making good laws has not been a major focus of attention in bureaucracies (Black 1995).

Laws must be designed to have compatibility and continuity with the established cultural principles (Anderson 1975, Klausner 1997). However, occasionally laws are contradictory to customary behaviour, which results in non-compliance (Kerwin 1994). This is a real problem in developing countries, which adopt western laws, which frequently conflict with customary behaviour based on traditional beliefs and economic pressures (Klausner 1997). Exemptions, if predictable, should be provided. For example, the UK Medicine Act 1968 provides a section called 'Emergency Supplies' allowing prescription drugs to be sold by a pharmacist without prescriptions if the specified criteria are met.

Laws should demonstrate a certain degree of specificity. Theoretically, the deterrent effects of law should vary considerably from one kind of offence to another according to the seriousness of the offence, but to establish them appropriately is problematic (Rhodes 1981, Cotterrell 1992, Black 1995). Field enforcers see difficulties in applying one set of rules across-the-board where offenders can violate laws in different degree (Baldwin 1990). Flexibility at site-level can erode sanction effects of regulations (Bardach and Kagan 1982). Inspectors who try to avoid unreasonableness may be accused of 'taking the law into their own hands', of favouritism toward a particular enterprise, or of jeopardising the health and safety of innocent persons (Bardach and Kagan 1982; 204).

The nature of law is anticipatory, so limitations of foresight are inevitable (Black 1998). The fact that laws are mostly in the hands of regulatory officers, who do not usually have experience in the field, makes laws sometimes either too broad (over-inclusive) or too narrow (under-inclusive); and they often aim at the worst case scenario (Cotterrell 1992, Kerwin 1994, Maccormick 1996, Black 1998). Empirical studies indicate that laws tend to be over-protective, especially laws that involve specific expertise where professional ideology is brought into the process by experts with the patronising sense of 'mother knows best' (Kelman 1981). A study about meat packaging regulations found that if regulations were

strictly enforced, no meat processor could remain open (Schuck 1972). Laws that are too strict possibly cause adverse effects such as an enforcer's reluctance to enforce them, corruption and bargaining (Kelman 1981, Kagan 1994).

Lawmakers are usually compelled by political pressure to make the law approved within the shortest time possible (Bardach and Kagan 1982, Black 1995). Time constraints and complexity of problems can result in lack of thorough responses from both the regulated and the regulators. Laws subsequently are defective, resulting in unreasonableness and unresponsiveness to the real situation (Bardach and Kagan 1982, Black 1997); leading to conflict with enforcers.

The impact of technical crime is often not easily seen at the time of conduct. Evidence or information from the field and causal relations on hazards are often inadequate, especially in drug regulations where decisions are usually based on texts or logic-based evidence (Bardach and Kagan 1982, Dukes 1985). One good example can be seen in the medicinal drug field where legalised drugs are withdrawn because of hazardous effects found after approval (Abraham 1995). These weaknesses cause inspectors difficulties in imposing harsh enforcement; but on the contrary, executives often demand rules that are more stringent with heavier sanctions as a sign to show their sense of responsibility (Bardach and Kagan 1982).

The clarity or predictability of harm caused by offences affects an inspector's decisions. Unfortunately, the harm caused by white-collar crime is not always clear; and accordingly there are problems in assessing the seriousness of offences to match with sanctions in the judicial system (Walker 1997, Francis et al 2001). Enforcement approaches are, thus, mainly determined by inspectors' subjective assessment of the type of hazard at issue (Baldwin 1990). Minor hazards or risks tend to prompt a less legalistic, less confrontational approach on the part of inspectors (Baldwin 1990). Conversely, in the case of major or serious hazards inspectors are more inclined to demand strict compliance, give direct threats of notices or prosecutions. Problematic hazard, hazards where possibilities and probabilities are not explicit, difficult to measure, define or decide what is a safer way, are often subject to a genuine process of persuasion and negotiation (Baldwin 1990).

The unclear harm or risk does not affect inspectors only. Courts are usually reluctant to punish 'white-collar' crime, especially by imprisonment, as the impact of the violations is often diffuse and complex compared to real crime such as manslaughter, rape or murder, especially when offenders are usually legitimate, socially useful enterprise (Sutherland 1949,

Benson 2001). Court decisions usually discourage inspectors from using their authority because judges frequently impose penalties that inspectors feel do not reflect the seriousness of the offence (Bardach and Kagan 1982). Besides, the courts often criticise inspectors' cases as not serious enough to bring to court where they are already overwhelmed (Rhodes 1981).

Laws should be designed for easy prosecution process (Baldwin 1990). There are many punishment measures to reduce court involvement, save resources and speed the prosecution process other than using only criminal sanctions, such as the use of disciplinary sanctions, adjudication or other administrative measures (Scholz 1991, Black 1995). Many regulatory authorities are allowed to use adjudication within the organisations, for example, the Statutory Committee of the Royal Pharmaceutical Society of Great Britain, which is empowered by the Pharmacy Act 1954 in respect of pharmacists, and also has powers under the UK Medicine Act 1968 in respect of registered pharmacy business.

The legislative process is as important as the aforementioned good characteristics of laws. Anticipation or identification of enforcement strategies or enforcement models along with the legislative process is important for effectively enforcing laws (Baldwin 1990, Cotterrell 1992), the same as it is in policy process (Pressman and Widalsky 1973, Walt 1994, 1998). Interaction among policy-makers, lawmakers, inspectors and other parties concerned should take place at the beginning of formulation such as in the form of consultation (Hogwood and Gunn 1984). Decisions in rulemaking, which are not centrally focused on how to make them operate effectively, make inspectors work in sharp contradiction among the existence of strong penal powers, and the practical preference of the use of persuasion and advice in the achievement of aims; and finally would end up in conflicts.

2.5 Working styles of regulatory authorities

Working styles of regulatory authorities can vary depending on their aims and objectives. The change in enforcement philosophy (mentioned in section 2.1) would expand an organisation's functions from limited prosecution functions to cover non-inspecting kinds such as education. The broader and more complex aims other than enforcing the laws may raise problems in interpreting the enforcer's roles and how the authority should be implemented, and coercive enforcement strategy may be undermined, all of which affect an inspector's job performance (Rhodes 1981). Regulatory organisations are affected by external factors, namely culture, business influences, political pressures or government

policies, resulting in changes of working styles as demonstrated in section 2.3. Consequently, working styles can shift over time.

Agency culture or working style is important to how enforcement is carried out (Kagan 1994, May and Burby 1998, Gunningham and Sinclair 1999). This is because the agency's aims or intentions are reflected in their administration process, behind the approaches used, the organisation's instruction to inspectors and how far the responsibility of inspectors extends for the maintenance and improvement of standards (Rhodes 1981, Cotterrell 1992). For example, in 1982 the UK Lord Robens's Report of the Committee on Safety and Health at the Work Place guided the direction for inspection that, '*The provision of advice and assistance towards progressively better (safety) standard is the basic function of inspection service*' (Rhodes 1981; 179). In this case, the management system and inspector's decisions would be geared towards advisory enforcement rather than punitive enforcement. Consequently, the gap between inspectors' practices and the organisation's expectation is reduced.

Inspectors come from different backgrounds and may have different aims or expectations regarding their job (Rhodes 1981, Baldwin 1990). These differences could drive inspectors to make different judgements from being coercive to accommodative (Rhodes 1981, Hawkins 1984, Baldwin 1990, Gunningham and Sinclair 1999, May and Winter 2000). Difficulties in enforcing laws arise when an inspector's personal aims do not fit with those of their organisation (Rhodes 1981). A clear working style would help in setting clear roles for inspectors so that they can perform in accordance to the organisation's aims or objectives (May and Burby 1998, May and Winter 2000).

A clear working style is also essential in giving direction to inspector training programmes, which will be streamlined towards the roles expected by the organisations. Enforcement can be carried out in many forms, so inspectors' roles can be that of many as well such as experts, advisers, lawyers or architects (Rhodes 1981). Fincham and Rhodes (1999; 43) see the importance of training as, '*to make clear what roles they are expecting to perform?*'. Role ambiguity is perceived as a threat to organisations as it creates stress and reduces organisational commitment, job involvement and job satisfaction (Handy 1999). Officers who are stressed in performing their jobs tend to not thinking beyond the immediate decisions, being unbothered by the discrepancy between what they are supposed to do and what they actually do, and make decisions without seeking out or considering relevant information

(Hudson 1997, Kanz and Kahn 1978). Inspectors whose roles are clear have less stress than inspectors who have mixed roles (Bardach and Kagan 1982).

Despite specificity of standards, different inspectors may see different things and evaluate or interpret the relative seriousness of a particular offence in different ways (Bardach and Kagan 1982); and there are also conflicts of interest in deciding whether a statutory requirement is being observed (Rhodes 1981). The differences regarding these judgements mostly depend on inspectors' views and attitudes (Rhodes 1981, Cotterell 1992). Training is, thus, a way to infuse a sense of mission and to balance officers' personal feelings, thoughts and behaviour with the organisation's goals and expectations (Kelman 1981, Fincham and Rhodes 1999). In a situation of imperfect correlation between regulatory requirement and actual hazards, lack of proper training could lead inspectors to make non-standardised decisions – being based mainly on their own attitudes. Many regulatory authorities spend more than one year on their training programmes to attune inspector's views and attitudes to comply with the organisation's working style (Kelman 1981, Lloyd-Bostock 1987).

Inspectors work out of sight of their managers. Monitoring is, hence, an important part of the inspection system to minimise laxity that possibly occurs, especially in situations where violation is rampant, as well as to prevent authority misuse (Scholz 1991). However, it is difficult to have an optimum monitoring system due to the lack of staff and evaluation criteria (Hudson 1997). Number of premises inspected provides evidence of activity, but not how effective the activity is (Hawkins and Thomas 1984). For example, inspectors may note only no-problem cases, and ignore those that violate the law, as they are more difficult to deal with and take longer. Likewise, if evaluation is aimed at number of offences detected, inspectors would show their efficiency by dealing more with easy cases or cases with greatest probability to be amended rapidly, and ignoring or overlooking the less obvious or complicated cases that could cause greater harm (Hawkins and Thomas 1984).

Lack of staff makes joint or re-inspection difficult. In the medicinal drug field where inspectors are understaffed, capable and experienced drug regulators have often been induced to accept senior positions with the pharmaceutical industry, apparently at substantially higher salaries (Dukes 1985). Many regulatory authorities use the form of supervision, in place of evaluation with the functions of monitoring and inducement, through inspection reports (Kelman 1981, Scholz 1991), for example, comparing inspectors' citation percentages, average penalty, number of inspections with serious violation, number of warnings or number of written inspection notices. It is suggested that the enforcement process should be

reviewed by outside agencies to increase the credibility of regulatory authorities (Bardach and Kagan 1982).

In bureaucracy the tall hierarchy and centralised administration creates top management conflict or misunderstanding with operative works, like field inspection work (Collins 1994, Morgan 1997). The tall hierarchy also leads to a greater possibility that information is filtered or distorted, and communication blocked (Collins 1994). Hierarchy can also adversely affect the free flow of ideas and information in an organisation, because subordinates may hesitate to advance proposals they think may run counter to 'official' policy or antagonise their superiors (Anderson 1975). Conflict regarding inspectors' decisions arises when hazards found in the field do not follow theories, which the laws usually are based on. A managerial system that supports systemic exploration of the views of field-level inspectors would help legitimise decisions made in headquarter offices thus would decrease the clash between theory and experience. However, that kind of climate does not frequently exist (Morgan 1997).

Inspection is a job involving professional judgement and a certain degree of discretion, which needs flexibility and responsiveness. These requirements conflict with the nature of the bureaucratic system where a number of regulatory authorities belong. This bureaucratic system is rule-bound, which does not allow responsiveness. This could cause conflict with inspectors who always legitimise their decisions with the back up of professional judgement (Friedson 1994, Morgan 1997). It would benefit the public if the authorities can move their administration towards '*technocracy*' which is defined as 'rules are exercised through uses of knowledge, expert power and the ability to solve relevant problems' (Morgan 1997; 157).

2.6 Summary

This chapter indicates that the enforcement continuum is broad with various use of techniques including incentives, bargaining, persuasion, education and coercion. Enforcement philosophy has changed over time. Instead of relying solely on enforcers, all parties concerned are involved in enforcement cycles. Recently innovative strategies such as self-regulation and community-based strategies are used in conjunction with punitive enforcement to achieve better compliance.

Enforcers are one of many mechanisms to minimise crime. Inspectors deal with technical crime, which requires special knowledge relevant to the field they are dealing with. Imperfect

laws, inspectors' professional background, and administrative problems collectively drive regulatory authorities to grant inspectors discretion, hoping to lessen the drawbacks and promote objectives of laws instead of merely punishing offenders. The professional background and experience of inspectors are perceived as important features in their making sound and intelligent decisions.

With limitations to each enforcement approach and style, a mixed strategy is perceived as the most effective. Most regulatory agencies are identified with the preference use of bargaining, persuasion, and advice giving, affecting the ways inspectors perform in the field. By using discretion, efforts can be geared towards more serious violations, administration can be more cost-effective without unnecessary cases being put through the time-consuming prosecution process. Management strategies, such as increasing openness or transparency, rotation system or re-inspection, are among measures to counterbalance discretion abuse.

Inspectors also argue for discretion as the persons closest to the real situation, and as professional workers who should be free at some level to make the best professional decisions for the public benefit. In their work, authority is preferably used as a last resort.

Chapter 3 - Research Methods

The previous chapters indicated that only having regulations could not guarantee effective enforcement. This chapter elaborates on the framework used in this study to explore inspectors' roles in the regulation of private pharmacies, and methods to acquire and analyse the data collected.

3.1 Main objective

To identify the underlying reasons preventing the TFDA inspectors using their legal authority¹ in pharmacy inspection.

3.1.1 Specific objectives

1. To study the regulations and the codes of practice used in pharmacy inspection in terms of content, inspectors' authority, sanctions and prosecution processes; and to compare these with what actually happens.
2. To contrast the official management system for managing inspectors and the inspection process with what actually happens.
3. To explore inspectors' views and attitudes towards the regulations and the management process.

3.2 Study framework

The discipline of policy analysis was adopted in this study in view of the fact that regulations are one form of policy – statements by organisations showing their functions and responsibilities to the public while imposing restrictions on the behaviour of individuals or groups (Lowi 1964, Anderson 1975, Cotterrell 1992, Black 1995, 1997). Policy analysis is useful because it focuses on the dynamics of process within organisations, exploring four phases of policy cycle; problem identification and issues recognition, policy formulation,

¹ Authority given to inspectors to enter licensed pharmacies and premises selling drugs to check law compliance as well as to collect, seize or detain suspected products for the purpose of prosecution issued by the Drug Act 1967.

policy implementation and policy evaluation (Walt 1994). This study sets out to explore inspection, one instrument by which government seeks to ensure the implementation of policy. The aim – identifying why inspectors do not use their legal authority – is to explore the policy gap between intent and implementation, focusing on actors – the inspectors.

There are a number of policy analysis approaches, but few related specifically to implementation (Hogwood and Gunn 1984, Walt 1994, Altenstetter and Bjorkman 1998). They can be roughly categorised into two approaches: the 'top-down' and the 'bottom-up' (Sabatier 1986, Lane 1987, Walt 1994).

The top-down approach is linear, normative and prescriptive, and starts with a policy decision at central level which is passed down for execution at lower levels. Implementation is judged by the extent to which legally mandated objectives are achieved over time (Sabatier 1986). Although it seems to fit the TFDA administration, there are a number of drawbacks to this approach. The linearity of the model is not compatible with the implementation, which is interactive (Grindle and Thomas 1991, Walt 1994, 1998). The model lacks a dynamic characteristic and so cannot provide a good analysis of policy change (Sabatier 1986). The conditions themselves are subjective and may be interpreted differently (Lane 1987). Finally, the top-down approach hardly focuses on the actors, especially those who are implementors – assuming that those who execute policy do not exercise any control or discretion over policy.

The top-down model is clearly criticised by Hogwood and Gunn (1984), who propose ten preconditions for perfect implementation as part of this prescriptive 'ideal' model. It is meant to be an instrument to help analysis of why perfect implementation is unattainable, and is based on the concept of authority – hierarchy, obedience, control and perfect co-ordination (Lane 1987). Hongsamoot (2000) tested this model to explore TFDA implementation, and found none of the conditions for perfect implementation was met. That is, contextual factors affected TFDA's functioning, resources were constrained, there was no agreement on policy objectives and so on. This suggests that the top-down model is idealistic, and prescriptive, but not useful in explaining why policies are not executed as intended.

The bottom-up model, on the other hand, is less explicit about the factors involved in implementation compared to the top-down approach (Sabatier 1986) and does not see the policy process as linear. Implementation is viewed as involving actors in the process of negotiation, bargaining and exchange rather than the imposition of authority alone (Lane

1987). The model views implementors as active participants in the implementation process (Hjern and Porter 1981, Walt 1994). It starts by identifying the network of actors involved in service delivery to detect those involved in the various levels of policy-making, and assumes differences in goals, strategies and activities used in implementing policies (Sabatier 1986). The strength in focusing on the perception of actors brings the main disadvantage to this approach. Important or interesting issues can be excluded if actors cannot recognise those factors, and hence cannot reflect on them (Sabatier 1986).

For this study, a broader approach to implementation was taken, in order to overcome some of the weaknesses of the top-down and bottom-up approaches. Walt and Gilson (1994) propose a broad policy analysis framework that focuses on the interdependence and interaction of four factors - content, context, actor and process (see Figure 3.1). The last three dimensions, which are often neglected by other approaches, are viewed as possibly making the difference between effective and ineffective implementation (Walt and Gilson 1994, Rathwell 1998, Walt 1998). Process is particularly emphasised as an important element '*providing understanding why the desired policy outcomes fail to emerge*' (Walt and Gilson 1994: 354). Their framework allows the exploration of interrelationship between actors, context, process and content, to explain why there may be a gap between policy intent and implementation (Rathwell 1998, Walt 1998, Mayhew 1999, Kiatying-Angsulee 2000). It provides a way of analysing policy implementation as an interactive and ongoing process of decision-making rather than a linear one (Walt and Gilson 1994, Walt 1998).

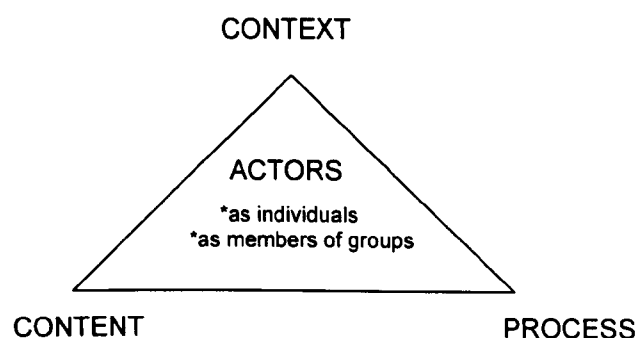


Figure 3.1: Walt and Gilson's framework for policy analysis

Source: Walt and Gilson, 1994; 354

The advantage of Walt and Gilson's approach is that it encourages analysis based on the interaction between the four different dimensions, with actors firmly in the centre. Actors are seen as a broad group – ranging from individuals to organisations. In pharmaceutical policy,

actors include various groups such as drug sellers, clients, lawmakers, experts or advisory groups in the law making process, regulators, the pharmaceutical business, interest groups, and the media. For this study, it was decided to focus on inspectors because it is they who initiate decisions on whether to use their legal authority or professional knowledge implementing TFDA rules and regulations. Although it might have been useful to explore the attitudes of pharmacy owners and pharmacists to inspectors and their use of authority, after due consideration this was dropped. First, as the researcher is an inspector, the reliability of interviews would be questionable especially in the Thai hierarchical society. Second is the problem of representative selection from 3,611 pharmacies and time limitation. Third, due to the lack of information and research in this area, the time required to prepare and pilot questionnaires is expected to be longer.

Personal attitude is found to profoundly influence decision-making (Ajzen and Fishbein 1980, Fincham and Rhodes 1999). A study of Thai community pharmacists shows that their personal attitudes have more effect in determining their dispensing behaviour than social influence (Plianbangchang 1999). The TFDA inspectors' pharmacy background is likely to affect their decisions; and understanding actors and their attitudes is important if implementation is to be improved. In this study, the inspectors' views and attitudes regarding pharmacy enforcement were explored including issues such as use of authority, job satisfaction and attitudes to the regulations they were enforcing. Concepts in criminology were also used to explain their decision, for example the principle of proportionality (Bagaric 2001).

Organisations do not work in a vacuum but are usually bound by their context or their environment (Walt 1994, Barker 1996) which varies over time. Context can mean structural, economical, political, historical or cultural factors; and can be at national or international level (Walt 1994, 1998, Grindle and Thomas 1991, Collins 1994). Context affects organisations in many ways, and others have shown that organisations' administration is controlled, designed and shaped in relation to its context (Pfeffer and Salancik 1990). Actors are influenced by the context surrounding them in both personal and work lives (Walt and Gilson 1994). In this study, two particular contextual factors were relevant to the TFDA enforcement in pharmacy: political influence and cultural influence.

Political context is a powerful factor that cannot be isolated from any organisations (Minogue 1983, Grindle and Thomas 1991, Walt 1994, Jacobson and Wasserman 1999). Thailand, since the absolute monarchy was abolished in 1932, has not had radical change in terms of

political ideology. This may be because no government has lasted long enough to initiate major change; the average life of a government is 16 months, or 6 months if the longer-lived army-backed regimes are removed (Economist 2002). Changes in government do not appear to have greatly affected the TFDA (the 6th and 7th Consumer Protection Programme Evaluation 1996, Kiatying-Angsulee 2000), although such changes appear to have more impact in developed countries, especially in relation to big business (Schwartz 1994, Jacobson and Wasserman 1999). What impact changes of government might have had in Thailand are probably reflected largely in appointment of executive levels where positions change frequently. Political impact, in this study, was explored through inspectors' perceptions.

Within the political context, the influence of business was also included, although it was extremely difficult to assess. Regulatory authorities are caught between business and consumers; and are often pressurised by business through the political system as indicated in chapter 2. In Thailand, business influence has become more powerful in the public sector through connection with politicians (Green 2000, Economist 2002). The influence of industry was explored in this study by asking inspectors how it affected inspection.

Cultural factors are argued to be an important factor pervading the policy environment, and influencing policy-makers' perceptions and political environment (Grindle and Thomas 1991, Walt and Gilson 1994). Thai national social values were of interest in this study due to their uniqueness. The Thai are known for their politeness, hospitality, hierarchy and conflict avoidance (Klausner 1997, Kiatying-Angsulee 2000). These characteristics nurture a patronage system and are likely to be contradictory to strict enforcement. Besides, in general, some claim that in Thailand there is generally lax conformity with rules or regulations, and that rule bending is often found (Klausner 1997, Kiatying-Angsulee 2000, Economist 2002).

Policy content has usually been the focus for policy analysis (Hogwood and Gunn 1984, Sabatier 1986, Walt 1994). In this research, the Thai Drug Act 1967 represented policy content. From the literature review, it is clear that inappropriate laws can harm effective enforcement, but designing good laws is difficult. The lengthy and formal legislative process itself creates limitations to have responsive and reasonable laws. Although there are no fixed rules of what constitute good laws, there are certain characteristics of law that could hinder effective enforcement. The Drug Act 1967, including the TFDA legislative process, was explored to find characteristics facilitating or hindering enforcement.

Finally, the central concern here was with the process of implementation. It is often found that policies are distorted after formulation during the process of implementation (Lipsky 1980, Sabatier 1986, Grindle and Thomas 1991, Jacobson and Wasserman 1999). The process or strategy is argued to be important for the success of implementation because it is the process that puts intent into action (Walt 1994, Jacobson and Wasserman 1999). The processes involved in this research aimed at the TFDA enforcement management process – how the TFDA enforcement process worked including how the Act was implemented and inspection undertaken. The official was contrasted with the actual process to discover constraints preventing inspectors from fully using their legal authority.

By using Walt and Gilson's framework in this study, the analysis covered organisational, procedural, behavioural and political factors, which should be helpful in exploring the failure of implementation and inspectors' roles in it. As a highly simplified framework, concepts from other disciplines are needed to enrich some of the analysis. This could be said to be a characteristic of policy analysis, which is both inter-disciplinary as well as multi-disciplinary (Hogwood and Gunn 1984).

In this study it was useful to draw on some organisational theories to explain some of the findings of the study, concepts related to motivation, role, conflicts in organisations and bureaucratic organisation characteristics were applied. For example, inspectors' roles are sometimes contradictory – protecting consumers and punishing offenders – which may be uncomfortable yet they keep working. Motivation was felt to be an issue relevant for the situation. There is no definite explanation of what motivation is, but it can be illustrated by Handy's (1999; 38-39) summarisation; *'Why work here and why work harder?'*. Motivation theories were used to understand what motivates inspectors to carry on their jobs, and how far they were satisfied with them. The theories were also used to explore the TFDA concerns in motivating inspectors through such things as training programmes, career ladder and advancement. Role ambiguity, which includes uncertainty about how one's work is evaluated, uncertainty about scope for advancement, uncertainty about scope of responsibility and uncertainty about other's expectation of one's performance (Handy 1999) may well be relevant to inspectors. Role ambiguity is said to be a cause of stress and leads to performance withdrawal (Fincham and Rhodes 1999, Handy 1999). The concepts of roles and conflict were, thus, applied in the analysis.

Concepts were also borrowed from the organisational literature, concerning the TFDA administrative process. The TFDA possesses the characteristics of a bureaucratic

organisation described by Weber (1947): its rule-bound functions are bound by rules, the division of labour and the principle of hierarchy. These characteristics, although presented by Weber for their greater technical efficiency, have a number of shortcomings. Bureaucracy concepts were used to explain the TFDA management problems.

3.4 Study methods

3.4.1 The case study strategy

The study aimed to explore the reasons behind inspectors' actions. The study used a case study strategy because it was focused on a specific contemporary group with a specific function without any control over contextual conditions (Stake 1994, Yin 1994). A lack of previous empirical work and the heterogeneous enforcement situation in each regulatory agency suggested the use of a case study method to obtain in-depth understanding, especially about the processes occurring in an organisation with limited time and resources (Hartley 1997). A case study strategy is appropriate for organisational study because it can provide an analysis of the phenomenon under study, both formal and informal, without isolation of the context and process involved (Hartley 1997), which were the objectives of this study.

Although the case study strategy has some limitations in terms of generalisability, it is important to have a detailed case study as a step towards generalisation (Stake 1994). The detailed examination, the specified conditions observed, can provide basic information needed for further research development or for comparison in different settings. Although it could have created richer information and greater generalisability (Miles and Huberman 1994), a comparative case study, such as a comparison between the TFDA and the UK drug inspectors, was not possible due to the limits of time and resources. Clearly, with any case study, adequate understanding regarding cultures, society, rules employed in the society, historical development, health care system and social value must be obtained (May 1994).

The TFDA drug inspectors of the Drug Control Division (DCD) were selected as a case study for enforcers' decisions regarding enforcement in pharmacy for many reasons. First, this study concerned pharmacy inspection, for which drug inspectors are the main responsible group according to the Drug Act 1967. There are TFDA narcotic substance inspectors who inspect pharmacies for the Narcotic and Psychotropic Substance Control Acts, but they mostly inspect for complaints or in collaboration with the police. Besides, this job was formerly done by the drug inspectors and has been separated only since 1997. Second, the

TFDA is a central organisation in enforcing drug regulation, responsible for promulgating the laws through to implementing them. Although the inspection authority was decentralised to provincial health offices in 1984, the TFDA remains a policy leader and supports the budget for the provincial health offices' drug inspectors. Besides, the provincial health officers have other responsibilities – pharmacy inspection is a minor part of their work, on which they spend not more than 10% of their time (Interview 2000) – and each province has its own inspection infrastructures. Third, the TFDA drug inspectors, on average, have served the office longer than any other TFDA inspector groups. Thus the group is well established and equipped with rich experience. Fourth, almost 50% of type A pharmacies are in Bangkok.

In this study, despite using the case study strategy, generalisability can still be obtained to a certain extent, especially for the Thai MOPH, which is currently where all health inspectors are working. All inspections are carried out in the same context of bureaucratic system; regulations are similar in terms of structures and application and all inspectors have the same professional background.

3.4.2 The qualitative approach

The nature of the topic, sensitive and complex, not only suggested that the case study approach was appropriate but also indicated that a qualitative approach was more appropriate than a quantitative one (Strauss and Corbin 1990, Bowling 1997, Hartley 1997). A qualitative approach was considered suitable for exploring the complexity of behaviour, organisational functioning and interaction of relationships and to assist in uncovering and understanding the basis for any phenomenon (Strauss and Corbin 1990, Silverman 2000). These factors are consistent with the aims of this study.

Interviews were the most appropriate method for learning about inspector's attitudes and roles in regulating pharmacies. Data obtained from interviews can be of various types, such as factual replies, attitudes, ideas, feelings, precepts, expectations and conscious reasons (Oppenheim 1992, Silverman 1993), all of which were required for this study. This technique enabled certain topics to be addressed within the time available (Dey 1993). Focus group or group interviews were not selected for use as a primary method because inspectors are very close to each other and 'groupthink' could have occurred which could have weakened the data (Miles and Huberman 1994).

Documentary research is used for two reasons: to collect data and information; and for comparisons between the researcher's interpretation of the events and those recorded in the documents – method triangulation (May 1997, Rice and Ezzy 2000). The method is indirect, unobtrusive and non-reactive (Robson 1993), but it can be biased (May 1997). The document itself can be biased from selective recording and researchers can be selective in reading and analysis. In this study most of the documents used contained factual data so bias was minimised. Documents included regulations related to pharmacy inspection and inspector's authority, the official managerial system, annual reports, government gazettes, press releases and inspectors' reports. Secondary document sources included a review of independent studies, journals, books, and grey literature. There was also more obscure data from documents searched, which might not be independent from the context. These included documents to search for business influence, TFDA working style and TFDA work environment, such as articles from related magazines, independent studies, and minutes of committees' meetings. However, these types of documents were not many and the researcher employed methods to increase objectivity (explained later). A list of the documents used in this study is provided in Annex 2 (which is also used as a research tool described in 3.5).

The study employed grounded theoretical sampling which stresses the importance of getting in-depth data more than number of interviewees (Strauss and Corbin 1990, Rice and Ezzy 2000). Interviews were conducted until no new theme emerged. Interviewees covered a range of officers, all those involved in pharmacy inspection at the TFDA in terms of duty and number. They included 12 field inspectors and seven ex-inspectors; one Secretary-General (SG) and one ex-SG; five managers and two ex-managers; and two regulatory officers. Field inspectors were officers who were the main enforcers of the TFDA drug enforcement and worked in the field. Ex-field inspectors were those who used to work in the field, but no longer go out to inspect. SG is the TFDA top executive. Managers comprise those who do not work in the field but are involved in the process of planning, supervising and monitoring, which included SG, directors, planners, Head of the Post-Marketing Section and Chief Inspector. Non-inspectors are those not working in the field, which includes SG, directors, planners and regulatory officers – those who have a legal background and work on the TFDA legislative and adjudication process, they work in the TFDA Regulatory Affairs Unit. As the number in each group, other than inspectors, was not many, they were combined to protect their anonymity (see Table 3.1 for detail). A list of interviewees is provided in Annex 3.

Table 3.1: Groups and number of interviewees

| Groups of interviewees | Groups of interviewees | Sub-groups of interviewees | Number of interviewees |
|--------------------------------|------------------------|----------------------------|------------------------|
| Inspectors | Inspectors | Field inspectors | 12 |
| | | Ex-inspectors | 7 |
| | Non-inspectors | Managers | Chief Inspector |
| Head of Post-Marketing Section | | | 1 |
| Secretary-General | | | 1 |
| Ex-Secretary-General | | | 1 |
| Planners | | | 2 |
| Director | | | 1 |
| Ex-managers | | | 2 |
| Regulatory officers | | | Regulatory officers |

Interviewing the ex-inspectors and the ex-managers was useful for their institutional memory of historical information. They were also more open and prepared to discuss sensitive issues such as interference or corruption, as well as to help clarify issues unearthed from the current inspectors in reference to the past processes. They, as well as other non-inspector interviewees, were recruited for the purpose of data triangulation (Rice and Ezzy 2000). Their opinions were used to clarify meanings because different interviewees may see the same phenomenon in different ways (Stake 1994).

3.5 Research tools

There were two tools used in this study; first the piloted open-ended semi-structured questionnaire (Annex 4 - 7), second the 'The Documents Pro Forma' (Annex 2). Four types of semi-structured questionnaires were developed for inspectors, managers, SG, and regulatory officers. They were translated into Thai and back translated to English to ensure the same meaning. The questionnaire for inspectors was piloted with four ex-inspectors to check content and clarity of the questions. The pilot was done three times in consultation with a Thai sociologist and my supervisor. The first two pilots deal with changes in content and how to put the right words into questions. The final pilot dealt with ordering and minor changes in wordings. The revised version was translated into English with back translation to Thai. The other three questionnaires were not piloted, but were adjusted during the process.

The document pro forma was developed to clarify documents collected and analysed. It was piloted only once by the same four ex-inspectors, with a few additional documents. Documents were collected more if data from interviews indicated.

3.6 Gaining access to data

The fact that the researcher has experience as a former inspector assisted greatly because of her insights into the problem and her ability to access material and to use questions appropriately (Miles and Huberman 1994). Official approval from the Secretary-General of the TFDA was obtained at the start. The purpose of the study was stated broadly to explore pharmacy inspection problems; the research question was not specified. Directors of related divisions and all interviewees were informed the SG approval, the meaningfulness of their contributions for the research was stressed in order to gain better co-operation. This was helpful to enable access to the required data and officers for the study. Documents used in the study were official and non-confidential.

The researcher had her office in the inspectors' room, which was helpful in observing interaction among inspectors. In addition, the researcher participated in meetings within the inspectors group and with other related groups. The researcher also joined field visits with inspectors, which were very enriching to the thesis.

For interviewing, the researcher also gained approval from the SG since government officers are not allowed to give interviews without prior approval. All interviewees were informed about the general scope of the study by a letter printed on the London School of Hygiene and Tropical Medicine headed notepaper. The school letter emphasised the importance of their contribution, and assured confidentiality and anonymity (Annex 8). The sponsors and an academic supervisor were named in the letter to encourage inspectors' participation. A letter of approval from the SG was attached. The researcher informed interviewees personally again before starting the interview. All participants were informed that the finished research would be made available to them.

3.7 Data collection

Given the researcher's background, bias was a main issue of concern from the beginning, which I tried to minimise (see section 3.11). I took a course in 'Social Science Research and Methodology', and attended a 'Qualitative Research Workshop' at the London School of Hygiene and Tropical Medicine to learn various techniques used in qualitative research and problems to be dealt with during the data collection period. This was to select the appropriate strategies and precautionary measures. These included consultation with my supervisors.

Before collecting data, I presented myself to inspectors and other colleagues as a student wanting to learn about enforcement in pharmacies. I also made it clear that I was trying to be objective and distant to the situation in the TFDA. This was to minimise any effects that might cause inspectors to feel a lack of confidence, or feel that I could report on their behaviour in the field to their superior (Fontana and Frey 1994).

Data collection started by documentary research, using the document pro forma, as a way to get oriented. Data collected were formatted to be able to keep track of them (detail as shown in Annex 9). Most of documentary data was collected during August 2000 to January 2001. Additional documents were collected during and after interviews so as to triangulate information obtained from interviews.

High participation was obtained as anticipated since inspectors found the research a good opportunity to voice their problems. An interview documentation sheet was developed to keep track of the interviews (Annex 10). I was able to conduct interviews with all the expected interviewees during February 2001 – June 2001. Detailed explanation about the study was not given other than the statement in the school's letter, in order to prevent interviewees from creating diffused perceptions before giving interview which could result in bias (Fontana and Frey 1994, Wengraf 2001). General topics or factual topics were raised at the beginning of the interview. Sensitive issues were raised at a later stage to avoid disconcerting the interviewees.

During the interview, where there were issues of jargon I followed them up and sought out the meaning to ensure that a full understanding of the issues was gained. Interviewees who failed to discuss issues of interest were prompted carefully, but without any expression of my opinion on the issues or on the interviewee's remarks, to minimise response error (Moser and Kalton 1971).

I conducted all interviews to reduce variation. As anticipated, familiarity tended to lengthen the interviews and sometimes interviews took longer to get to the point. However, the researcher was enriched and gained more insight into situations through those dialogues. Three interviewees were asked for more clarification later. The interviewing took place in a private room with only the interviewee and I present, to avoid distraction, interruption and influence from colleagues.

Tape recording was used in order to capture words and expressions, which was helpful in analysis. This also helped the interviewer to better concentrate on 'listening', follow-up and questioning more effectively. Considering the established rapport between the interviewees and the interviewer, the use of a tape recorder should not create negative atmosphere. Each conversation was recorded on two tape recorders, the second one started about five minutes after the first, to ensure continuity in recording. The conversations after the recorders were switched off were included in the analysis. I wrote up the off-record data directly after the interviews finished to ensure completeness, including summary of the interviews. Normally one interview was conducted per day.

3.8 Data analysis

Document analysis was mainly finished before the interview started to give the researcher fundamental and theoretical information to facilitate the interviews. The issues analysed followed the document pro forma to make the process objective and this was used along with the data obtained from interview. The data were derived from 33 interviews of 30 interviewees. All the recorded conversations were transcribed by a person who did not know interviewees and were checked with the original audio-records by another person who did not know interviewees, for cross-checking. The interviews were conducted in Thai and analysed in English. The Thai transcriptions were not translated into English to minimise translating which is suggested to avoid 'the original subtleties of meaning loss in translation' (Strauss and Corbin 1998; 286).

Analysis of data from interviews was conducted along the interview period. Data were categorised to explore key constructs, patterns, themes, contrasts, regularities, variations, and singularities. (Silverman 1993). The coding approach employed grounded theory methods (Strauss and Corbin 1990), which means that the data obtained are categorised, then related and integrate into identified categories to find main themes to explain the phenomena observed. In this study, data from the transcriptions were first broadly divided into four groups based on context, content, process and actors. Overlapping data were put in to each group to which they belonged. All data were examined and assigned categories based on information obtained (open coding). Examples of categories were: heavy sanctions, peer pressure, self-motivation, negative reinforcement. Then, data were put back together to explore connections between categories (axial coding). Most of the concepts found at this stage were grouped as themes (for example, expectations or flexibility of rules and processes), and reported in chapters 4 and 5 under the various titles and sub-titles (4.1

Expectations of pharmacy enforcement; 4.1.1 The Thai Food and Drug Administration; 4.1.2. Enforcement of the Drug Act etc. Finally, core cross-cutting themes were drawn out around issues such as friction between the two enforcement approaches, inspectors' conflict with the Drug Act 1967 and constraints within the management system.

Data collected from interviews were integrated and triangulated with data from documentary research. Constant comparison among the data was undertaken, and compared with issues identified in the literature and studies reviewed. This was to sensitise the researcher in the analysis process, and to reduce personal bias (Strauss and Corbin 1998). Direct quotes from interviews and factual data were included to show how the analysis and interpretation were obtained (Rice and Ezzy 2000).

3.9 Reliability

Reliability in documentary analysis was enhanced by employing measures that ensure the same findings would be obtained if the researcher or other researchers repeated the study in the same way (Silverman 1993, Miles and Huberman 1994, Yin 1994). One measure was to use the document pro forma, which was used firstly as a standardised way of categorising issues and collecting data, which is important for reliability (Silverman 1993). A second measure was to cross check the data, and to ensure correct understanding, analysis and interpretation.

The topic of document analysis was largely fact-finding, thus bias was minimised. However, interpretation of documents was an issue of concern as Hodder (1994) mentioned that 'documents, closer to speech, require more contextualised interpretation'. The researcher took into account the contextual factors, such as working styles at some specific period, characters of the involved SGs. The database obtained from document research was formatted and separated from the analysis in order to trace back the original data, another measure to increase reliability (Yin 1994).

In interviews, a number of steps were taken to maximise reliability. Piloting the questionnaire was undertaken to ascertain clear respondent understanding of the questions (Silverman 1993) – to ensure that the questionnaire was understood in the same way and then answers could be coded with minimal uncertainty (Silverman 1993). The researcher was the only interviewer, thus minimising interview variation (Silverman 1993). The interviews were transcribed verbatim with all expressions captured by tape recording such as pause, sigh

and intonation, which helps better interpretation and so increases reliability (Silverman 2000). Transcription and analysis were in retrievable forms and kept separately, another measure to increase reliability (Rice and Ezzy 2000). My experience, as a former inspector, was helpful in probing, but not directing. At the end of each interview, I took note of the interviewee's main reaction and attitudes, including all remarkable events during the course of interview. During or at the end of each day, I wrote down full notes of observation of events that occurred during the day.

3.10 Validity

Validity was enhanced by a number of measures. My familiarity with the settings and materials helped to ensure accuracy and inclusiveness of the materials needed for the study, and the correct understanding of the content of documents, hence greater validity (Miles and Huberman 1994). In addition, the questionnaires and the document pro forma were piloted with four ex-inspectors to better ascertain the inclusiveness and to check for face and content validity. Then, the instruments were refined and adjusted. The study included all level of inspectors and managers, ex-inspectors, ex-managers and regulatory officers, the main stakeholders in enforcing the Drug Act 1967. In this way, the data obtained should be exhaustive and strong (Miles and Huberman 1994).

Respondent validation was conducted after preliminary analysis was finished to gain more confidence on validity (Silverman 1993, Yin 1994). Two meetings were arranged for field inspectors to respond to the data collected and to assure the researcher's interpretation.

Validity was enhanced with the use of multiple sources and mode of evidence, or triangulation (Denzin 1978, Silverman 1993, Miles and Huberman 1994, Yin 1994). Two out of four types of triangulation were used in this study: the data source and methods triangulation. Different groups of officers, not only the current field inspectors, were interviewed, including current and ex-workers. This was hoped to bring corroboration of data and ensured no premature closure of data collection (Silverman 1993, Rice and Ezzy 2000). It also aimed to have a cumulative view of data drawn from different contexts, which have different biases and different strengths so they are complementary (Miles and Huberman 1994). Data collected from documents were triangulated with data from interviews and vice versa. Data from interviewees such as problems and specific events received from any interviewees were triangulated with some other interviewees on an unidentifiable basis.

3.11 Limitations of the methods

The fact that I am an inspector meant that I possibly identified myself too closely with the issues studied, regardless of the efforts to minimise this as described in section 3.7. One potential issue emerged during the study. A question about conflict of interest due to inspectors' double role of being both professionals-in-charge and inspectors was not included in the checklist of the questionnaire at the beginning; it was only during the interviewing process that I recognised this to be a potential problem. However, this also indicated the advantage of using an insider researcher, otherwise this issue would be missed as it is rather a personal issue that outsider researchers would hardly have known.

Knowing all the interviewees had advantages in saving time to get orientation with the study setting, gaining access, understanding and collecting the information needed from both the documents and inspectors. Nevertheless, there were some potential disadvantages such as researcher's bias as mentioned earlier, on which many precautionary measures were applied. First was the use of grounded theory to develop the categories and themes instead of having them set before conducting the research. Second, the validity and reliability were carefully controlled. Third, triangulation was employed to verify and enhance the depth of the data. Fourth, the document pro forma was one measure to maintain objectivity and to prevent bias or self-selectivity.

Despite all the precautionary measures and the use of triangulation, the Thai culture limited the depth of data collection to a certain extent. Open criticism is not common in the Thai culture, so true feelings or conflicts might not be identified. This was more difficult in this study which sought out the issues that were sensitive and could turn out to be negative to inspectors. On two occasions I was asked not to record. Although the topics were not directly related to pharmacy inspection, it showed the interviewees' sensitivity and caution. Criticism tended to be expressed about officers in other spheres, not about individual inspectors or close colleagues. I found it was difficult to get exhaustive or systemic data regarding allegation of corruption, unfairness of promotion, interference in the system or industry influence. Besides, these types of issues were hardly documented. However, this was compensated to some extent by interview with the ex-officers who were about to retire or were retired.

While I made every attempt to be objective and transparent, there were some limitations due to the nature of the interview method. Interviewees sometimes were found to be defensive or

normative. Most of the data received resulted from interviewees' feelings which were subjective and existed in their individual frame of thought (Wengraf 2001). The issue of inspectors having personal relationships with pharmacies either through family businesses or being professionals-in-charge themselves was one example. Although this could mitigate inspectors' independence, only in a few cases was this perceived to be a potential problem, or that there might be conflicts of interest. Being colleagues, I had difficulty in probing deeply in this issue which was considered personal or private despite its potential to cause vested interest in inspectors' decisions.

It is recognised that the issues touched on were sensitive and although most could be triangulated with documents, thus confirmed or negated, some could not. There may have been some untouched issues which others would have recognised. Nevertheless, given the triangulation of methods, the researcher feels secure that most of the information in this study is both reliable and generalisable.

However, generalisability is limited where conditions are different from the settings in this study. For example, while provincial health office inspectors have the same educational background as the TFDA inspectors, and all work under the same Drug Act, according the same rules, it may be that the perceptions of Bangkok inspectors are slightly different from those inspectors in the provinces. Each province has different enforcement management processes, some being more flexible than others. There are thus potential limits to generalising the findings in this study, from Bangkok to the whole of Thailand, although from my experience in the TFDA I do not think there would be major differences. It is true, however, that the findings from this study would not necessarily be generalisable to other countries.

3.12 Summary

This study explored the policy implementation gap based on views and attitudes of inspectors. Walt and Gilson's approach was used as an analytical framework. Issues related to the actors, content, context and process were incorporated in the study to find out the underlying reasons why inspectors do not fully impose their legal authority.

A qualitative approach was considered suitable for this study. Limited by resources, the case study strategy was selected with the main methods chosen being documentary analysis and semi-structured interviews. The researcher being an inspector herself had both advantages and disadvantages. Her familiarity with the data helped in getting and accessing the right

data. However, bias could have influenced her research. This was balanced by the document pro forma, developed as a main tool in documentary data collection, as an objective measure to increase reliability and validity as well as the use of grounded theory in collecting and analysing the data. The familiarity also helped in gaining the in-depth data from interviews. The main disadvantage was the issue of neutrality, and so a number of precautionary measures were carried out before starting data collection to increase reliability and validity. In addition, the use of grounded theory in sampling and analysis was hoped to build up the themes and analyse the data rigorously. Data from interviews were triangulated with data from documents where possible along the analysis process.

Chapter 4 - Expectations and Realities of Pharmacy Enforcement

'Using only legal sanctions cannot solve the problems.' (Interview-1)

Enforcement approaches can take various forms. This chapter explores the TFDA regulatory administration and contrasts it with inspectors' views and attitudes. There was a clash between the TFDA legalistic rhetoric on enforcement in pharmacy and inspectors' actions.

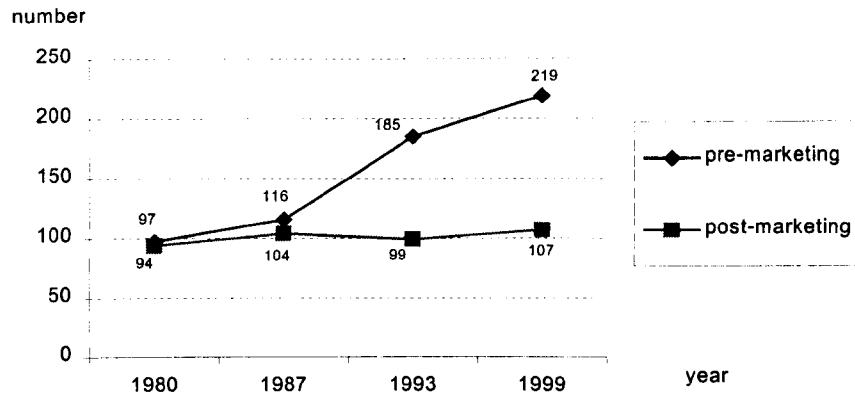
4.1 Expectations of pharmacy enforcement

4.1.1 The Thai Food and Drug Administration

Consumer protection on food and drugs in Thailand was first documented in 1922. The then small department of the Ministry of Interior was moved and expanded to be one department of the Ministry of Public Health called the Thai Food and Drug Administration (TFDA). Medicinal drugs are one of the seven products under the TFDA regulatory control (see Annex 11 for details of staff). The TFDA functions are similar to consumer protection organisations in many countries such as the UK Medical Control Agency or the US Food and Drug Administration.

The TFDA is a multi-functional agency. Enforcing regulation is one of its many functions (The Royal Gazette 1993). Harsh measures have been taken against those breaching the drug laws especially producers and sellers of fake drug (TFDA Annual Reports 1979-1987). However, these measures have declined over time as others have emerged around public relations and education (TFDA Annual Reports 1990-2000). Between two areas of enforcement, product registration (use of compliance enforcement) and inspection (use of deterrence enforcement), inspection has always had less staff support. In 1980, the number of officers registering products, who also proposed issues needing to be regulated, the so-called pre-marketing control, was equal to those doing post-marketing, which includes inspection. Over time this has been eroded, as shown in Figure 4.1.

The imbalance in manpower means that there are more officers working on promulgating regulations than enforcing regulations. This is the case in the Drug Control Division where

Figure 4.1: Pre-marketing and post-marketing staff

drug inspectors belong (Annex 1). Experts have criticised the resources imbalance between pre-marketing and post-marketing control, which has been likened to a boy with huge upper limbs and tiny legs, finally the boy could not walk well (Bowarnwattana and Siripan 1992, Loven 1994). The situation has long been reported and suggested for change, but there has been none. This has led to a common perception among inspectors that inspection is not a priority concern of the TFDA (Interviews).

The TFDA has been well known for its contribution to education since 1990, and was recognised by Government for its outstanding activities in public education in 1990 and 1997. The budget on education has risen from 35% to 53% of the total TFDA budget between 1990 and 1999 (TFDA Annual Reports 1990-1999).

Regarding drugs, the TFDA has achieved some success in promoting manufacturers' standards through promotion of Good Manufacturing Practice (GMP)¹, while pharmacies and importers have been subject to largely punitive enforcement rather than educational strategies. However, the GMP policy is not recognised as a form of enforcement, but a form of 'technical measure' (TFDA Annual Reports 1989-2000). The number of GMP certified drug manufacturers has increased since the start in 1985, from 30.4% of the total manufacturers in 1989 to 73.9% in 1999 (the TFDA Annual Report 2000). The GMP issue espouses the TFDA policy to improve international recognition and increase export income, and caught the attention of MOPH ministers especially after the Thai financial crisis in 1997. There has been no enforcement goal other than the number of inspections required annually in the TFDA plans, despite the frequent statements of violation and lack of rigorous

¹ GMP is a universal principle mainly used in drug manufacturers for quality assurance.

enforcement (the TFDA Annual plans 1989-2001, the 7th and 8th National Health Development Plan, MOPH).

4.1.2 Enforcement of the Drug Act 1967

The TFDA is the main organisation responsible for implementing drug regulations as well as assuming exclusive responsibility for proposing and revising medicinal drug acts. The Drug Act 1967, later called 'the Act' is supplemented by the 1994 Pharmaceutical Board Act, which gives the Board authority to monitor pharmacists' ethics and practices. The Board's roles, though limited and without official connection to the TFDA, are expanding to cover pharmacists working in private pharmacies (personal communication 2001).

It was only in 1967 that administrative measures were introduced to recall unqualified or suspected products and suspend or revoke licences, in addition to criminal sanctions – fine and imprisonment. Licence suspension can be broadly applied to those who violate the Act; while revocation is only for those who are unqualified to be licensees. The Act is written objectively, all technical terms are defined and offences are clearly spelt out. From interviews (2001), there was no complaint regarding the clarity of the Act. No discretion is allowed by the Act, and there are no statements of exemption. 'Selling' is defined broadly covering the actions of possessing, keeping or maintaining drugs. The maximum penalty is for selling fake drugs, which is subject to 1-20 year imprisonment. The lowest penalty is a fine of 1,000 baht (The Drug Act 1967).

Inspectors must act based on their designated authority as described in chapter 3. They have no authority to fine in situ, they can only make citations, collect evidence and send cases to the TFDA to act accordingly. According to the Act and the Thai judicial system, violations to the Act brought to the office by inspectors can be dealt with in two ways.

- 1) The TFDA deals directly with offences having only a fine penalty; a fine or imprisonment penalty in which offenders are willing to pay the maximum fine; and requests for product recall, licence revocation or suspension. The last two measures must be carried out through the National Drug Commission, which is a national body functioning as an approval body.
- 2) The police investigate offences with imprisonment penalties. They can detain suspects up to seven days without warrant. Cases are then passed to the state's attorneys for consideration. If approved, cases are then passed to courts for sentencing based on the

evidence collected by inspectors. Offenders to the Drug Act are treated as criminal offenders.

The following sections show that, in practice, there is considerable deviation from the way the 1967 Act is stated.

4.2 Implementing the Act at the TFDA level

Implementing the Act does not follow the legalistic rhetoric the Act espouses. What actually happens in the TFDA regarding enforcement is that there was deviation at both the TFDA and the inspector levels. Uncertainty in the TFDA enforcement styles, a flexible approach and a lax situation in the TFDA environment were also found. The TFDA lax and inconsistent decisions and policies were felt by inspectors to be hypocritical and convinced inspectors that full enforcement was not encouraged (Interviews-1,8,11,12,14,22).

4.2.1 Flexibility in the TFDA enforcement approach

This research suggested that the Act is seldom implemented as designed, the TFDA seemingly took a flexible strategy. Instead of sending cases with imprisonment sanctions to the police, the TFDA had established the '*Violation Adjudication Committee*' (VAC) by a TFDA administrative order, not endorsed by the Act, to determine what sanctions should be imposed on offenders (TFDA Order 387/1998). This was to avoid imposing too harsh punishment on those who transgressed unwillfully, but because of lack of knowledge or appropriate technology (Interviews-16,18,23).

By the Order, decisions were made by the VAC members who are all TFDA directors, regulatory officers from the Regulatory Affairs Unit working as secretariat. The VAC was presided over by one of the deputy-SG. Decisions were made by casting votes and were recorded in the VAC meeting minutes. Violations were judged based on the VAC Guidelines (1991). Its decisions could be various: dropping, reversing or upholding the cases; requiring further investigation or evidence; follow-up of cases; fines; warning; proceeding to police or a combination of measures. Warning is used in a significant portion of cases (TFDA Annual Reports 1979-2000, Inspection Reports 1990-2000). The use of a warning dates back to 1979 and has been used often since then (TFDA Annual Report 1979-2000). This obviously indicates the flexible approach adopted by the TFDA.

However, it seemed that the VAC enforcement process was not well accepted by the members and inspectors. Normally Directors sent junior officers to represent them (VAC meeting minutes 1995-2000, Interviews-9,18,22). To some interviewees, this suggested a lack of interest from those who are not directly involved (Directors of not-related Divisions) or lack of interest in enforcement. At the same time, since 1991, the VAC no longer has the inspectors who detected the offences joining the process nor do they receive any feedback about the decisions (the 1991 VAC Guidelines). Inspectors know the outcome only when they have to follow-up particular cases (Interviews-1,4,6,10,14,15,18,27). They are invited to the meeting only if there are unclear points, but this was rare (Interviews-18,23, VAC meeting minutes 1995–2000). This was said to save inspectors' time but met with little appreciation from inspectors (Interviews-4,14,15,18,21). On the contrary, the process seems to cause tension between the VAC and inspectors.

A number of inspectors were doubtful about letting the VAC alone play its part in the adjudication process (Interviews-4,13,15). They felt that it was their responsibility to take their cases through the process, as they were the ones who knew the situation not the VAC, *'who sit and make decisions in air-conditioned rooms'* (Interview-1). Besides, they felt their participation would help them learn from their mistakes and make the next cases more solid (Interviews-4,13,15).

With the lack of inspectors' participation or consultation in the VAC process, the principle of having the VAC seemed to be undermined. As well as creating tension between inspectors and the VAC, inspectors were disinclined to take cases for the VAC's consideration because they felt the VAC decisions were lax and inconsistent (Table 4.1).

Table 4.1: The VAC contradictory cases

| Charges | Total offence reviewed | Cases not following the Guidelines |
|---------------------------------------------------|------------------------|------------------------------------|
| Absence of pharmacist during registered duty hour | 839 | 27 |
| Sell sub-standard drugs | 5 | 1 |
| Selling and purchasing entry record problems | 104 | 69 |
| Sell drugs without proper label | 20 | 7 |
| Sell drugs other than permitted | 17 | 1 |
| Sell withdrawn drug | 3 | 1 |
| Sell expired drug | 8 | 3 |
| Sell non-registered drug | 17 | 4 |
| Sell fake drug | 6 | 3 |

Source: Inspection records during 1980-1996

4.2.2 The lax and inconsistency of the VAC decisions

Despite the flexibility of the Guideline, the VAC did not follow its own rules. Table 4.1 indicates the cases not sentenced according to the Guideline. Where prosecutions should have followed, the VAC gave only official warnings for offences such as selling without licence, selling fake drugs, sub-standard drugs or expired drugs (Inspection Records 1980 – 1996, Interviews-4,6,18).

The inconsistency was likely to affect inspectors' decisions (Interviews-1,2,3,6,7). For example, there was a case against an international chain store selling drugs without licence; the VAC issued a warning instead of prosecution. Some inspectors later on used this sentence as a precedent not to make citation of small grocery stores, otherwise, they said, *'It's unfair'* (Interviews-6,13).

Occasionally, sanctions were imposed unpredictably (Interviews-15,30), and inspectors felt that offenders not causing great harm were sometimes punished more than they deserved, whereas severe violations were sometimes only lightly punished (Interviews-1,3,10,18,27, 30). Although they could not say how often this occurred because they did not follow all cases, the inconsistency made a number of inspectors reluctant to send small cases to the VAC for consideration.

With no participation in the adjudication process and no feedback to tell them the reasons why cases were dropped, reversed or did not follow the VAC Guidelines, inspectors felt sceptical about the role of the VAC (Interviews-1,4,10,13,15,18,27). Ambiguous decisions affected inspectors' decisions in many ways and were felt by them to be one of the obstacles to fully enforcing the Act.

In interviews, inspectors assumed that political influences had intervened in the VAC process (Interviews-1,4,6,10,14,15,18,27,30). If offenders appeal, inspectors are rarely invited to hear whether appeals are reasonable or not, or otherwise clarify what they had observed. This lack of communication caused some inspectors to feel that the prosecution process was not transparent (Interview-1,10,18,27). This meant a number of inspectors felt they should not risk themselves to take cases to the VAC, which would be released later (Interviews-1,8,18).

4.2.3 The lengthy VAC process

According to the hierarchical system, the official adjudication process can take 115–145 days to proceed to the police (the 1991 VAC Guidelines, Pisajpen 1997). Besides the lengthy process, there was case lag. The VAC meetings being held only when there are sufficient number of cases to be considered (VAC meeting minutes 1995 -2000) is one reason why the process takes a long time before decisions are made. Usually it took more than one year to get offenders to court (Interviews-4,7). Serious cases requiring laboratory analytical results and cases that are appealed take much longer due to the complicated steps taken. A number of inspectors explained that the lengthy VAC system was ineffective and undermined their authority (Interviews-4,5,7).

'The process is so long that even I myself can't remember the cases. How about the offenders, they would have forgotten their wrongdoings.'(Interview-4)

In their view the lengthy process cannot provide the immediate deterrent effect, which could reinforce offenders to make corrections (Interviews-1,3,4,13,15). They compared selling drugs without licence to the sale of alcohol without licence, where offenders are fined immediately, and as often as they are caught.

4.2.4 The cautious role of the National Drug Commission (NDC)

The NDC comprises 21 representatives from each department of the MOPH, two other related Ministries, two Faculty of Pharmacy and the National Council of State (The Drug Act 1967). The NDC is presided over by the Permanent Secretary of the MOPH. One TFDA deputy-SG acts as the Commission Secretary, and the Drug Control Director as an assistant secretary. NDC meetings are held irregularly, between 3–11 times a year (NDC meeting minutes 1988–1999). The NDC is a national approval body for withdrawing product registration and premise licences including suspending licences.

Inspectors did not view the NDC as a helpful enforcement tool. Most of the NDC meeting agendas were concerned with quality and availability of drugs. The NDC seldom suspends or revokes licences, though so empowered. Between 1988-1999, 75 meetings were held with only three in which licence suspension and revocation were proposed (NDC meeting reports 1988-1999). Licence suspension of pharmacies occurred only for two cases which

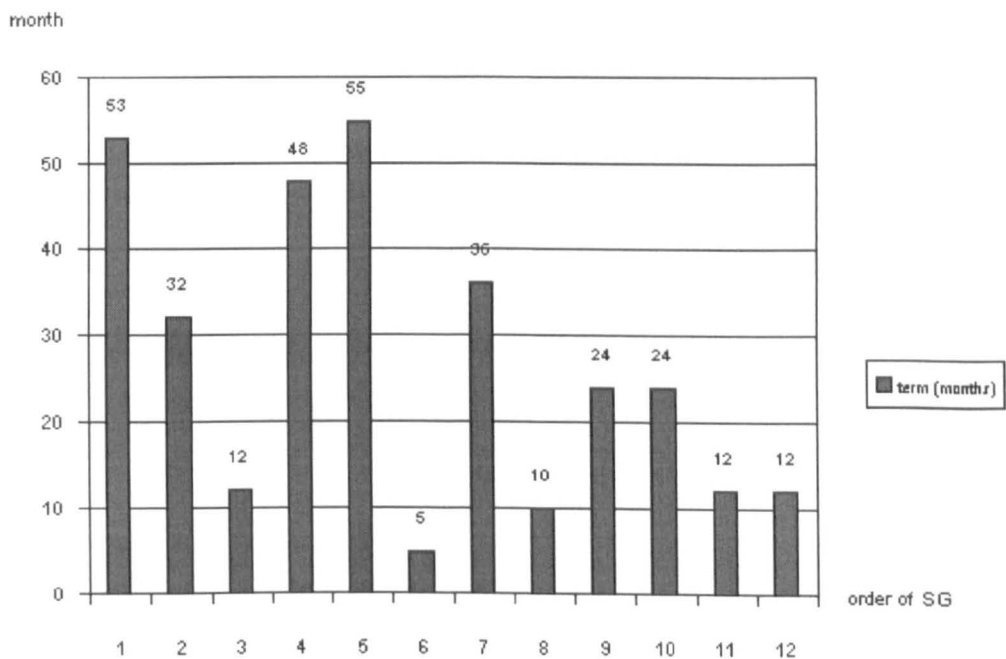
made repeated major violations; 21 licences were revoked mostly because of not having a registered professional-in-charge (NDC meeting minutes 1988-1999).

For the NDC to make decisions, cases must be proposed by the TFDA. The rarity of occasions suggests that in fact the TFDA does not want to use 'heavy-handed' measures against those violating the Act. From the experience of one manager, the members of the Commission viewed licence suspension as a strong punishment that should be used only under special circumstances (Interview-29).

4.2.5 Discontinuity in the TFDA pharmacy enforcement policies

Policy discontinuation is a top cause of the administrative problems in the TFDA (Secretariat Working Group 1991, Bowarnwattana and Siripan 1992, Hongsamoot 2000, Kiatyingangsulee 2000, DCD report 2001), including enforcement policy (Hongsamoot 2000). The Secretary-General seldom serves the expected four years at the TFDA. On average, the SG's term lasts for only two years and two months (see Figure 4.2). There is seldom any explanation of the reshuffles, and the great majority of inspectors doubted the political neutrality of the SG appointment (Interviews).

Figure 4.2 : Secretary-General terms 1979 -1999



Source: The TFDA Annual Report 2000

The stability of the SG is important. In the TFDA bureaucratic system, h/she has the strongest voice and usually takes directive roles in the TFDA administration (Interviews-8,17,23). It has been a tradition in the TFDA that top executives are physicians from other MOPH departments, and are appointed by the Prime Minister with approval from the Minister of Public Health (TFDA Annual Report 1999). Most inspectors felt that frequent changes caused problems in enforcement due to the lack of understanding, lack of familiarity and lack of long term policies (Interviews-5,8,9,11,12,14,15,19).

There were at least two occasions that two SGs used their own views to stop enforcement activities. The first occasion was when inspectors had been inspecting pharmacies selling drugs outside the registered duty hours in 1985 by the then deputy-SG's order (Inspection record dated 11 July 1985). Inspectors were asked to take serious action regarding the offence. This caused chaos to pharmacies as the great majority of pharmacies violated the law. But soon after the inspection had started, the owner of one of the inspected pharmacies appealed to the SG, claiming that it was unfair to prosecute him unless all pharmacies were inspected and prosecuted too. The then SG asked the Inspection Division to revise the activity (Inspection record dated 24 July 1985). Although he did not state clearly to cancel the activities but it implied his disagreement (Interview-9), which was strong enough to stop the activities (Interview-9). Second, a routine check for presence of pharmacists, which had been conducted since 1981, was stopped by one SG's order because he/she felt the activity was not worthwhile. This was decided without any consultation with inspectors (Inspection records dated 15 July 1991). These two examples indicate that the SG holds supreme power in the TFDA and can cause sudden change – a situation that can undermine inspectors' authority.

However, a few SGs brought positive ideas regarding enforcement in pharmacy. For example, they tried to gain compliance through means other than inspection and punishment. They have viewed pharmacies as agencies which can co-operate with the TFDA to contribute better services to communities (Interviews-25,28). One SG in an interview with the Advance Business Magazine in 1988 said,

'Those pharmacy owners are not immoral or hardhearted. They have good social status, some of their children have pharmacy graduation. Their ancestors sold drugs all their lives, saving a lot of lives. They should not be problematic.'(Anon. 1988; 15)

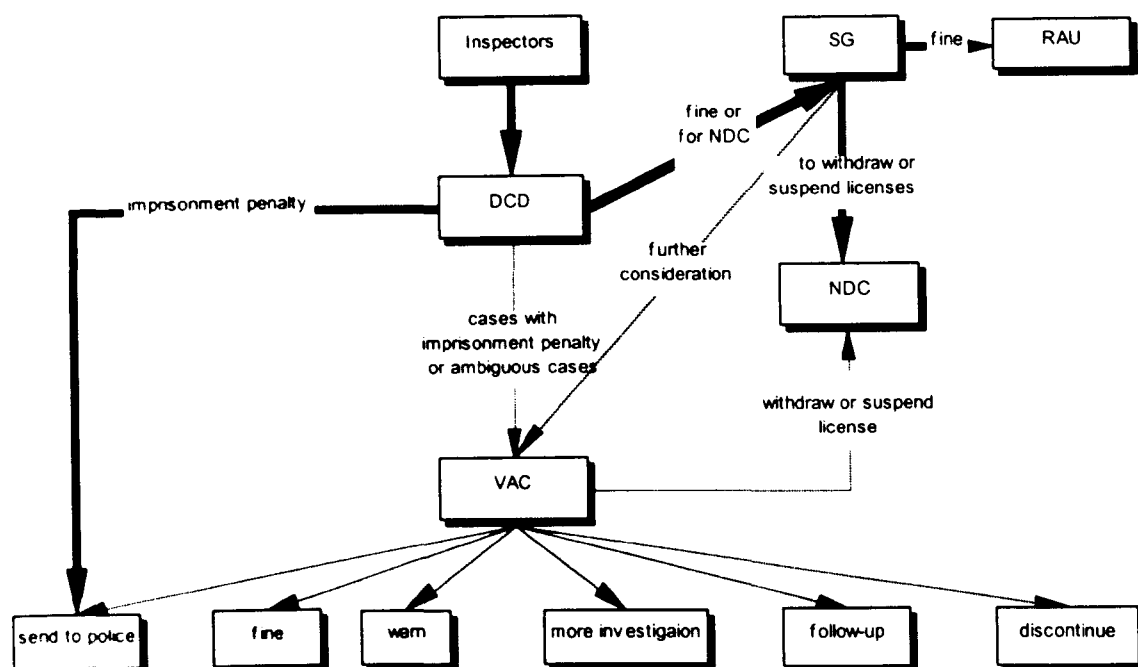
Such policies to encourage law adherence were introduced on three occasions. In 1987, the 'Self-Regulating Policy'² started and was implemented for almost four years (Inspection records 1990). During that period inspectors were ordered not to take legal action but to use the educational style instead. The Policy stopped after the SG was moved. In 1994 'the Standard Pharmacies'³ was introduced and re-introduced in 1998. These policies, which did not conform to traditional TFDA practices, were, again, discontinued after SG reshuffles.

The pattern was a new SG came with his/her own ideas or with the MOPH Minister's policies, which are usually of high priority, and abandoned the previous SGs' policies. Meanwhile, the TFDA officers did not want to risk themselves pursuing policies which were not following the Act, or might cause conflict with the current SG (Interviews-8,24). The frequent changes caused a number of inspectors to feel that enforcement mostly got the SG's attention only from time to time and for a short period, and there was little interest in tackling the roots of the problems (Interviews-1,4,5,6,7,12,21,30). For example (Interview-7), in 1999, there was a complaint to the then MOPH Minister about the absence of pharmacists as professionals-in-charge in pharmacies. Instead of using this opportunity to find a long-term solution, inspectors were ordered to re-inspect pharmacists' presentation. However, before inspection started, TFDA had publicised the inspection. The data from one week's inspection was reported to the Minister, and the inspection stopped afterwards.

In sum, the TFDA itself exercised flexibility in its enforcement administration at different levels, illustrated in Figure 4.3. The **thick lines** represent the processes assigned by the Drug Act. The **dashed lines** represent the processes not assigned by the Drug Act but which are commonly used.

² This policy urged pharmacies to form a group to visit, advise and monitor pharmacies in their constituency.

³ This policy was to issue certificates to pharmacies that met certain standards set by the TFDA. Standards ignored some legal items.

Figure 4.3: The TFDA flexibility in enforcement

VAC = the Violation Adjudication Committee

NDC = the National Drug Commission

RAU = the TFDA Regulatory Affairs Unit

DCD = the TFDA Drug Control Division

4.3 Implementing the Act at inspector level

4.3.1 The TFDA drug inspectors and their work load

The TFDA inspectors are officially required to have at least a pharmacy background. They mainly learn how to inspect by on-the-job training without formal job induction (Interviews-8,9,11,20,21,22). New inspector recruits are paired with senior inspectors who are subjectively selected by the Director (Interviews-8,21). New recruits stay with their trainers for at least two months, and may only then be moved to work with other inspectors. Later, it depends on mutual agreement between inspectors and their superiors to select their partners because inspection is traditionally done in pairs or teams. Although there is pair switching from time to time, there are no fixed rules. Training is highly dependent on the senior inspectors as to how seriously or consciously they impart their experiences.

The three inspection manuals and inspection training programmes do not spell out inspectors' roles or the TFDA expectation of inspectors (Inspection training curriculum 1992–1999, Inspection Manuals 1979,1989,1998). The contents of the manuals are mainly on regulations, report writing and evidence collection for prosecution. The manuals are said to be more like textbooks than practical manuals (Sriprapanh et al 1994). All inspectors but one said that they had no time to read any manuals (Interviews), and preferred to ask or follow their senior partners because in reality there were a lot of different details that affected decisions, whereas the manuals state only principles or simple cases.

Given the on-the-job training approach and the Thai hierarchical culture, group cohesiveness was enhanced, but senior inspectors could have considerable influence. High peer pressure was detected which causes inspectors to make relatively similar decisions.

Figure 4.4: Three inspectors inspecting a pharmacy



Up to 30 June 2001 there were twelve inspectors. They expressed satisfaction with their work, and eight out of twelve had been with the TFDA for at least 15 years. Figure 4.4 shows three inspectors while on their duty, one of which was a newly recruited inspector. Most inspectors and ex-inspectors interviewed had some ideas about inspection but without clear aims (Interviews). Most inspectors had worked before enrolling but their experiences were not directly related to community pharmacy practice (see Annex 12 for detail).

Each year the 12 inspectors are responsible for inspecting 150 out of the total 180 manufacturers, 700 out of 4,022 pharmacies and 200 grocery stores (to check sale of drugs without licence) (DCD Annual Plans 1998–2001). Pharmacies are selected at inspectors' convenience, there is no systematic selection. Recently, most pharmacy inspection is on complaint cases and follow-up cases (Inspection reports 1998–2000). Calculation by using work standards (two hours for one pharmacy) suggests that 46 inspectors are needed to cover the same target instead of the current 12 (Nantawijarn 1993) (see more detail in section 5.2). Officers from other sub-sections are borrowed from time to time, to fill the teams. The only way for inspectors to meet targets is to inspect quickly, which may lead to missed violations or turning a blind eye to them. One inspector said,

'The target is very overloaded that we almost 'fly over' pharmacies.' (Interview-6)

4.3.2 Inspectors and warning authority

The TFDA Order on Violation Adjudication No. 0701/RAU 80 (1992) authorises inspectors to issue official warnings but only in cases not related to manner of selling or product quality. Examples include not having sign plates in pharmacies, mixing up types of drugs on dispensary shelves and incorrect entry records. Those who were non-inspectors were reluctant to delegate more warning authority to inspectors; they felt that inspectors should take all offences to the VAC to avoid any accusation of corruption (Interviews-16,17,23,29).

4.3.3. Inspectors and their implementation of the Act

The study showed the gap between policy intention and policy execution at the TFDA level. The gap also occurred at the level of inspectors. All inspectors acknowledged that they were not empowered with discretion by the Drug Act, yet they admitted using discretion (Interviews). There has been a dispute among inspectors, at least since 1959, regarding their authority and eligibility of using discretion, without any conclusions (Interviews-8,9,11). How authority should be exercised was not found in any documents (Inspection Manuals 1979, 1989, 1998, Inspection SOP 1996), so ideally inspectors are supposed to make citations and impose legal actions on all offences encountered. However, most inspectors believed that they should be eligible to drop charges where violations are conducted unwillfully (Interviews-1,15). This is in accordance to the Penal Code 1956 clause 59, which has higher status than the 1967 Drug Act. Clause 59 states that, ' A person shall be criminally liable only when he commits an act willfully'.

Despite the belief that they should possess some discretion, none used it openly (Interviews, Inspection Records 1980–1996). They were inculcated by their seniors not to record offences if legal actions were not imposed no matter what the reasons were (Interviews). This is because there is another regulation, clause 157 of the Penal Code, scrutinising all authorised officers to ensure the appropriate use of their authority. It says: 'Whoever being an official, wrongfully exercises or does not exercise any of his functions to the injury of any person or dishonestly exercises or does not exercise any of his functions shall be punished with imprisonment of one to ten years or fine of 2,000–20,000 baht or both.' Inspectors believed that they would risk being charged with 'duty negligence' if they recorded their exemption of any offences (Interviews-2,3,5,14,19).

Although expected to have little room for discretion, historically inspectors have not followed this notion. With many reasons (see following sections) they did not use sanctions officially available to them but set their own '*substituted measures*' to be used in place of the official sanctions (Interviews). The substituted measures have long been used without scrutiny as far as the most senior inspectors could recall, before 1959 (Interviews-9,11). The measures can be used in combination with each other or with official measures depending on situation and seriousness of infringement (Interviews). They include destroying illegal products by owners, threaten using official sanctions on the next visit, threaten using frequent visits, giving verbal warnings and bargaining to take only minor offences into account in exchange for immediate correction of a major offence, bargaining to drop offences in return for giving more in-depth information.

Imposing legal authority in all cases was not practicable (see more detail in section 4.4 and chapter 5). The VAC case lag and lengthy process were among other rationales given for not using official sanctions (Interviews-1,4,5,20,27,28). The great majority of inspectors felt that using their professional judgement and their substituted measures yielded greater benefit to consumer protection, otherwise most of their time and TFDA resources would have been spent on minor cases (Interviews). In their view all pharmacies commit violation one way or another (Interviews).

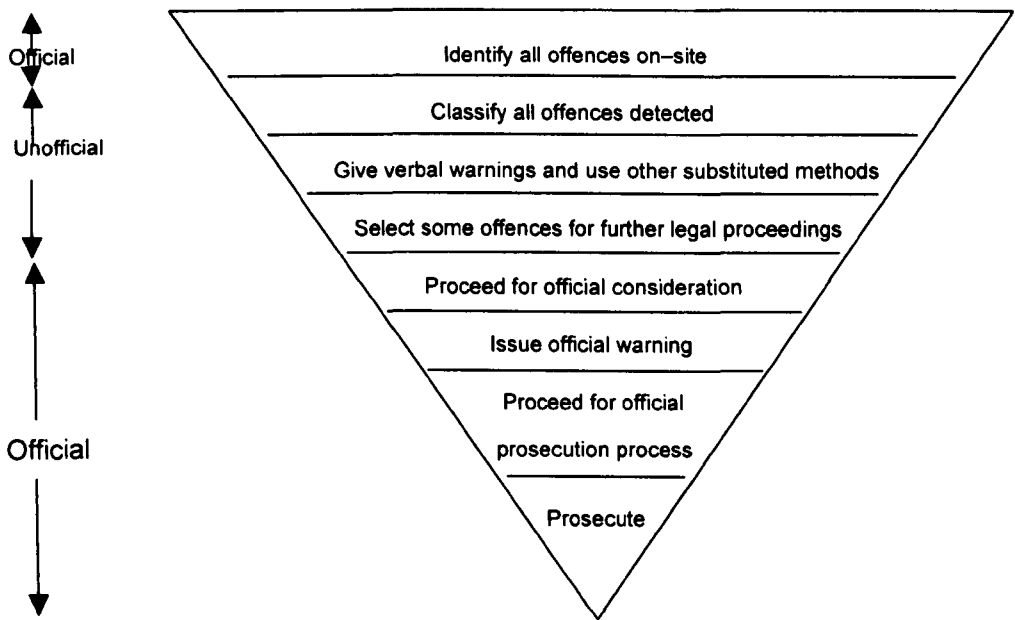
From inspectors' experiences, the substituted measures helped inspectors get the job done with less confrontation or conflict and help them bargain better with offenders (Interviews-4,9,11,26). Senior inspectors pass down the 'bargaining technique' to their juniors (Interviews-4,5,8,9,11,15,21).

' We show 'the regulated' all their offences. Then tell them that we are going to take only one or two offences into account because of whatever reason such as it is policy, it is evident, because they have been warned before, or someone has complained. But the offenders must get rid of the illegal products found or assure us of improvement in their practices. It is preferable to explain to them all penalties including the dropped charges especially if the charges have imprisonment penalty. Usually, they accept because we normally take legal action on offences committed by intention or have moderate penalty. In this way we can leave the place safely and sometimes with 'thank you' from them too.' (Interview-5)

Consequently, cases officially charged and recorded are a minor portion of all cases detected. Transgressions were, thus, first screened along the inspection process followed by the VAC, the police and courts as illustrated in Figure 4.5. But no one could estimate the proportion (Interviews).

Given that measures have been used for a long time, and the Thai culture of avoiding conflict, inspectors might use the measures without thinking thoroughly about the pros and cons; and they seemed unable to see other alternatives. At first a number of inspectors felt that their substituted measures were tantamount to the official punishment (Interviews-4,15,18), but they later accepted that they could not confirm how effective the measures were. Some admitted that offenders may sense that the substituted measures are not real and can bargain (Interviews-1,26).

Figure 4.5: The triangle of inspectors' decisions on legal action taken



There were drawbacks in using the substituted measures, inspectors accepted (Interviews). Some inspectors confessed that saying they would follow-up was an empty threat only because the chance to come back was slim (Interviews-13,26,27). As there were no official records, most use their own memories and only a few inspectors wrote their actions down in their personal notes (Interviews-3,4). But if they were moved to work in another geographical area, it was entirely up to the personal interests of those who replaced them as to whether they would use the informal notes or not (Interviews-4,6,26).

4.4 Inspectors and the TFDA legalistic rhetoric

The flexibility and uncertainty in the TFDA enforcement played only a part in inspectors' reluctance to use their authority. Other aspects were also highlighted in interviews.

4.4.1 Inspectors and the context regarding enforcement in pharmacy

4.4.1.1 Problem recognition and the Thai culture

With concerns limited largely to researchers, problems regarding drug utilisation, partly caused by violations in pharmacies, have not been a high priority at national policy level (MOPH policy 1992–2000). Other health problems such as traffic accidents, smoking, occupational health and addictive substances have been on national public policy agenda (Pattapong and Anupong 2000). Problems regarding violation in pharmacies are of such little interest that even SGs showed a lack of concern. Two SGs expressed their views that the absence of professionals-in-charge and the sale of drugs without professionals-in-charge were not urgent issues, in a television programme (Anon. 1999) and in interviews (Anon. 1988).

Many inspectors felt that the problem of pharmacy regulation was too big for a single organisation, and that the lack of recognition may lead to laissez-faire management due to the lack of public pressures and scrutiny (Interviews-1,4,13,15). Had violations caught continuous attention from newspapers, enforcement in pharmacy would have been supported more and carried out with less obstruction from the business sector. All inspectors interviewed felt overwhelmed by the long-term nature and enormity of widespread violation⁴,

⁴ Violations that occur regularly in most pharmacies. They include selling out of the registered duty hour, absence of professionals-in-charge during the registered duty hour, selling drugs without supervision of professionals-in-charge, selling prescription drugs without prescriptions, selling drugs without licences, selling drugs other than those permitted and offences about drug entry records. This type of violation is sometimes called 'customary violation'.

and expressed their feelings as *'impossible to change situations by using only inspection'* (Interviews).

In general, enforcement is not well observed in Thailand; violation in pharmacies is only one area among others. The Thai culture of avoiding conflict and hierarchy including the patronage system are not healthy for enforcement work and reinforce the preference for flexible enforcement. Punishment is viewed as fit for only the 'hard-headed' offenders, otherwise it should be used only as a last resort (Interviews-2,3,8). These views were shared by the great majority of inspectors and their managers (Interviews).

'Our society likes the softly-softly approach. Tension is always expected after using strict enforcement.' (Interview-28)

The views that enforcement is equivalent to punishment is one constraint. Some managers viewed punishment as against the MOPH philosophy: to help, not to punish people (Interviews-19,24,29). In at least two cases, two SGs had voluntarily changed their job because of this discomfort (Interviews-9,11,22). Some SGs even suggested that the TFDA become a technical agency rather than a regulatory agency (Interviews-19,23). For some even the word 'enforcement' is undesirable as one senior officer explained,

'Don't use the word enforcement, it gives a sense of punishment. Better use 'Post-marketing surveillance', it sounds more technical. Thus better accepted. It is only us, inspectors, who accept the term enforcement, the others - especially most SGs - don't.' (Interview-24)

The Thai patronage culture may create conflicts of interest through the relationships between inspectors and pharmacists. They are all professionals and many are friends. Their managers and colleagues are also pharmacists, who have friends as pharmacists as well. Some inspectors complained that they are in-between, it is difficult to penalise those who are in the same profession. Yet, they were claimed to 'pick' on the same profession and turn a blind eye on businessmen (Interviews-1,21). Not only do pharmacists have links with inspectors, pharmacy owners also have some connections especially with managers and MOPH ministers. These relationships can cause pressures on inspectors, especially with cases that have imprisonment sanctions (Interviews-4,8,11,14,20). Therefore, inspectors were trapped between their duty and business influences. Subsequently, many inspectors took legal action only in cases that were outstanding and serious so that they could explain

their justification to anybody that might ask for their help in mitigating the cases (Interviews-3, 4, 8, 11, 14, 21, 27).

The TFDA job of enforcement was sometimes in conflict with other MOPH jobs. For instance, the Thai traditional medicines being promoted nation-wide were mostly against the Act because most of them were not registered. This is difficult to enforce fully as it would disrupt traditional medicine promotion policy, which was run by another MOPH department. In addition it is known that licensing and registration processes required by the TFDA are complicated and take time, and it is very strenuous for small traditional medicine businesses to get approval. Traditional medicines are therefore often ignored by inspectors unless harms are clear or there are specific TFDA orders (Interviews-10,27).

4.4.1.2 Business Influences

Most inspectors felt that business influences exist (Interviews), and that was a reason why enforcement was not in the main interest of executives (Interviews-1,2,3,4,5,7,15). They also perceived that pressures from both individual pharmacy owners and the Retail Pharmacy Association (RPA), whose members are largely businessmen, are strong. None of the inspectors agreed that 'legalism' was viable (Interviews).

'It is the SG who will be first in trouble due to pressures from pharmacy owners. Then, we will be pressurised by SG or other executives. Some violations have existed too long to be touched such as selling drugs without pharmacists' supervision or absence of pharmacists. It is also the politics thing.' (Interview-3)

'Nobody in the TFDA or even the MOPH is affected by violations occurring in pharmacies. In addition, influences exist in that business. So, why should executives under departmental level be concerned about it?' (Interview-17)

'So far, SG has not touched issues about selling drugs, because they do not want conflicts with the RPA which is understandable. It has been this way since the beginning, why any of them need to push the button, especially they do not stay long.' (Interview-25)

The relationship between politicians and the RPA has long been established (RPA Magazines 1979-2001, TFDA Annual Reports 1979-2000) leading to co-operative relations. For example, the RPA annual meetings have been presided over by the Minister of the MOPH together with the SG (RPA Magazines 1979 – 2001). In return, the Association helps

the MOPH such as donating medicines and money in catastrophic events, disseminating educational information and circulating regulations. Two ex-SGs now are consultants to the RPA (RPA Magazines June 2001).

The RPA also has close relationships with other powerful Associations, nationally or internationally, such as the Proprietary Pharmaceutical Association (of multi-national companies) and the Thai Pharmaceutical Manufacturers Association (of domestic manufacturers). The close links are indicated by supportive interactions between associations, and by names of people who are consultants to the RPA (RPA Magazines 1979-2001).

Supporters of the RPA are big businessmen, senior or high-ranking politicians, ex-MOPH Ministers, ex-SG including well-known academics (RPA Magazines 1979-2001). The RPA is powerful because it plays a significant role in supporting Members of Parliament, especially those appointed at MOPH Ministries (RPA Magazines 1979-2001).

The power of the RPA can be indicated by its victories in major conflicts over policy with the TFDA and MOPH on at least three occasions. It started with the issue of the professional-in-charge's duty hours in 1979 (Box 1). Most of the inspectors claimed that this case was the starting point of hard-to-solve problems in pharmacies and showed the powerful business influences (Interviews-1,4,5,8,12,14,20).

The second occasion was in 1981 (MOPH ministerial order 1981) when the MOPH tried to set quotas in order to encourage pharmacies to move to rural areas. Meanwhile new pharmacy licences were intended to be issued only to pharmacies where pharmacists were both owners and professional-in-charge, and must certify to the MOPH that they would be present all day. The Association took the issue to court, which concluded that such order was against the Thai Constitution regarding the right of performing business.

The latest confrontation was in 2000, when the newly drafted Drug Act proposed to abolish type B pharmacies, within a five-year grace period. The RPA appealed to the MOPH Minister and the Parliament, and finally, the proposal was dropped (Interviews-16,23,25, the Parliamentary Health Subcommittee meeting minutes 1999).

Box 1 The interpretation of professional-in-charge duty hour

The 1967 Drug Act in its 1979 amendment has made clearer that professionals-in-charge are to be physically in their registered pharmacies during registered duty hours. This caused chaos to type A pharmacy owners. Before the revision, pharmacists were traditionally hired without any explicit demands for them to routinely work in the pharmacies where they were employed. The salary paid to pharmacists was, thus, on a part-time basis – not high. The new revision brought the sense that pharmacists were to be employed full-time and then their salary would be increased by at least three times. This did not mean only higher expenses for pharmacies, but it was estimated that at least 1,000 pharmacies, about 25% of total type A pharmacies at that time, needed to be closed down. The estimation was based on the fact of the inadequate number of pharmacists. Actually the Act gave a three-year grace period for universities to produce more pharmacists and for pharmacies to adapt themselves. However, there was no compromise.

The RPA heavily resisted for over four years (RPA Magazines 1982-1985), and ended up by going to the Council of State, the highest organisation for regulation interpretation. The decision reached in 1985 was that the registered duty hours could be at any period of time during the business hours of pharmacies, but pharmacy and prescription drugs could only be sold with the pharmacist's supervision (the Tribunal Committee Decision 1985).

After this interpretation most pharmacies (except those owned and run by pharmacists) hired professionals-in-charge to stay for a certain period, usually 5.00–8.00 p.m. In practice, pharmacy owners illegally sell pharmacy and prescription drugs all day violating the law. Professionals-in-charge usually do not stay during the duty hours. This interpretation causes three contravention – professionals-in-charge absence during the duty hours, selling drugs out of the registered duty hours and selling drugs without professional-in-charge's supervision.

Currently 70% of total pharmacies or about 7,800 pharmacies committed these three offences. The great majority of inspectors felt that these are national problems and enforcement alone by 12 inspectors cannot help (Interviews-2,3,4,5,6,8,11,12,13,26,27). It is the TFDA that made this issue difficult by accepting the three-hour registered period in the first place (Interviews).

4.4.2 Inspectors' views and attitudes on their job and legal authority

4.4.2.1 Views and attitudes to their job

Despite the risky nature of their jobs, inspectors seemed to be relatively motivated. A number said that they are proud of themselves in maintaining their honesty throughout despite pressures and seduction (Interviews-4,5,8,10,12,27). They appreciated certain job characteristics such as autonomy; flexible work hours; travelling around; learning from the real things, not just from theory or through papers; and investigating activities, which are more challenging than routine paper work (Interviews).

Although they could not define precisely their roles, they broadly identified themselves as '*protecting consumers from unqualified medicinal drug*' by inspecting pharmacies to ensure that the Act is observed, and to take legal action on offenders (Interviews-1,2,3,4,7,8,10,12). Yet, they felt that they needed to use their professional knowledge to make judgements and give advice to the regulated, not only to take legal action (Interviews-11,18,27).

'We are employed to use our knowledge in making decisions, not just taking people to court. Why bother with our pharmacy background, if the TFDA wants to only check regulatory observance, anybody can do that. If we are supposed not to use discretion, we are just slavish to the regulations.' (Interview-15)

Inspectors' views and attitudes to their jobs were relatively similar (Interviews). They may transfer and adjust their ideas informally and naturally as they work in pairs or in teams. They share offices - often one large room - which gives opportunities to shift individual's ideas towards the group norm. Given the 'no conflict', 'hierarchical' Thai culture and group cohesiveness, this also strengthens peer influence on inspectors' decisions.

4.4.2.2 Views and attitudes regarding legal authority

Most inspectors interviewed were using their legal authority cautiously, and normally use it as a last resort. For them, using authority had many effects at the same time – protecting consumers, punishing offenders and creating confrontational atmosphere (Interviews).

The great majority of inspectors felt that fully exercising their authority did not always solve problems especially for the 'widespread offences', which was opposite to the views of the non-inspectors (Interviews-4,16,17,18,19,23,30). From inspectors' experiences, violations are due to many exogenous factors, such as the Thai health care system, care seeking

behaviour, and economical factors, as well as the impractical and unrealistic Act (see chapter 5). Therefore, their authority may, at best, have only short-term deterrent effects. They preferred to pay attention to the optimum use of their authority while using other means – their substituted measures – to bring compliance and sort out causes of violations (Interviews-2,10,12). In the majority's view, prosecution was not the right measure to solve the widespread problems, because most offenders hardly changed despite being prosecuted (Interviews-1,2,3,12,22,26). They felt that apart from not being helpful, punitive enforcement can possibly cause chaotic situations (Interviews-13,15,26).

For example, if the required presence of the pharmacist is to be checked more seriously, it could have the opposite result, and instead of ensuring that pharmacists stay in pharmacies, they may quit the job. Consequently, pharmacies would need to close down, and inspectors would have more work checking whether they were really closed or not. This would also adversely affect low-income people who cannot afford to go to hospitals or private clinics. Another example given was a collaboration with the police in 1994, when inspectors inspected one community well-known for selling traditional medicines, mostly non-registered, seven times in one year by an order of the then deputy-SG (Inspection records 1994). Each time about thirty offenders were arrested by the police and prosecuted. But the offences continued. Inspectors suggested that, given the popularity of the drugs, sellers with high profit were tempted to risk the chance of being caught. The majority of inspectors said that harsh enforcement was not the solution for this kind of problem and it was a waste of their time (Interviews-1,4,6,7).

Most inspectors interviewed were more willing to impose sanctions on 'sporadic violations'⁵ because they felt that this type of offence could be corrected (Interviews). Thus applying legal authority would be worthwhile to create deterrent effects. However, factors such as intention and penalty level were still matters of concern (see 5.1.3).

Inspectors also viewed their authority as a supportive tool in dealing with complicated cases such as the issue of fake or withdrawn drugs, when pharmacy owners could be good sources of inside information. They felt, a 'softly-softly' approach often works much better than an aggressive approach (Interviews-8,27,28). In those cases, they bargain by ignoring some minor offences to obtain the needed information.

⁵ Violations not regularly found in pharmacies. These include selling fake, non-registered, sub-standard or withdrawn drugs.

Most of the inspectors said that in deciding to take legal action or not, it is necessary to consider related factors such as harm caused and intention of offenders to decide whether they deserve the said penalty or not. Their decisions put high pressure on offenders: some committed suicide, some were imprisoned, some were corrupted by the police and so on. Most of the inspectors have heard or witnessed the greater-than-expected negative consequences that occurred to offenders (Interviews-2,10,12). Consequently, their decisions must be justified; risk and punishment was always weighed (Interviews-1,2,3,4,15).

'Authority should not be exercised excessively, but needs thorough consideration. If offences are conducted because of carelessness or lack of knowledge, offenders should be given opportunity to make correction. This is the important sense for inspectors.' (Interview-8)

'There was an offender committed suicide after being charged. Although this has been rare and that inspector did as it should be, he could not cope with it. The rest of us just gave him support the best we could.' (Interview-10)

'Once you apply your authority, there are consequences not only to the offenders but maybe also to their families and their children. So it must be used cautiously otherwise you may feel bad yourself.' (Interview-12)

For inspectors, authority is there no matter whether it is used or not (Interviews-7,8,12,21). In their views, 'a slap on the wrist' in most cases was enough, and that frequent visits without fully exercising their authority would reduce violation in pharmacy. But the problem was that nowadays they had much less time to spend on pharmacy inspection (Interviews-4,6,7,15).

'From my twenty year experiences, frequent visits would deter wrongdoings. The owners are afraid of being caught. But, whenever this monitoring is ignored, they know and slip away from the right track to illegal things that are usually tempting in terms of profit. Our visit is to remind them about the regulations.' (Interview-21)

4.4.3 Assault

Inspectors' authority does not only give them power over the regulated, it also causes them difficulties too. Inspectors sometimes face threats or assaults from offenders. This may be one reason forcing them to use their authority cautiously. Although only one official record about assault on one inspector was found (Inspection record dated 9 September 1982), a number of inspectors had had some experience (Interviews-1,8,9,11,18).

'Someone phoned me at home asking what I wanted, implying threats. I explained him the situation and told him that it was not possible not to take legal action. He phoned two more times. The last time I challenged him to talk face-to-face, otherwise I wouldn't keep quiet. But he quit calling since then.'(Interview-1)

'....while writing records, I saw the owner came from upstairs with his gun. He put his gun down on another table nearby. My team leader came to the man and talked quite a long time. I kept on writing and nothing happened.'(Interview-8)

For their own safety as well as to get the job done, most inspectors used the 'bargaining technique' and usually picked offences with moderate sanction levels, so that offenders would not argue, or feel outraged (Interviews-1,2,3,4,5,6,8,9,11).

'We need to balance everything: our responsibility, our safety and time constraint. If you take all offences, they may not let you and will try every possible means to stop you. You can see the consequence, it will take you longer time to convince them and to make sure they are not angry with you.' (Interview-2)

4.4.4 Discouragement

The great majority of inspectors and ex-inspectors felt that their work was not understood, acknowledged or recognised in any level in the TFDA (Interviews-1,4,8,11,12,13,21,30). A few said that neither the SG nor deputy-SG has been out on inspection with them (Interviews-4,7,21). Though they seemed to be relatively self-motivated, for a great majority of inspectors it was exhausting to use only their authority without support from other measures; they expressed their feelings as *'haven't been able to get rid of any single problem since working'* (Interviews-1,2,3,4,5,6,9,21,22,30). Inspectors felt that they received only lip service about the importance of their jobs from executives. Manpower shortage has never been a real concern, even while having policies focusing on inspection e.g. in 1997-1998 (Interviews-1,4,8,11,12,21).

Inspectors felt that they are the only group dealing with these problems, and that even the courts do not see the harmful effects caused by violations and usually deliver only lightweight punishments (Interviews-1,21).

'The main thing is that no one has ever been serious about violation in pharmacies. There has never been a case such as death from drugs dispensed

from pharmacies publicised in a newspaper. It is just a routine work. Inspect to fulfill the action plan. That's it.' (Interview-7)

A number of inspectors felt that they are the minority in the TFDA and receive less promotion than those who work on the registration side (Interviews). Despite their risk and difficulties in confronting the regulated, most of the promotion or training abroad has been given to pre-marketing officers (Interviews-4,21). Some braindrain occurred in 1989 - 1991 when inspectors were promoted to only level 6 whereas the other officers moved up to level 7. It took about two years to show the responsible organisation that inspection used technical knowledge as well as other kinds of officers, and by then the problem was solved (Interviews-8,21, Inspection Division Personnel Profile).

4.5 Summary

In this chapter, friction between the TFDA enforcement expectation and realities was identified. The TFDA gave out a mixed message. The TFDA did not show commitment to follow the legalistic rhetoric espoused by the Drug Act 1967. Though not endorsed by the Act, the TFDA has employed flexible measures such as giving warnings. Policy inconsistency and discontinuity regarding enforcement in pharmacy were indicated, especially in comparison to the well-established use of both compliance and deterrence enforcement approaches to drug manufacturers. The MOPH ethos, business influences, and professionalism were found to be against legalistic enforcement.

On the contrary, inspectors were expected to perform legalistically – taking legal action on all violations detected. No guidelines or other evidence was found allowing inspectors to use discretion. Neither is there any exemption in the Act itself. All inspectors interviewed perceived that they have no legal discretion. They also felt that they could be punished as negligent if they do not impose legal action on offences found. Yet they insisted that legalism was neither effective nor practisable. Consequently, inspectors risk themselves in using their professional judgement not to pursue legal action in cases considered not worthwhile, and not report these exempted cases to protect themselves.

Basically inspectors' views and attitudes were in contrast to the legalistic approach required. All inspectors interviewed shared similar ideas; they were doing a professional job not merely punishing offenders. They felt it was salient that inspectors should use their authority cautiously.

Chapter 5 - Inspectors, the Drug Act 1967 and the Inspection Process

'Just applying your authority is easy. But we are not doing jobs like robots. We have thoughts, we are pharmacists, we know about the problems in the medicinal drug and health care systems. Making decisions is the most difficult bit. You need to balance everything to make the most of it. Improvement should be gained at the expense of those offenders, otherwise you are just a slave to the regulations.' (Interview - 1)

From interviews, inspectors said 'going by the book' was easier to do than to think of how their authority should be appropriately exercised. Yet they risked using unauthorised discretion not only due to the context and their own attitudes indicated in chapter 4, but also because of imperfections they perceived in the Drug Act, which convinced them that a legalistic approach, or 'going by the book', is neither suitable nor able to increase compliance. Consequently, inspectors are only half-heartedly enforcing the 1967 Act. This chapter shows their conflicts with the 1967 Act and the TFDA enforcement management process that contributed problems in using inspectors' legal authority.

5.1 Inspectors and the Drug Act 1967

5.1.1 Inspectors' contribution to the legislative process

Contrasts between inspectors and non-inspectors were found in interviews. Inspectors unanimously agreed that the Act was difficult to enforce fully and caused enforcement problems (Interviews). However, those mainly involved in the drafting process thought differently. They insisted that the Act was suitable, the problem was enforcement (Interviews). In their views, if enforcement were more effective, pharmacy practices would have been in better shape. However, none had been out in the field. This reflected the compartmentalisation in the TFDA, and the lack of communication.

Traditionally, the TFDA Regulatory Affairs Unit, with lawyers and other experts appointed, is the main responsible unit for the legislative process in the TFDA. These expert opinions dominate the drafting or revisions with rare support from data in the field (Interviews-16,29). The 1967 Act adopted and amended the content of earlier Acts, which had been modelled

on the UK and the US with different health care contexts from Thailand (Tanasit et al 1996, Assawawilai 1999, Kiatying-angsulee 2000). Some interviewees regarded those involved in the legislative process as having a patronising attitude, 'Mothers know best', and a tendency to make 'over-protective' regulations to best protect consumers who are perceived to be not educated enough to protect themselves (Interviews-1,28,29).

The inspectors interviewed perceived the Act to be the gold-standard for the country (Interviews). Despite being the main enforcers, inspectors' contributions to drafting or revision of the Act had been minimal. Usually, one inspector represented the whole inspector group (Interviews, the Drug Act Revision Working Group meeting minutes 3/1996) and field inspectors felt that their experiences did not count in the TFDA administration or the legislative process (Interviews-1,21,27).

Those who are in charge of drafting and revising TFDA regulations felt their responsibility was only to draft a 'good law', how the law will be enforced was not included (Interviews-16,23,29). Lack of time was raised as the explanation.

'It should not be our responsibility to think through enforcement. Just putting the content is very overwhelming. Usually we run out of time and are under pressure to finish it as soon as possible.'(Interview-23)

The management process employed was top-down (Hongsamoot 2000). Decisions were made at the top level and relayed downwards, and consultation with inspectors was not perceived to be necessary (Interviews-16,23).

'They (inspectors) must follow the regulations once enacted despite their disagreement.' (Interview-16)

Minimal consultation with inspectors throughout the drafting and revision processes meant there was no regular channel or meeting to collect feedback or problems from the field, for discussion with higher ranking officers. Although inspectors can make their own observations and pass them through the hierarchical system (and one interviewee said this sometimes had a good response), this was unusual (Interview-29). Inspectors were also concerned that they would be labeled as non-conformists if they challenged those of higher rank (Interviews-2,3,6,26).

When there were new regulations such as withdrawal of certain drugs, inspectors were not informed thoroughly of the rationale or justification for new or revised regulations (Interviews-4,11,20,27). They themselves needed to learn from the ordinance, which did not state in length the reasons. There were times when the lack of clear understanding affected inspectors' decisions. The phenylpropanolamine (PPA) case was an example. In 2000 the TFDA withdrew drugs containing PPA based on studies in the US (MOPH ministerial order No. 1140/2000). The products had been popular because of their effectiveness and low price. Most inspectors were not convinced about the said adverse reactions (Interviews). Two inspectors said they stocked some of these products for their children (Interviews-15,18). Some inspectors said they would not take legal action against pharmacists or pharmacy owners in this case, as they felt unclear about the reasons (Interviews-13,18).

Figure 5.1: Inspectors inspecting the withdrawn PPA - contained drugs



Given the minimal participation and consultation, this prompted the enforcement gap between the Act as drafted and the Act to be implemented, because problems in enforcing the Act were not taken into account in the legislative process. The next section showed conflicts expressed by inspectors.

5.1.2 Inspectors and their conflicts with content of the Act

In the view of most inspectors, widespread offences have always existed and are difficult to bring to compliance because of the impractical and unrealistic nature of the 1967 Act (Interviews); as two inspectors expressed, violations occurred *'once the first drug Act started'*

(Interview-8), and 'you'll always find offences in any single pharmacy' (Interview-11). The offences perceived and often raised by inspectors as examples of unrealistic and impractical over-regulation, reflecting the unrealistic and impractical nature of the Act, are selling without licences and selling drugs other than permitted (Interviews).

As described in chapter 1, the group 'Household remedies', which are allowed to be sold freely, is too restrictive and not popular, being perceived to be ineffective. The problem is hampered by the Act, which allows commercial advertising for both the Household remedies and the Ready-packed drugs. While the Government Pharmaceutical Organisation, the main producer of the Household remedies, does not promote its Household remedies, private pharmaceutical companies heavily advertise their Ready-packed drugs. Common products advertised include three popular cold remedies: Tiffy®, Nutacold® and Decolgen® (The Ministerial Order 1987). In 1991, these three products had almost 100 million baht spent on TV advertisements (Working Group on Thai Drug System Analysis 1994; 571). Because of heavy advertising, most small grocery stores sold the three drugs, mistaking them for Household Remedies (Interviews-1,6,11,18) (see Figure 5.2).

Figure 5.2: Manners in which groceries sell drugs without licences. Drugs sold are in circles.



This caused conflict for inspectors. In their views the list is over-regulated, and those drugs for which commercial advertising is allowed, should be placed on the Household-remedy list. *'If they were not safe enough, the TFDA should not approve the advertisement'*, one inspector said (Interview-6). The massive number of grocery stores violating the law was difficult to cope with. The items of drugs sold, from the inspector's standpoint, were relatively safe and in other countries they are OTC drugs (Interviews-4,7,15).

Consequently, inspectors do not regard this contravention as serious, because they do not think these drugs are harmful unless they are sold wholesale, or with other potent drugs (Interviews-1,3,4,5,6,7,8,11,20,21,27). However, they are contravening the Drug Act by not acting on those drug sellers. This is indicated by the high discrepancies between inspectors' records and the independent study result shown in Table 1.3.

Another conflict for inspectors regards the 'Ready-packed Drugs'. This group of drugs is perceived by inspectors to be so under-inclusive that *'no type B pharmacies can make a living if they strictly follow the Act'* (Interview-13). Consequently, most inspectors usually charge pharmacy owners only when they carry prohibited drugs that are potent drugs, such as prescription drugs or injections, or carry too many items such as more than five types of antibiotics (Interviews-1,4,5,9,11,26). This means that they illegally allow drugs they perceive to be safe and necessary to be sold in type B pharmacies.

All inspectors interviewed disagreed with the TFDA in using only inspection to tackle these widespread violations (Interviews). They felt that it was neither effective nor efficient. First, those who violated the Act were the majority, but inspection could cover and prosecute only a small portion (Interviews-1,4,26). The coverage of pharmacy inspection ranged from 12.1–21.3 % (Table 5.2), and with insufficient manpower, it was unfeasible to prosecute all the violated pharmacies. Second, violations continue unless businesses are closed, which is impossible to oversee. Third, the majority of Thais, especially the poor, need the service provided by pharmacies, and inspectors feel sympathetic to their needs (Interviews-8,11,13,26).

Without clear policy statement or complaints, the great majority of inspectors would not make citations on such widespread violations as they might be blamed or sued for being selective (Interviews-2,3,6,13). However, policies sometimes had no effect if the inspectors did not agree with the principles. In 1995, inspectors were ordered to inspect all type B pharmacies, and enforce those violating the law. The number of type B pharmacies inspected jumped

from 41 in 1994 to 659 in 1995, but the citation rate remained almost same (14.6% compared to 13.2%, respectively) (Prosecution records 1994-1995, Wittayapiboon 1995) suggesting that inspectors were passively resisting the law they disagreed with.

5.1.3 Inspectors' conflict with sanctions

5.1.3.1 Penalty level and imprisonment sanctions

Sanctions determined by the legislative process were largely out of the hands of inspectors. Heavy punishment was viewed by executives as a measure to gain better compliance and show a sense of responsibility. Many SGs asked the TFDA regulatory officers to increase sanction severity, which the officers said they could not argue against despite knowing that it was not theoretically correct or suitable for many drug act violations (Interviews-16,23). Comparison of penalty levels between the Drug Act 1950 and 1967 supported the interviews (see Annex 13).

In spite of pressure, inspectors still displayed reluctance in making decisions to impose sanctions on offenders, especially imprisonment, while non-inspectors argued that courts seldom imprisoned offenders unless cases were very severe such as producing fake drugs (Interviews-16,23,25). The usual sentences were probation for one or two years with a low fine (e.g. 700 baht); but in non-inspectors' view, it was essential to show tough enforcement for deterrence.

'It is necessary to be tough to set an example, otherwise no one would respect the Act.' (Interview-17)

Inspectors knew sentences might be relatively lenient, but they still felt that high penalties would not create as much deterrent effect as expected, unless they were used with other measures such as timely sanctions, certainty of sanctions or campaigning prior to enforcement (Interviews-4,19,26). Many inspectors expressed concerned about overkill or being inhumane (Interviews-2,3,8,12,20), while non-inspectors thought differently. This conflict may have been because non-inspectors were distanced from the 'offenders', whereas inspectors had to face them.

In reality, as explained by most inspectors, the situations did not go as smoothly as felt by non-inspectors, and there were predictable adverse consequences (Interviews-2,3,4,8,11,12,13,14,15,18,26). For example, in some cases offenders would be investigated

by the police, and unless put on bail, they would be detained at the police station. Inspectors were informed directly from offenders or heard from other inspectors that the police officers involved charged offenders 'under the table' (Interviews-1,4,6,8,11,12,15,20,24). These illegal charges ranged from 50,000 - 400,000 baht, which inspectors felt offenders did not deserve compared to their breach and the harm caused (Interviews- 8,13,27).

Before deciding to make citation of offences with an imprisonment penalty, inspectors usually balanced the evidence of intention, scale and impact of violation and harm caused (Interviews). Some inspectors suggested that the TFDA should use incremental strategies. For example, a fine for the first time transgression in cases that are not severe or where harm is not evident and keep imprisonment sanctions only for repeated severe offences (Interviews-1,27).

5.1.3.2 Across-the-board character of penalties

The Act, in the view of many inspectors, contained too many across-the-board sanctions regardless of the various degrees of offences. In many cases pharmacies are identified in the same penalty range as manufacturers and importers (see Table 5.1).

Table 5.1: Charges and penalties on manufacturers, importers and drug sellers

| Charges | Penalties |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Manufacturing, importing or selling without licence | Imprisonment no more than five years and a fine of no more than 10,000 baht |
| Manufacturing or selling drugs to licensees not allowed to sell the drugs | A fine of 2,000 – 5,000 baht |
| Manufacturing or selling drugs during absence of professional-in-charge | A fine of 1,000 – 5,000 baht |
| Selling or importing fake drugs, knowingly | Imprisonment of 1 – 20 years and a fine of 2,000 – 10,000 baht |
| Selling or importing fake drugs, unknowingly | A fine of 1,000 – 5,000 baht |
| Selling or importing sub-standard drugs, or withdrawn drugs, knowingly | Imprisonment no more than three years and a fine of no more than 5,000 baht |
| Selling or importing sub-standard drugs, or withdrawn drugs, unknowingly | A fine of no more than 5,000 baht |
| Manufacturing, importing or selling non-registered drugs | Imprisonment no more than three years or a fine of no more than 5,000 baht or both |

Source: The Drug Act 1967

A number of inspectors did not agree with these across-the-board penalties because selling can apply to international wholesalers as well as to small grocery stores in remote villages, yet all are subject to one penalty range. Non-inspectors argued that courts would sentence

according to the scale of violation, but this uncertainty discomforted inspectors (Interviews-1,2,4,13,15,27). They gave examples of punishment regarding advertising (Interviews-3,30). Small companies selling traditional drugs were fined at the same rate as of those big companies advertising modern medicines with much greater coverage (Interviews-3,30).

They felt that penalties should be more specific and not highly reliant on the court's judgement. Their concerns were that offenders might be punished more than the inspectors perceived they deserved (Interviews-1,26). Consequently, across-the-board sanctions made inspectors focus more on drugs they felt were more dangerous, and ignore offenders carrying less harmful drugs (Interviews-1,6,11,12,26).

5.1.3.3 Sanctions in relation to harm caused

From interviews, harm or risk was of major concern to inspectors (Interviews-1,3,4,8,9,11, 12,27). Using their judgement, often based on the relationship between the level of sanctions and harm caused, was difficult because most contravention do not result in clear harm. The case of expired drugs is one example of uncertain harm that causes inspectors' lax decisions (Interviews-2,3,12,26). In their views, although drugs are supposed not to be effective beyond their expiration dates, manufacturers usually set expiration date three to six months shorter as a precautionary measure. Harm will depend on other factors too, such as types of active ingredient, how long they have been expired, storage conditions and manufacturers' standards.

Uncertainty especially from consumers' utilisation of self-medication and lack of adequate data forced inspectors to use their professional background and experiences with regulatory control when confronted by violations (Interviews). Box 2 gives examples of inspector's concerns regarding harm. The more evidence of harm, the more willing inspectors were to make citations. However, there were always other factors taken into account in making decisions.

Box 2 Inspectors and their concerns related to harm***Smuggled drugs***

Many of the modern drugs smuggled into Thailand are from Pakistan or India because of their cheaper prices. Inspectors were divided on this offence and made different decisions (Interviews-1,2,6,23,27,30). Some felt that registration indicated quality, so they tended to be tough on non-registered drugs. Others felt that registration was just a legal requirement and did not represent quality; most of the smuggled drugs were qualified, so they were more lax.

In recent years, laboratory analytical results have showed that the smuggled modern drugs have changed from having good quality to containing lower than standard or almost no active ingredients (Interviews-4,15,26,27). This phenomenon has changed inspectors' views on non-registered drugs. Those who used to be lax are more serious (Interviews-1,4,27), resulting in more violation cases presented, as indicated in Table 1.3.

Steroid tablets

Professional judgement played a role in inspectors' conflict with the regulations in the case of steroid tablets. These drugs, though potent and can cause harm, are cheap and effective. Some inspectors believed that the consumption pattern clients used, off and on, is not as harmful as long-term use, on which the side effects are based (Interviews- 1,4,11,26). For them, selling steroid tablets without prescription was acceptable as there may be emergency cases for the poor who cannot afford to go to hospitals or private clinics, such as asthma, and in such cases steroid tablets can be life-saving. This was unacceptable to a few, but as there is little empirical evidence to prove their harm in the current situation, inspectors normally did not charge this offence.

Sale of withdrawn drugs

Inspectors had less sympathy with this offence because drugs are mostly withdrawn due to problems of efficacy and safety (Interviews- 3,11,12,20,27). Usually, names of the withdrawn drugs are circulated to pharmacies or some are publicised in newspapers. However, inspectors still tended to be reluctant to prosecute in two different instances. First, when the drugs were newly withdrawn. Second, for withdrawn drugs that are not potent or dangerous or not well-publicised. From their experiences, pharmacies owners are often not able to check the withdrawn drugs by themselves (Interviews-3,11,12,20,27). The ministerial orders, though circulated to each pharmacy, are mostly specified in terms of generic names (chemical names) instead of brand names. A number of pharmacy owners know drugs only by tradenames and cannot identify generic names, which are usually in English. The orders do not state brand names because those brand names can be re-used after changing formulations (The Drug Act 1967). This made inspectors feel that the problem is partly due to the regulation itself, and that the owners deserve lenient decisions (Interviews-3,11,20).

In contrast to the above examples, inspectors mentioned one case where they had serious concerns despite there being no legal control. This concerned the 'sale of conditional registered drugs' - drugs, which are still on clinical trial in Thailand, and restricted to use only in hospitals or clinics. However, these drugs sometimes appear and are sold in pharmacies. Since this is a new phenomenon, it is not covered by the Act. Nonetheless, inspectors felt that this issue should be under strict control due to the potential danger the drugs may cause. But as it is not covered by the Act, inspectors have to take legal action on other transgressions instead, for example regarding records, despite having punishment only a fine of 2,000–5,000 baht (Interviews-18,27,30). One inspector (Interview-18) said, *'it's better than letting them go freely.'*

5.1.3.4 Sanctions and offenders

Basically, inspectors felt offenders should be given the opportunity to correct their offences, except for those committing serious transgressions or repeated violations (Interviews-1,3,4,8,12,20). Offenders should not be punished 'to death' or be unable to run their business. The heavier the sanctions are, the more consideration inspectors take before making decisions.

For sporadic offences, inspectors tend to be stricter, but from interviews, most inspectors wanted to be sure that the breaches were conducted knowingly. Therefore, they paid attention to quantity, location of products found, history of the pharmacies, manner of selling, and owners' co-operation in answering their questions (Interviews). Some said that if the products were found hidden in drawers, they tended to take the offence seriously (Interviews-1,4).

Most of the inspectors shared the view that mistakes can unintentionally or recklessly occur in pharmacies where there are thousands of drug items (Interviews-1,4,12,26). Selling fake drugs and selling expired drugs were always raised by every single inspector, regarding both their harm and the certainty to take legal action (Interviews). Yet, most of the time their final decisions were asking pharmacy owners to destroy those products (Interviews-1,4,8,10,11,12,15, 27,30). They believed that most offenders committed offences because of recklessness, and they felt that the imprisonment penalties were too heavy.

'From my experience, most of the time the sellers don't know, even though some of fake drugs are noticeable. They just simply don't take a close look at their drugs.'

Mostly they trust their wholesalers. Sometimes fake drugs do look exactly the same as the original ones, making it hard for even us to differentiate.' (Interview-27)

Unclear harm when accompanied with heavy sanctions made inspectors more sympathetic to offenders, especially those who conducted widespread transgressions (interviews-2,3,4,6,10,12,20). They perceived that this kind of offenders violated the law because the Act is not realistic.

'No one has ever paid attention to causes of problems. So, the problems are there forever. Repeated violations occur because there is no solution. Pharmacy owners take those risks. I felt sorry for them, and afraid that taking legal action continuously will lead them to jail or licence suspension.' (Interview-22)

Many inspectors felt that offences can happen due to lack of knowledge (Interviews). By law, pharmacists are required to check the quality of products, but in reality it is usually left to pharmacy owners who often do not have health professional backgrounds. Therefore, inspectors felt the owners should not be fully punished (Interviews-5,12,27,30). Although inspectors generally feel sympathy towards offenders, this was not the case for easily identified violations, such as in the case of non-registered drugs, which can be detected by checking labels, and withdrawn drugs that had been publicised in newspapers (Interviews-2,3,4,30).

Regarding fake drugs, inspectors sometimes did not take legal action against sellers right away, in order not to alert the producers (Interviews-24,27,28).

'If fake drugs are found, I won't tell the pharmacy immediately. But, I will try to trace back and collect more data to estimate the magnitude of the problem. I prefer to investigate more to crack the whole gang. However, it depends on types of fake drugs. If they are potent, sure, we can't be that quiet.' (Interview-27)

Occasionally, inspectors do have conflicts in charging those who break the law. For example, they do not want to charge the elderly, but at the same time they do not want the elderly to sell drugs that might harm clients (Interviews-6,10). Or they do not want an infringement to continue but, at the same time, do not see how punishment can stop them (Interviews-1,5,6,9,10).

5.1.3.5 Difficulties in prosecution

The 'zero-discretion' approach applied to inspectors means that they, in theory, are supposed to take all cases to the TFDA for consideration. However, the Act was found to be one of the barriers to prosecution, resulting in a number of cases not being brought to the TFDA prosecution process.

The 1967 Act is controlled by the Penal Code 1956 clause 59, which says that 'A person shall be criminally liable only when he commits wilfully....' (Interviews-1,12, the Penal Code 1956). However, 'wilful' is not defined by the Drug Act. This means that selling or possessing only one illegal tablet is considered violating the Act. But, quantity and manner of committing violation are seriously considered by the VAC, the police and courts.

All inspectors interviewed expressed the view that they would not take legal action against cases where evidence did not strongly indicate 'wilful' action (Interviews). Such cases, from their own experiences, were likely to be dropped or discontinued at the VAC, the police or court level, which they felt was a waste of time and resources. Besides, they often felt stigmatised as incompetent (Interviews-1,30). When intention is obvious, such as putting stickers over expiry dates, where large quantities of expired drugs were found or deterioration is evident (Interviews-1,3,4,6,15), they felt more confident about making a charge.

In fact, illegal actions performed willfully or unwillfully are recognised by the Act. The unwillful offences are subject to only a fine. Nevertheless, in reality they are not easily differentiated and caused conflict between inspectors and the VAC. Some inspectors expressed that they risked themselves being mistakenly suspected of corruption in specifying that offences were conducted unwillfully, yet such specification was usually turned down (Interviews-18,27,30). Those who were in the VAC process explained that they wanted the police, who properly learn how to investigate thoroughly, to make that judgement (Interviews- 16,18).

The definition of selling that covers possessing is difficult to apply in the case of expired drugs. If there is no proof of sale, pharmacy owners always appeal that though the expired drug are on dispensary shelves, they would take a look before dispensing, and cases are usually dropped, so most inspectors felt discouraged from making charges on expired drugs (Interviews-1,13,20).

In the absence of any guidance for decision-making in the manuals or guidelines (Inspection Manuals 1979, 1989, 1998, Inspection Training Curriculum 1992–1999), inspectors concluded from their seniors and their experience the conditions that would make cases solid enough for prosecution (Interviews-1,4,12,13,20). The conditions comprised issues that could be considered collectively or individually. They were quantity of illegal products, physical appearance of the products, location found, and actions disguising flaws. Consequently most offences were dealt with by inspectors' substituted measures and were not brought in for the VAC consideration (Interviews).

5.2. Inspection working procedures

5.2.1 Reporting and recording systems

Inspection work procedures indicate greater workload if legal action is taken: more paper work and activities (Inspection SOP 1996). However, inspectors claimed that this has an effect only on minor cases (Interviews-2,11,12,27). In doing inspection, there are three official results – no offence found, offences found are subject to the inspector's warning, offences found are subject to VAC consideration – each of which has different cycles of management.

Cases with no offence are the easiest. Inspectors only fill in the 'Inspection Form' and the 'Sample Form' if samples are collected. Samples must be kept in a container sealed and co-signed by pharmacy owners and inspectors. The container must be labelled with the same details written in the Sample Form – details of brand name, active ingredients, quantity collected, batch number, expiry date (if any), manufacturers, importers (if any), pharmacy address and collection date. Usually one inspector fills the forms while another checks drugs in pharmacies. In cases where offences found are subject to a warning, inspectors must write down the details in another form, the 'Interrogation Form', in addition to the Inspection Form. The cases are then passed to the DCD Director for endorsement and forwarded back to the same inspectors to follow-up.

The most complicated process is when legal action is taken. Inspectors need to spend at least two hours on this, compared to the 20–30 minutes spent if no offence is found. They are required to fill in the Inspection Form, the Interrogation Form, the 'Product Seized Form' (if illegal products are taken to the TFDA) or the 'Product Detained Form' (if illegal products are detained at the pharmacy). Often, the illegal products need laboratory test results to be used in court, so the Sample Form is also needed.

If offenders resist, it takes longer to convince them, because forms are supposed to be co-signed by inspectors and offenders. Records are then considered official evidence. If offenders do not co-sign, inspectors need to ask the police to step-in or to have a policeman co-sign as a witness that there is no prejudice against offenders (Interviews). Back at the office, inspectors must summarise and report to the Chief of Inspectors to proceed to the Head of the Post-Marketing Section and the Director respectively for further processes.

Each case can take inspectors at least five working days if it is sent to the police (Interviews-1,4,12,15,27,28). Inspectors who make charges are appointed to make official complaints on behalf of the TFDA (Inspection Manual 1998). Then the appointed inspectors go to the police station and hand-in all evidence of violations and give all the details, but it takes time before appointments are set (Interviews-1,4,20). If offenders defend, inspectors need to go to court too.

All cases from the latter scenario are sent to the VAC. If the VAC decides to give a warning, cases are sent back to inspectors to follow-up to ensure that violations have been corrected (The 1991 VAC Guidelines). The whole system of reporting, prosecution and follow-up (see Figure 5.3), some inspectors admitted, made them turn a blind eye on some minor violations in order to reduce their burden (Interviews-11,26,30). Often, it takes more than a year (except for very serious offences) to complete follow-up due to their occupation with other work that has deadlines, GMP inspection and complaint cases (Interviews-4,27). Having follow-up cases stocked up is seen as incompetence (Interview-26). Therefore, inspectors often act in a way so as not to create follow-up.

'Sometimes, if the cases are not serious, I prefer to use substituted methods so that the cases would not pile up in my cabinet.' (Interview-1)

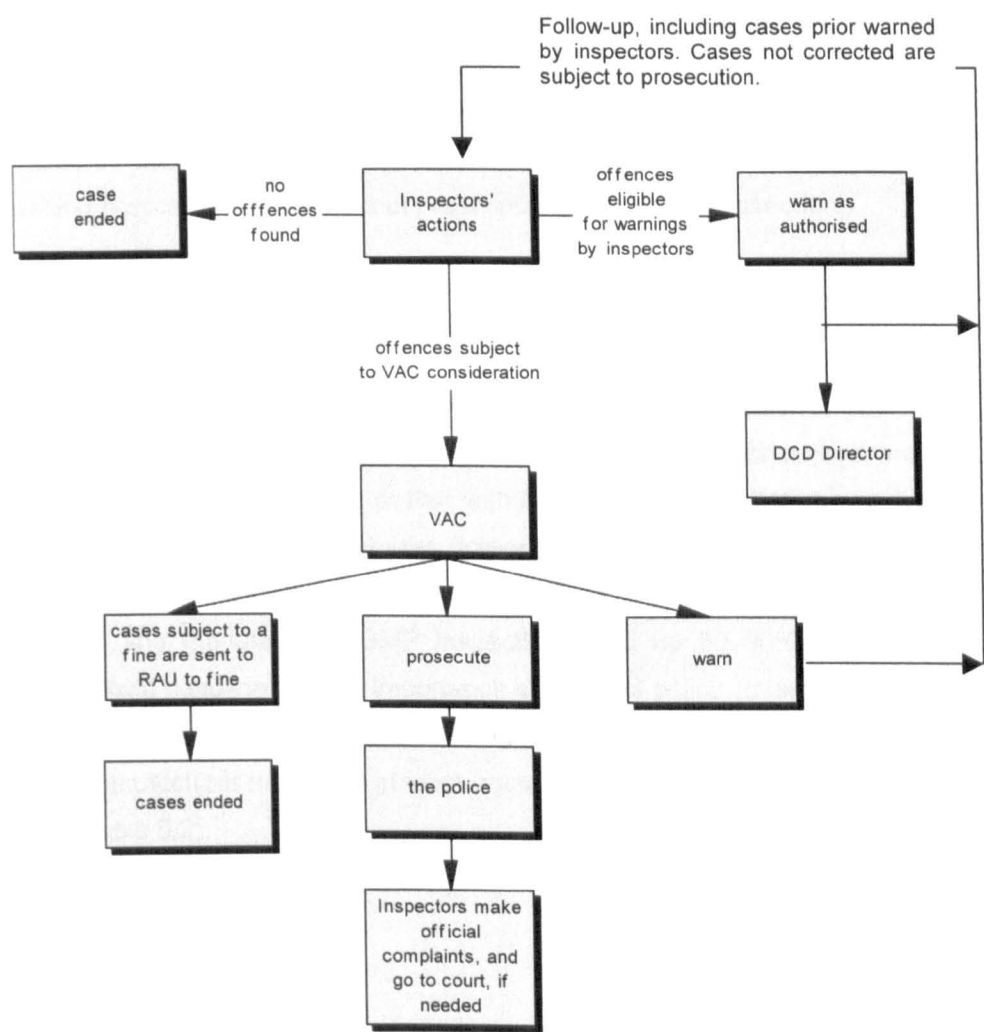
'For every warning, we need to follow-up and report. I feel that it is better to just tell them that they have committed violations, sometimes bluff them about the next inspection. This saves our time for more serious cases.' (Interview-3)

One inspector said that though authorised to give written warnings, he preferred giving verbal warnings, to avoid follow-up.

'Imagine, if I record, I need to get back again for follow-up, and these issues are so insignificant. Lots of work is waiting, why should I spend much time on it? I just verbally warn them.' (Interview-26)

If corrections are not completed, the VAC can order inspectors to take legal action at the next visit, as illustrated in Figure 5.3. Either way means more work for inspectors. From inspection records, the followed-up cases showed that the offences were corrected with no newly found offence (Inspection records 1980-1996). However, given the matter of the process, it is not clear that this reflected better practice by pharmacists or pharmacy owners, or inspectors turning a blind eye on small offences.

Figure 5.3: The follow-up cycle



5.2.2 The evidence collection practice

In addition to filling various forms, the procedure required for evidence collection is complex. Traditionally inspectors need to gather evidence by themselves; the requirement has never been revised for at least twenty years (Interviews-8,9,11). For example, if there is a complaint of selling drugs without a pharmacist present, inspectors cannot just go there and take photos to show the selling activities (SOP 1996). They must get someone to pretend to be a client and use a marked banknote to buy drugs (SOP 1996). Evidence for prosecution includes the drugs sold, the marked banknotes (which indicates proof of sale) and other related material. Due to lack of budget and difficulty in getting surrogate clients, inspectors themselves sometimes pretend to be customers seeking illegal products (Interviews-2,10). The risky nature of this technique, and the fact that there are not many inspectors to take turns as simulated clients, make this technique possible only with serious offences (Interviews-2,3,4,11). Such actions also raise ethical issues, which, in a stronger legal system, could be used against inspectors. Consequently, offences requiring proof of sale, such as selling prescription drugs without prescriptions, are rarely prosecuted.

5.2.3 Work prioritisation

It is the same group of inspectors who monitor manufacturers, importers, pharmacies and grocery stores that sell medicinal drugs without licences. The prioritised work is that publicised by the media, complaints, or that with deadlines, in conjunction with seriousness of offence no matter what type of premises (Interviews-1,2,3,6,19,21, Inspection SOP 1996). By this categorisation, there has been much less attention given to pharmacies compared to manufacturers. The manufacturer GMP inspection used up 60–90% of inspection time because of its fixed deadline¹ and its importance in terms of policy (Interviews, TFDA Annual Plans and Annual Reports 1989–2000). Coverage of manufacturer inspection has been over 100% (each manufacturer inspected at least once), while coverage of pharmacies has been far less (see Table 5.2).

¹ The TFDA issue GMP certificates that are valid for only one or two years. If certificates expire, manufacturers cannot sell drugs to public hospitals as a part of regulations. Thus, practically, GMP inspection is likely to be the first priority followed by complaint inspection, pharmacy and importer inspection the last priority.

Table 5.2: percentage of manufacturers and pharmacies inspected compared to the total licences

| Year | % inspected of the total number | |
|------|---------------------------------|----------|
| | Manufacturer | Pharmacy |
| 2000 | 129.3** | 12.2 |
| 1999 | 202.8** | 21.3 |
| 1998 | N/a* | N/a* |
| 1997 | 55.4* | 3.3* |
| 1996 | 106.9** | 18.0 |
| 1995 | 103.8** | 17.6 |
| 1994 | 102.2** | 13.8 |
| 1993 | 118.7** | 16.6 |
| 1992 | 220.2** | 14.3 |
| 1991 | 402.6** | 12.1 |

* re-organisation in mid-1997 caused some work interruption

** were inspected more than once a year

Most inspectors prefer GMP to pharmacy inspection as it is a more professional and more educational process, while pharmacy inspection tends to be enforcement activities (Interviews- 1,2,3,4,13,19,21,24,25,27). One inspector said,

'You can see changes in manufacturers, they are willing to improve themselves. It is less confrontational than working with pharmacies.' (Interview-26).

In addition to professional preference, a number of inspectors expressed other reasons for leaning towards GMP inspection. Some inspectors felt that inspecting manufacturers was more important than the others, as they are origin of drug quality (Interviews-4,8,21,30).

Many inspectors felt problems in pharmacies are gradually decreasing. There are more pharmacies owned by pharmacists, from 13% in 1967 to 30% of all type A pharmacies in 1999. The increased numbers means fewer problems about selling out of the registered duty hours, absence of pharmacists and selling drugs without pharmacists' supervision (Interviews-1,3,13,21). Besides, the Board of Pharmacy also checks those pharmacies claiming to have a pharmacist staying all day long, which supplements inspectors' work (Interviews-1,2,3,12,19,25).

A number of inspectors pointed out the importance of pharmacies in creating direct hazards to consumers (Interviews-4,12,18,19,27,29). They felt that situations of drug quality in manufacturing had stabilised. One analysis showed that in the last ten years the number of sub-standard drugs has been maintained, and the remaining problems are due to the use of

low quality raw materials and lack of R&D, which does not involve enforcement (Anon. 2001).

'It may be time to switch the focus on areas other than GMP since it is not much a problem now as it used to be.' (Interview-29)

Being increasingly overwhelmed by GMP inspection from the increased number of GMP certified manufacturers, inspectors have less time for pharmacy inspection. Consequently, they focused more on the coverage than taking legal action, if it was not necessary. They felt that *'just visiting'* has significant deterrent effect (Interviews-4,12,13,15,21,26).

5.3 Support from management system

Once a law is enacted, managing its implementation is crucial, otherwise the law remains intention only. The data obtained suggested some potential management aspects were not conducive to legalistic enforcement in pharmacies.

5.3.1 Salary and welfare

Inspectors receive the same salary as other civil servants. As pharmacists, they also receive a special government supplement, which is given to civil servants in certain professions to maintain them in the government system. However, the total salary is still not competitive with the private sector. The only welfare the TFDA provides for inspectors is life insurance, which started in 1998, after repeated requests. Other MOPH officers do not have this kind of welfare. A number of inspectors felt that they did not have sufficient support and incentives from the government system in comparison to their risk (Interviews-3,6,7,10,13).

All inspectors but one had extra part-time jobs to reduce wage discrepancies. Four out of twelve current inspectors work as part-time employees in hospitals in the evening, four work in pharmacies and three help their families run pharmacies. They are neither barred by any rules for having double roles nor required to declare their interests. Their direct involvement can be advantageous in gaining insights into what is going on in the regulated business. But it can also make inspectors feel sympathetic towards pharmacy owners, ignore offences or support the status quo to protect their own benefit.

'I, myself, find it is hard to go and work at my registered pharmacy every day. It is tiring both the journey and to make yourself compatible with the owners. How can I enforce other pharmacists to abide by their responsibility, while I can't.'
(Interview-4)

Having two jobs is not only a problem of conflicts of interest, but it possibly affects how they work too. One inspector pointed out that there were times inspectors did not take full legal action in order not to arrive late at their part-time work places. Further, it was mentioned that for cases requiring out of office hour inspections, it was difficult to get sufficient inspectors because they were occupied by their part-time jobs (Interviews-21,24,30).

5.3.2 Advancement

In terms of annual advancement, which concerns salary increase, inspectors are subject to the three appraisal categories of the civil servant performance evaluation: a rare decrease in salary, with or without other sanctions; a common one-step salary increase for satisfied performance; or one and a half or two-step salary increase for excellent performance. The great majority of officers fall in the second group because the quota allows not more than 10% of total officers in each division to fall into the third group. The performance criteria were found to be subjective and to rely on manager's decisions (the Civil Servant Performance Appraisal Order 1995).

Most inspectors interviewed could not tell how they were appraised. But they seemed not to be bothered by the system, although some said that only half of those graded as 'excellent performance' were accepted (Interviews-4,13). Most of them believed that their managers tried to give everybody a chance by rotation and compromising.

There is another kind of advancement, which is far more competitive than the annual advancement appraisal. Inspectors start from level 3 and can move up to level 7 without ceiling if their capabilities meet specifications required by the government (the Civil Servant Performance Appraisal Guideline 1995). Higher competition is seen in moving to levels 8, 9 and 10. Decisions are made on behalf of 'the Selection Board' (the TFDA Performance Appraisal Guideline 1997), but the Director of the division with vacant positions usually has the strongest voice (Interviews). Appeals can be made but are unusual (the TFDA Performance Appraisal Guideline 1997, Interview-8).

Most inspectors felt that decisions were made based on the manager's satisfaction and the rotation system (Interviews-1,4,26). Again, no one could confidently tell what criteria were used (Interviews). The subjectivity of the appraisal and promotion systems could prevent inspectors from using their legal authority in two ways. First, they may try to conform to their managers and their colleagues. Being in step with others is important in the Thai culture as well as in the Thai bureaucratic system (Interviews-2,3,26). They do not want to be viewed as over-zealous, authoritarian or hard-hearted especially when criteria for job appraisal and promotion are subjective (Interviews-2,3,5,14,30). Consequently, individuals' decisions are heavily patterned by pre-existing ones (Interviews), which tend to be lax.

'I don't want to be either a black sheep or a swan in group of crows, depending on one's standpoint. The image is with you forever, and definitely affects your promotion.' (Interview-3)

Second, they were not confident that they were well protected if they used their authority straightforwardly (Interviews-15,18). Enforcement affects the business sector, and politicians (for example Minister of Public Health Ministry) or high-ranking officers (such as SG and Directors) as indicated in Chapter 4. Businessmen may put pressure on inspectors and the system. To avoid negative impacts, inspectors would have taken only serious offences. Consequently, the current systems of appraisal and promotion possibly induce inspectors to be less confrontational to both their superiors and the regulated to protect themselves for their career progress.

Regardless of the uncertainty in advancement, inspectors earned self-growth through their work. The GMP inspection was in a better position than pharmacy inspection, which has much less training (Training Programmes, DCD, 1997-2000). Inspectors were systematically trained locally and internationally on the principles of and how to conduct GMP inspection, which is a world-wide principle. This could be one reason why inspectors paid less attention to the subjective appraisal and promotion systems. In contrast, punitive enforcement is used dominantly in pharmacy inspection without comprehensive training programs standard.

Currently, eight out of twelve inspectors are in level 8 and they realised the difficulties of reaching level 9, since there are only nine positions for the whole TFDA. Working as GMP inspectors, they can be promoted in the international GMP system from local GMP inspectors to international GMP inspectors; or they can move from GMP auditors to be auditors in the ISO (International Standard Organisation) system, then be local lead assessors and international lead assessors respectively. Furthermore, the knowledge gained

can be used even after retirement as consultants or auditors or experts of international organisations such as WHO.

Overall, advancement provided by the civil servant system was not conducive for pharmacy inspection, and probably hindered the use of legal sanctions.

5.3.3 Monitoring system

Inspectors were monitored in a hierarchical style. They were subject to their Chief Inspector, Head of Post-Marketing Control Section and the Drug Control Division Director respectively. Managers are usually overwhelmed with administrative work including meetings. However, they sometimes went out to help inspectors inspect when short-staffed (Interviews). There is no re-inspection system or any system to check the quality of inspections except through inspection reports. The rotation system, where inspectors take turns geographically, stopped four years ago when most activities turned to dealing with manufacturers rather than pharmacies (Interviews-4,27). Most inspectors felt that being familiar with their catchment would be more useful for improving manufacturers' practices because they can follow-up and assess changes, which usually take many months (Interviews-13,27).

Generally inspectors were monitored from reports and checked on how many inspections were carried out compared to annual targets (Interviews-4,11,15,21). However, most inspectors accepted that though there is no punishment if the target is not met, they felt obliged to meet the target (Interviews). There was a shared feeling between inspectors and their managers that inspectors did the best they could (Interviews-4,21). Managers interviewed said that although they had not been out very often, news usually leaked if inspectors misbehaved (Interviews). This was because, in their view, the community was small and connected in the system (Interviews-22,23,24) .

The importance of monitoring was not recognised. Only two inspectors saw the importance of a good monitoring system as a way to encourage just and standardised performances (Interviews-22,29).

'Monitoring system is key to enforcement. If inspection is not monitored properly, it will lead to under-enforcement. Basically, no one wants to exercise authority. It is much more easy to take no legal action.' (Interview-22)

A strong monitoring system exists only on complaint inspection and issues appearing in newspapers (Interviews-3,6,10, Inspection SOP 1996). These cases are followed up by either the TFDA Complaint Committee, the DCD Director or SG (Interviews-1,4). Inspectors are required to report the results within certain periods, delays in action are negatively considered (Interviews-2,4). These cases are usually treated seriously and inspectors usually impose fully their authority (Interviews-4,6,13,24).

5.4 Summary

This chapter investigated support for the full use of inspector's legal authority through the Drug Act 1967 and inspection enforcement management system. A number of constraints existed in many forms.

Inspectors were found not whole-heartedly enforcing the Act. The unrealistic and impractical content of the Act was felt by the great majority of inspectors as the cause of the widespread violations, and inspection should not be the only measure aimed at bringing better compliance. Heavy sanctions as well as across-the-board sanctions, viewed by executives as of greater deterrence, caused inspectors difficulties in taking legal action. A number of factors such as harm caused and intention were used to justify their decisions. In addition, inspectors clearly demonstrated a tendency to be sympathetic to pharmacy owners. The TFDA legislative process, with minimal participation and consultation of inspectors, probably exacerbated this implementation gap. Antagonistic views between inspectors and non-inspectors were found in a number of instances. Besides, the Act possessed contents difficult to use in courts.

The inspection work procedures and management were discovered not to be conducive for legalistic enforcement. Fewer chances for career advancement, and lower importance of pharmacy versus GMP inspection, difficulties in collecting evidence, the complicated process in prosecuting offenders and the weak monitoring system were all hindrances against legalistic enforcement. Further, because of double roles as both professionals-in-charge and inspectors, conflicts of interest may exist.

Chapter 6 – Discussion and Recommendations

6.1 Introduction

Data revealed from independent studies and inspection reports suggest that many offences that break the 1967 Drug Act do not get officially reported. This formed a main research question for this study: why inspectors failed to fully exercise their legal authority by not reporting offences committed by those in pharmacies. The failure to use their legal authority could mean that the public who buy medicinal drugs directly from pharmacies may be prone to harm caused by illegal practices such as selling sub-standard drugs, expired drugs and non-registered drugs.

The study focused specifically on inspectors' points of view in expressing what they perceived as problems preventing them from using their legal authority. This study is not intended to defend or judge inspectors' views and attitudes, but to understand the issue from their viewpoint. Such understanding is fundamentally important to policy makers if enforcement in pharmacy is to be improved. The main theme of this study was thus on policy implementation focusing on actors. The approach of the research followed Walt and Gilson's policy analysis framework (1994), which was used to explore four factors - actors, content, process and context - which would illuminate the research question.

In this chapter, from the triangulated data, I will draw together and discuss the main findings arising from the study in order to explain why there is a discrepancy between violations committed and those reported by inspectors. Findings are presented together with recommendations and suggestions for future research with reference to the objectives of the study.

6.2 Discussion of findings

Regulation is one way that governments seek to protect the public. Inspectors are regulatory agency enforcement arms to ensure law adherence. To protect consumer safety in

consuming medicinal drugs, the TFDA is responsible for enforcing the Drug Act 1967, which falls within criminal law.

In exploring the big picture, this study indicates a gap between the *intent* of legalistic rhetoric enforcement and the *actual* use of flexible enforcement in the TFDA. The strain between the uniformity required by policies or laws and the diversity exercised by implementors is not unique to the TFDA (La Fave 1962a, Lipsky 1980, Pressman and Wildavsky 1984, Jacobson and Wasserman 1999), but problems in other inspectorates may not be as big as that in the TFDA. For example, inspectors in other regulatory authorities are allowed some level of flexibility, unlike the TFDA enforcement strategy, which requires its inspectors to 'go by the book' – charging all offences. Since the inspectors do not agree with this legalistic approach, it seems that they do not exactly follow what is required of them.

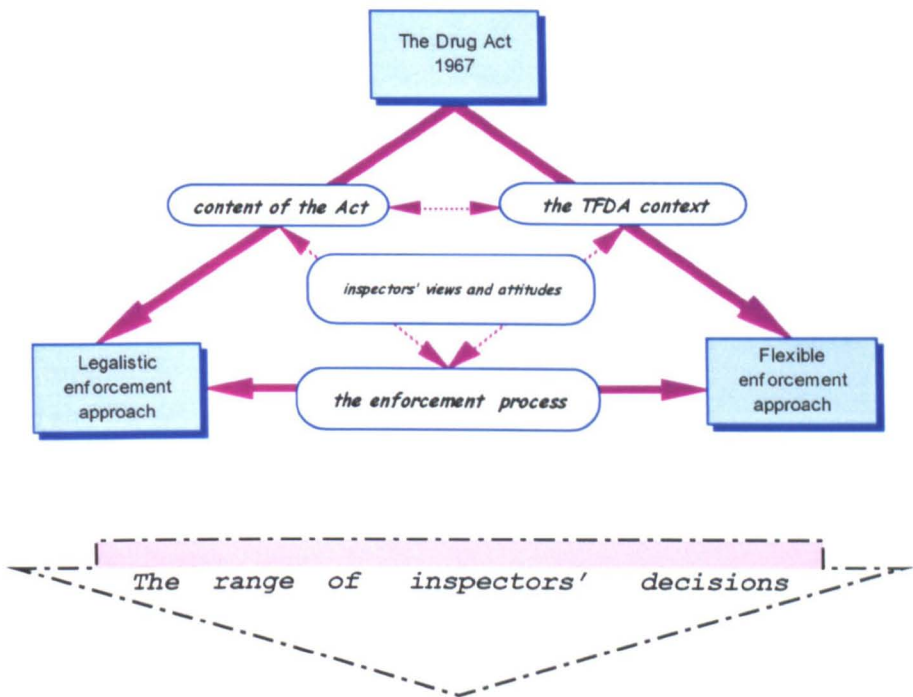
The gap in the TFDA is so large that most offences are not dealt with according to the rules laid down. Often inspectors use their professional judgement in unofficial ways, and not according to the 1967 Act and the TFDA administration. Cases reported and thus appearing in inspection data were a small fraction of the total offences detected. In general, only the most serious cases were considered as deserving prosecution, while cases perceived by inspectors as minor, or where harm was not clear, or evidence was not solid enough for prosecution, were dealt with unofficially. The outcome of this phenomenon is not clear, but drawbacks are predictable. First, decisions are mainly dominated by inspectors' personal attitudes rather than being structured by the TFDA expectations and legal systems, so inconsistency possibly exists. Second, cases are treated unofficially and off-the-record, so they are unlikely to be followed up. This means there is less chance to set stricter enforcement if offences are not corrected. Third, data missing from the enforcement system means difficulties in strategic planning. Fourth, the actions possibly make lawbreakers feel that enforcement is negotiable or open to compromise. Finally, all the drawbacks would add up and erode the deterrent effects created by the 1967 Act.

The situation in the TFDA is not encouraging, although inspectors seem to be able to justify their actions. They feel that they put themselves at risk in using discretion, but they cannot perform according to the rules. Consequently, inspectors are more comfortable in working on GMP inspection where less confrontation and better advancement are obtained; pharmacy inspection is perceived as routine work and is conducted mainly to meet the annual target.

The problems within the TFDA enforcement of pharmacies, reflected in this study, reinforce the notion that successful implementation requires conducive conditions, otherwise it will be adapted by the 'street-level bureaucrats' (Lipsky 1980, Jacobson and Wasserman 1999) no matter how precise policies are, such as in the form of regulations as suggested by this research. At 'street level' inspectors have clearly adapted their practices to suit their own perceptions.

The four elements, following Walt and Gilson's (1994) policy analysis framework, help to explain the implementation gap. There is no single issue that causes the gap. Figure 6.1, adapted from Walt and Gilson's framework (1994), demonstrates the gap, interrelationships among the four elements involved and the result of the gap. The reasons contributing to the implementation gap leading to the failure to use legal authority can be summarised into three interrelated main areas: friction in enforcement practices; inspectors' conflict with the Drug Act 1967; and constraints in the TFDA enforcement management system. For the purpose of explanation and discussion, these are presented separately.

Figure 6.1: The summarised situations of inspectors' exercising of their authority



6.2.1 Friction between the two enforcement approaches: legalistic and flexible

Compared to other regulatory agencies, this study suggests that the TFDA appears to enforce its regulations less strategically. Generally, regulatory authorities show disparate use of authority, with the balance towards bargaining and advice giving (Rhodes 1981, Hutter 1986, Braithwaite et al 1987, Cotterrell 1992, Baldwin 1995). The US Environmental Protection Agency bargains with both polluters and states and local officials in order to reach tolerable decisions and secure compliance (Anderson 1975). In Britain prosecution by regulatory authorities is relatively rare, being not more than 5% of the offences detected (Carson 1970, Gunningham 1974, Cranston 1979, Vogel 1986). In Australia, despite a shift towards enforced self-regulation and conciliation after 1970, one study showed seven types of regulatory agencies that ranged from being stringent enforcers to being largely conciliators, but none used only punishment measures (Braithwaite et al 1987). The mixed strategies used are hoped to enhance organisational flexibility in coping with the complex and uncertain enforcement situation and to reduce the burden of inadequate levels of staff.

Theoretically, legalistic enforcement is the predominant TFDA strategy for pharmacies. This is in contradiction to the notion that legalism alone does not function well where the majority of the regulated are lawbreakers (Packer 1968), which is the case for pharmacies in Bangkok. Enforcers can be easily demoralised due to the overwhelming number of cases, seeing no hope for improvement, and feeling indifferent to offences (Hudson 1997, Bagaric 2001). This is mainly due to the limits of punishment in changing offenders' behaviour, since it is known that most offenders do not change their behaviour even if punished (Bandura 1969, Bagaric 2001, McLaughlin and Munice 2001). Besides, legalism can create very difficult situations for regulatory agencies. The insufficient numbers of staff means that only a minor proportion of the regulated are inspected and charged, which may become selective and cause resentment among the regulated. Offenders can appeal, political influence may be involved and the enforcement activity may finally be cancelled, which has occurred in the TFDA. This undermines inspectors' authority.

Legalism does not promote organisations' efficiency in many instances, and it seems that TFDA inspectors recognise this and adjust their decisions. First, most regulatory agencies normally have inadequate levels of staff to inspect frequently enough to ensure regulatory observance. The TFDA inspectors can at best achieve an annual average of pharmacy inspection of only 21.3% of total pharmacies in Bangkok. This indicates the extreme

insufficiency of staff numbers. Coverage would be even lower if legal actions were applied to all offences detected because prosecution takes a much longer time – three to five days per case compared to the 30 minutes if offences are not reported (Baldwin 1995, Interviews). Second, severe and non-severe offences would be treated the same, with no prioritising, if legalism is used. Twelve inspectors to deal with 5,038 licensed premises plus outlets selling drugs without licences strongly suggests a need to prioritise the actions of the TFDA.

Most regulatory agencies depend on inspectors' expertise and experience in the field to enhance their capacity. Inspectors are allowed certain levels of discretion so only cases considered by inspectors to deserve full prosecution are taken up. The US Occupational Safety and Health Agency divides violations into five levels based on severity, and inspectors can impose different fines on-site for violations in the lower levels. Inspectors of the Royal Pharmaceutical Society of Great Britain can give verbal warnings for minor infringements, but more serious cases are referred to the Society's Council for further consideration. The TFDA inspectors' use of their professional judgement, in fact, is in line with many regulatory agencies as the way to maximise the efficiency of organisations, except it is not officially accepted.

Ironically, the legalistic rhetoric, though required by the TFDA for its inspectors, is not followed by the TFDA itself. Numerous examples of infringement of rules were found in this study – from the establishment of the VAC, the VAC decisions, cases brought to the NDC and the GMP inspection policy (see sections 4.1, 4.2 and 4.3.2). These measures seem to circumvent strict adherence to the laws, and reflect many aspects of the Thai context, acknowledgement of low levels of knowledge among the regulated, the Thai social characteristic of compromising, the MOPH ethos of 'help not punish', and the existence of powerful business influences. The situation suggests that in reality the Thai context is not suitable for strict enforcement. Besides, the general situation in the TFDA shows a decline in enforcement interest. The TFDA itself has become a multifunction organisation with a greater budget towards education. Inspector staff numbers have been relatively eroded over time in comparison to other types of staff. Overall, the general context does not encourage inspectors to use the harsh enforcement required by the Drug Act 1967. By promoting a legalistic enforcement of pharmacies, but actually allowing considerable flexibility, the TFDA gives out a mixed message, creating friction for the inspectorate.

Policies are sometimes not explicitly expressed but are reflected in the organisation's decisions (Anderson 1975). This was found in this study. The TFDA annual policy

announcement, and particularly in certain years, e.g.1997–1998, promoted strict enforcement. But enforcement has had minimal impact, since the TFDA policy is not vigorously implemented (Hongsamoot 2000). On the contrary, inspectors have adopted the flexible TFDA decisions as their policy, such as the VAC exemption in taking legal action on grocery stores selling drugs without licence. Another example was the victory of the RPA in the four main arguments with the TFDA (see 4.4.1.2). Although in principal, independence of regulatory agencies should be unimpaired, it is not always the case. Inspectors perceive the pharmaceutical business to be powerful, and may want to avoid difficult situations by performing strict enforcement only if necessary. Political influence does not exist only in Thailand, but seems to be universal for regulatory agencies. Many studies in the US show the changes between deregulation and re-regulation during 1970s to 1990s due to the change of presidential administration (Barnett 1990, Dempsey 1994).

Friction with legalistic enforcement is apparent not only with the TFDA administration, and the general Thai and MOPH context, but also within the inspectorate body. This study suggests that the TFDA inspectors share the educational line of other inspectors, that they are doing a professional job not merely taking offenders to court. Consequently, they often use bargaining techniques or education rather than heavy-handed measures. The legalistic rhetoric is, thus, contradictory to inspectors' intentions. The bureaucratic administration that requires rule-bound decisions is clearly not compatible with how inspectors view themselves, which is often a problem found in regulatory agencies (Anderson 1975, Morgan 1997, Fincham and Rhodes 1999, Handy 1999).

Drawing from this study, it seems that the nature of the inspection job is full of friction, anticipated and felt; inspectors do not like confrontation with powerful businesses, methods for enforcing regulations, hostile reactions from the regulated, or to feel themselves unwelcome at pharmacies. In general, they try to decrease confrontation by taking into account the objectives of their job and their own safety. Threats or assaults do not occur only with the TFDA inspectors but with other inspectors as well (Frank 1984). The safety issue, another clash with the legal rhetoric, may be one cause of inspectors' cautious use of authority.

In general, inspectors are viewed as a bridging mechanism to reduce pitfalls occurring between regulations and management systems (Rhodes 1981, Bardach and Kagan 1982, Hawkins and Thomas 1984). However, this concept does not seem to be recognised in the TFDA. Based on this study, I would argue that the rule-bound nature of the TFDA does not

benefit the agency, or take advantage of inspectors' expertise and experience in the field. Regulatory agencies would be better off designing enforcement strategies that are practical and effective.

Regulatory authorities perform in context, such as business influence and culture, and within limitations in their administrations and punishment measures. Flexibility is thus generally adopted as a measure to cope better with the complexity in the real world, and to overcome problems caused by regulations and management. The results of this study suggest that the TFDA principle of legalistic enforcement clashes with the context and inspectors' views and attitudes, and consequently does not produce effective enforcement as intended.

6.2.2 Conflict with the Drug Act 1967

This study suggests that inspectors' conflict with the 1967 Act is an essential factor in not using their legal authority, and reinforces the notion that implementors are, in fact, active participants in the implementation process (Hjern and Porter 1981, Walt 1994, 1998, Walt and Gilson 1994) and they adjust policies along the implementation process (Lipsky 1980). This section shows that implementation deficits occur when implementors' views and attitudes are incompatible with the organisations' goals. It is thus essential that implementors understand and agree with the policy they are implementing (Sabatier 1986, Hogwood and Gunn 1984), and that in formulating policy, implementation is seen as a strategic part of the policy process (Walt 1994). For effective policy implementation, it is necessary that potential problems be considered in advance of implementation itself and that appropriate procedures are designed into the programme (Hogwood and Gunn 1984, Cotterrell 1992, Baldwin 1995, Walt 1998). However, this does not always happen since the process of making policy is often separated from the implementation process.

This separation is evident in the TFDA. The various Drug Acts have been drafted with minimal contribution from inspectors. Consultation of inspectors in the enforcement process is also rare. Those involved in law making view inspectors as mere implementation 'agents', which may be a result of the top-down administrative style used in the TFDA (Sabatier 1986), and may reflect power centralisation in the bureaucracy. The bureaucratic organisational structure of the division of labour may also contribute to high compartmentalisation in decision-making (Collins 1994, Morgan 1997). Further, the fragmented TFDA management process has contributed to the separation between policy formulation and implementation (Hongsamoot 2000). This separation may explain some of

the antagonistic views expressed between those non-inspectors who normally have stronger voices in the legalistic and regulatory process, and inspectors who view themselves as professionals who know the situation best 'at street level' and feel their decisions are based on better rationale.

Generally, people with a power orientation – inspectors – will have different goals and ideologies from those with a role orientation – lawmakers (Handy 1999). Inspectors want a practical not utopian law that is based on the Thai situation. Lawmakers, on the other hand, want a 'good law', modelled on Acts from developed countries (Tanasit 1996, Aswawilai 1999). They are not involved in responsibility for implementation. This difference in goals and roles would cause conflict (Fincham and Rhodes 1999, Handy 1999), as indeed this study shows. In addition to conflict, the distrust expressed in the interviews on both sides (for example, in the issues of giving discretion to inspectors and the VAC decisions) also jeopardises the possibility of successful implementation, which usually involves responsibility and trust of involved officers (Lane 1987).

Lack of constructive interaction and negotiation between the two groups does not benefit organisations (Pressman and Widalsky 1973, Lipsky 1980) and affects implementation. The separation between inspectors and non-inspectors in the TFDA means that the Act is mainly based on legal experts' views, and tends not to be responsive to the real situation. Problems in executing the Act in the field are not considered. At the same time, inspectors lack the opportunity to learn the rationale and justification behind regulations, which would enhance their understanding and help their decision-making. Lack of consultation inflates inspectors' conflict with the Act and reduces their agreement and commitment to enforce the Act.

Inspectors' disagreements with the contents of the Act and sanctions proposed deserve attention. Many studies in Thailand support inspectors' perceptions that the list of Household remedies should be expanded, and that Ready-packed drugs should be included in the Household Remedy list (Chuengsatiansup et al 2000). Efforts in using regulation to change drug consumption behaviour against the established beliefs without using education measures have been found ineffective and sometimes caused new problems due to products shifting (Sringernyuang et al 1991, Jarupach et al 1992, Bhutta and Balchin 1996).

Sanctions can deter not only offenders but also inspectors. Imposing criminal punishment to 'white-collar' offenders is usually not straightforward. First, it has been difficult to impose criminal sanctions against high-status offenders due to their roles in the society (Benson

2001). Second, inspectors, not only the TFDA inspectors, always justify their decisions as well as differentiating offenders in relation to sanctions imposed by regulations, instead of complying with laws which usually adopt 'the worst case scenario' principle (Baldwin 1990, Kerwin 1994). Nevertheless, the lack of clarity and uncertainty of harm caused by white-collar crime does not allow easy justification for inspectors and even for courts. It has been argued that tobacco control in the US is not always effective because the police and courts do not believe in its danger despite heavy educational campaigns (Jacobson and Wasserman 1999).

With unclear and uncertain harm caused by pharmaceutical products (Abraham 1993), plus the socially accepted status of offenders, this would inevitably mitigate against sanctions to be imposed on offenders by inspectors. Consequently, as seen from this study, heavy sanctions tend to induce reluctance in inspectors to formally note offences. Inspectors seem to use the concept of proportionality as used in criminal justice, for example an offender should be handed a sentence that is in accordance with what his/her act deserves, and mitigating circumstances should be taken into account (Bagaric 2001, McLaughlin and Munice 2001). This creates conflict between TFDA lawmakers and executives who want to promote greater deterrence across-the-board, and inspectors who usually take many factors into account to differentiate offenders and justify their decisions.

Using discretion and justification is viewed an important part of exercising inspectors' authority to minimise drawbacks which laws or enforcement processes may possess (Rhodes 1981, Bardach and Kagan 1982, Hawkins and Thomas 1984). The nature of justifying decisions leads to more conflict in enforcing the 1967 Act when offences need to go to court, that is, need to be dealt with outside the TFDA sphere. The majority of TFDA inspectors shared the feeling with other inspectors that criminal sanctions are usually too heavy, especially for first-time offenders. The across-the-board nature of the Act – sellers, manufacturers, importers assigned in the same range of penalty despite having different scale of impact and let the court decide – aggravates this conflict. Across-the-board sanctions are seen as highly undesirable by inspectors – but not by managers and executives – because of their uncertainty. Inspectors cannot be certain of what penalty offenders will incur. Uncertainty is an underlying cause of stress and may induce easier decisions (Handy 1999). In such cases inspectors may control results by using their own discretion, justified by a different set of criteria than those set out in the law.

6.2.3 Constraints in the TFDA enforcement management system

Management is responsible for organising the conditions and methods of operation so that people can achieve their own goals best by directing their own efforts towards organisational objectives (McGregor 1960). Successful implementation, thus, relies on good and appropriate management, and where implementation is largely seen as a technical process deficits occur (Walt 1994). Exploration of the management system in this study revealed no aspect that supported the TFDA's legalistic rhetoric. Pharmacy inspection is not prioritised. Most of the inspector's efforts were spent on manufacturer's GMP inspection, which provides better professional self-growth and career ladders for inspectors. The TFDA legal process requires much more work, especially cases with imprisonment. Evidence required for prosecution is complex and daunting. The monitoring system, in general, is weak. Job promotion and appraisal are perceived to be subjective and inspectors felt that they could not necessarily be free from business influences.

Considering those constraints, I would argue, based on the result of the study, that the TFDA seems to perform enforcement as a symbolic activity, rather than aiming to decrease violations. In addition to the management constraints, enforcement at the pharmacy level is mainly left to inspectors to decide with little systematic involvement from the agency; inspection is used as the main enforcement strategy, despite inadequate numbers of inspectors, and the system does little to support or promote inspectors.

In most countries, inspectors usually play important roles due to their expertise in the field (Blackie 1970, Rhodes 1981). This is in big contrast to the TFDA inspectors, who are separated from lawmakers and executives who make decisions on their behalf. They are not recognised for their expertise in the field, while those working in administration have higher status. Their perceived inferiority in relation to their peers affects their morale and motivation. With this kind of mindset, strict enforcement is unlikely to be pursued because of the confrontation and adverse effects possibly occurring. The effects may be considered as negative reinforcement which produce two actions – escape or avoidance – which could deter their decision to take legal action (Fincham and Rhodes 1999).

The TFDA administration is fragmented and it is job-oriented rather than problem-based management (Hongsamoot 2000). These administrative problems cause difficulties in pulling together different parties to solve problems. From my participation in the inspector's annual plan meeting, the discussions were mainly based on how many inspections were to be

conducted without considering using resources from other divisions. Participants were all inspectors, except one from the TFDA Evaluation Section, Technical Division. Participation and consultation between different groups are rare (Hongsamoot 2000), which, in terms of management, is not fruitful for organisations (Fincham and Rhodes 1999).

Lack of participation in the VAC decision process is another area of conflict, and this study found that the VAC has a closed system of decision-making, which excludes even those inspectors who have reported cases. Ambiguity in the VAC decisions, with minimal inspector participation and without feedback information, could demotivate inspectors as well as create tension and distrust (Fincham and Rhodes 1999, Handy 1999). In comparison, the adjudication process used by the Royal Pharmaceutical Society of Great Britain is more open. Apart from the committee members, inspectors, defendants, as well as media are present.

While in many countries, inspection is considered a prestigious, well-paid and highly competitive job (Blackie 1970, Kelman 1981, personal communication), TFDA inspectors have the same (relatively low) salary as ordinary civil servants. This means that many take a second job to reduce the discrepancy between their public sector wage and what they might earn in the private sector. Most inspectors are professionals-in-charge of pharmacies or drug importers. These two roles are not compatible and possibly lead to stress due to role conflict (Handy 1999). To decrease the stress, inspectors may try to rationalise their decisions. One inspector said 'No one can exactly follow the Act, even I can't do it myself, how can I enforce other people do it?'. That reaction, plus the fact they are themselves acting as pharmacists out of hours, would be one explanation for their lenient views in certain violations. Although the 1996 WHO Guideline for Inspection of Drug Distribution Channels does not clearly address the issues of independence and conflicts of interest, having a double role in such cases, inspectors can be seen as having a vested interest in weak enforcement, which may possibly lead to biased decision-making. Having double roles is particularly restricted in the US under the 'Ethics in Government Reform Act 1989', which prohibits federal employees from engaging in outside employment or any other outside activity that conflicts with their duties, especially with financial interest (Roberts 1994).

The TFDA inspectors' roles are not documented, but the preferred role, suggested from interviews, is likely to be as educator rather than enforcer, compromising rather than sticking to the rules. Their adopted role, possibly passed on through inspectors' on-the-job training, is clearly against the TFDA legalism expectations. While on-the-job training is good in the

sense of creating high cohesion among inspectors, it may also create high peer influence or groupthink and lead to less reflexivity (Fincham and Rhodes 1999). So, it seems that inspector's decisions are quite similar, leading to what Foucault calls 'normalising judgement' involving 'the establishment of limits of accepted behaviour, standards to be achieved' (Foucault cited in Fincham and Rhodes 1999; 263). Those who comply are rewarded, but anyone falling outside the routine is automatically defined as deviant. In addition, decisions made in the same way are less likely to be criticised and ease the tension that may exist in using discretion (Silveria 1998). Peer pressure has a strong influence and decisions made can be adopted without thorough or critical thinking on the impact on enforcement. This is indicated by inspectors' reluctance to confirm the effectiveness of their substituted measures – the measures they have perceived as practical, morally accepted and been applied over 20 years.

Monitoring and evaluating inspection work is usually difficult due to the lack of appropriate criteria (see section 2.5). The TFDA role ambiguity may hamper these weaknesses. The historical use of discretion by inspectors and the problems of under-recording without scrutiny show the weak TFDA management systems of monitoring and evaluating job performance. Weak monitoring systems can lead to ignorance or laxity (Scholz 1994). From interviews, inspectors admitted that they were more stringent on complaint cases than routine ones because they were monitored.

The complicated prosecution process also plays a part in discouraging legal action, especially in cases that inspectors considered not serious. From their experience, it can take five workdays per case. This is significant when they try to meet the targets set for them in the annual plan, targets which they feel are already overloaded. Consequently, cases with evidentiary problems are not brought to the TFDA; inspectors have learnt from their senior's or their own experiences that such cases are not usually prosecuted. This is done without approval from the TFDA but with the inspector's sense of saving time and resources, and to avoid being stigmatised as incompetent.

An adequate level of staff is one condition for successful implementation (Hogwood and Gunn 1984). Lack of staff is a fundamental problem in regulatory agencies, including the TFDA, because inspection is a labour intensive job. The problem drives regulatory agencies to employ various strategies to compensate for lack of staff, as discussed in 6.2.1, but this is not the case for the TFDA. The insufficiency of staff is unlikely to be solved in the short run due to the Thai government downsizing policy. In combination with other constraints in the

TFDA enforcement system, the TFDA inspectors are convinced that using their professional judgement together with their substituted measures is the best strategy in the light of insufficient staff.

6.3 Conclusion

This thesis has reviewed the sensitive issue regarding the use of inspectors' authority. The study emphasises the importance of choosing the particular blend of strategies that fit with the agency's enforcement problems and context, and shows that where this does not occur a clash or conflict arises, resulting in deficits in implementation. The research suggests that implementors' understanding and agreement with policy should be of great concern to prevent adjustment or ignorance, their conflicts should be recognised and minimised. Implementation should be considered an interactive process, not merely 'top-down' activities; communication between implementors and lawmakers should be built into the whole process of law making and enforcement. Enforcement should be integrated as a part of legislative process where potential problems are considered in advance, together with the view of using other supplementary measures to achieve effective enforcement. The appropriate enforcement management process is important to help inspectors work in accordance with the organisation's goals and objectives.

Inspectors reflect the aforementioned problems in terms of what they take into consideration in their decision-making. Analysis from the empirical data shows that there are certain technical factors inspectors collectively used to decide their actions. The factors involved are demonstrated in Table 6.1 below. To induce inspectors to use more of the official sanctions, the TFDA administration should aim at ameliorating the factors and their conditions in the far right column of Table 6.1, which are elaborated in more detail in 6.4.

Table 6.1: The salient factors considered by inspectors before making decisions

| Factors | Decisions | |
|-------------------------------------------------------------|-----------------------------|-------------------------------|
| | Likely to take legal action | Unlikely to take legal action |
| 1. Harm or risk of offence | Clear and certain | Unclear or not certain |
| 2. The perceived impact of violation on health | High | Low |
| 3. How easy the offences can be identified by the regulated | Easy | Difficult |
| 4. Level of legal control | High | Low |
| 5. Penalty level | Fine | Imprisonment |
| 6. Feasibility of prosecution | High | Low |
| 7. Type of inspection | Complaint | Routine |
| 8. Burden to inspectors | Little | Heavy |
| 9. Effects of sanctions | Cause changes | Cause no changes |
| 10. Type of offence | Sporadic | Widespread |

6.4 Recommendations

Four main potential areas of recommendations drawn from this research are suggested to decrease the implementation gap. They are built up around the four elements of Walt and Gilson's policy analysis framework.

6.4.1 Inspectors' views and attitudes

This study shows that inspectors' decisions rely on their professional knowledge and experience to make judgements rather than what is required by the 1967 Act. Peer influence through on-the-job training, the Thai national social value and socialisation process are likely to play a part in their attitude to the work that they do as well as their decisions. However, none of these issues facilitates the use of legal authority. Inspectors should be constantly tailored in relation to TFDA expectations as to how they should operate and the underlying rationale or reasons. Clear perception and clear roles are essential for organisations' expectations to be met (Vroom 1967). These are aimed to decrease the friction seen in this study. However, this will occur only when the TFDA makes clear its enforcement style, which is one recommendation suggested in 6.4.4.

Regardless of TFDA enforcement style, inspectors should be more regularly and structurally trained, not only for work procedures as it is now (Inspection Training Curriculum 1992-1999) but also for the technical issues focusing on harm, risk or health impact of violation. This is to

overcome inspectors' tend-to-be lax decisions usually found in cases with unclear or uncertain harm indicated in this study. The TFDA may need to shift its research theme from situation analysis (Srikamol 1997) towards exploration of the cause of problems and health impact in the Thai communities. Such exhaustive knowledge and information does not only help inspectors make more appropriate judgement, but it could help in balancing peer pressures among inspectors and enhance standardised decisions.

Apart from more structured training programmes, inspectors should be given time for regular meetings among themselves to discuss problems they encounter. This includes workshops or meetings for drug inspectors across the country. Regular group discussion would not only help inspectors release pressure and get encouragement from their peers, but would help bring confidence to their decisions as well as to discuss for better alternatives (Kelman 1981).

Stressing the significance of the job is another way to strengthen inspectors' motivation to overcome the difficulties and deficits in their work. The TFDA training programmes have never aimed at this type of objective. For example, how inspection can save people's lives from using fake, deteriorated or expired drugs. This kind of training is used in the US Occupational Health and Safety's inspectors (Kelman 1981). However, this needs to be cautioned not to create too strong feeling against the regulated.

Pharmacy owners and pharmacists should be regularly trained by the TFDA especially on regulatory issues such as how to check labels for expiration date or registration number. Information to urge regulation compliance should be constantly disseminated to pharmacies such as a list of offences and penalties, recent problems found in pharmacies or guidance for rational use of medicines. The already co-operative style between the TFDA and the RPA would be helpful in arranging such training. This aims not only to decrease offences but to assure inspectors that the regulated have enough regulatory and technical knowledge, which would give them more comfort in imposing legal actions.

The problem of inspectors having double roles needs to be re-addressed, though the issue was dropped more than twenty years ago due to difficulty in recruiting and maintaining inspectors. Independence is required not only for the regulatory agency but also for its inspectors to make unbiased judgement. However, solving this problem will be difficult and can only be tackled over the long term. One way will be to recognise inspectors as different from other civil servants and pay them higher salaries. Another way would be to promote a

law that forbids inspectors from playing a role in pharmacies. The potential impact of the double role on enforcement should be discussed and consulted in detail among all concerned, especially with the Bureau of Budget and Bureau of Civil Servants for legal amendment in the future.

6.4.2 The Drug Act 1967

The Drug Act was found to be constraining enforcement mainly in two instances – its content and its sanctions. Some aspects of the content need revision, and could be applied rapidly; for example, expansion of the Household Remedy List and the Ready-packed List, and revision of the prescription drug list. Other issues need to be re-visited and may need more strategic measures; for example the issues of selling drugs out of the registered duty hour, selling drugs without supervision of professionals-in-charge and absence of professionals-in-charge.

Penalties need to be re-designed so they facilitate enforcement. The study has shown how heavy sanctions, especially imprisonment, are barriers to imposing inspectors' legal authority. The intention of having a strong law should be traded against the possibility of using it. This is not to suggest that the Drug Act should abandon its criminal nature, which stresses the importance of severe danger caused by some violations and provides a deterrent effect. Nevertheless, its disadvantages should be taken into account and more appropriate sanctions and penalty levels should be devised.

Offences and sanctions should be classified in relation to their severity and harm caused, instead of imposing across-the-board sanctions as now occurs. This may reduce the unwillingness to impose sanctions from all parties concerned. In terms of sanctions, drug sellers should be considered separately from manufacturers and importers due to the scale and impact of violations. Sellers should also be differentiated between retailers and wholesalers. The differentiation would bring more certainty and confidence to inspectors that punishment would be within the scope expected and would satisfy their feelings about proportionality.

The evidence or potential harm of drugs that are highly controlled, such as prescription drugs, should be made clear to inspectors in order to convince inspectors that sanctions are necessary. Training, as mentioned in 6.4.1, can do this. Besides, new regulations should be

interactively addressed to inspectors through meetings, not simply through papers as it is now.

The current criminal sanctions cause conflict for inspectors. Other regulatory authorities try to minimise dealing with the police or court in many ways. Using adjudication and imposing disciplinary sanctions is one measure, punishing only when violations are conducted repeatedly or there is a persistent failure to correct violation is another one (Kelman 1981). Giving regulatory agencies authority to fine or giving warning that appears in criminal records for the first-time transgressors of offences that carry an imprisonment penalty should be considered. The Thai government should equip a wider range of sanctions, leaving the serious offences with criminal sanctions for greater deterrence. More varied sanction measures would not only reduce conflict because offenders need not go through criminal prosecution procedures perceived by inspectors to be too heavy, they would also shorten the time spent in the prosecution process. Resources would be used more efficiently too.

The adjudication process is used in the TFDA through the VAC. However, as it is not legitimised by the Act, the VAC cannot function in full and relies on the police and courts to a certain extent. If legitimised and authorised to impose disciplinary sanctions, the VAC would be more advantageous to the TFDA enforcement. However, the VAC would need to be open and transparent in its dealings in order to gain credibility and acceptance from both inspectors and the public.

Some regulatory agencies decentralise authority to inspectors, by grading offences. This increases efficiency as well as enhances inspectors' motivation. However, it may not be suitable for the Thai context where the public tends to be cautious about the abuse of power unless there are clear measures to balance the possibility of misusing such power. Again, the TFDA needs to make such measures open and ready to be monitored.

However, changing or revising laws takes a long time. In the meantime, to alleviate constraints caused by the Drug Act 1967, new management measures could be helpful.

6.4.3 The TFDA enforcement management process

6.4.3.1 The inspection process

In the light of the inadequate number of inspectors, their work should be more clearly prioritised, and redundant work should be reconsidered and reduced. From my observations,

too many reports are demanded of inspectors. Paperwork is the task that inspectors like the least about their job (Interviews, Kelman 1981). Instead of writing at least three report forms per case, reports could be integrated and reduced to only one form.

The current follow-up system is daunting. Decisions regarding minor cases should be treated as information to create a better targeting system for inspection but should not be followed-up. Efforts should be pinpointed on those who have previously committed offences as a prioritised group. The current routine follow-up practice makes a number of minor cases pile up and causes inspectors to feel that their job is unfinished, and then discourages them from making records even in cases where they can issue a warning.

Evidence needed for prosecution should be revised to make it easier to collect. The need for proof of selling should be re-considered otherwise the difficulties in data collection itself are the barrier to exercising authority. Administrative staff should take over making appointments with police, preparing documents related to the cases, and so relieve inspectors of some of the time-consuming but essential administrative parts of pursuing violations. This could save inspectors time to spend on inspection as well as decrease their frustration in dealing with the police.

6.4.3.2 *Participation from Inspectors*

Fragmentation and compartmentalisation in the TFDA bureaucratic administration needs to be overcome to minimise the antagonistic views between lawmakers and law-enforcers. Participation and consultation with inspectors in any changes, revision or promulgation is strongly suggested. With increased participative roles, inspectors would gain more self-esteem and thus be more motivated and enforce regulations more whole-heartedly (Fincham and Rhodes 1999). Instead of having one inspector represented in the TFDA legislative process, arranging a workshop for the whole group would enrich input for better, responsive regulations. Real problems would be taken into account, which would help balance the over-protective legal control trend exerted by experts, and thus reduce the gap between intent and practice.

Regular meetings, such as every two months, between enforcers and executives should be established. Enforcement problems would be taken into the office to find out solutions, which may require support from executive level. The improved communication not only yields more

responsive regulations but also enhances inspectors' involvement, interest and increases their commitment through better motivation (Handy 1999; 279).

Motivation theories recognise participation in decision-making as an important factor for individual satisfaction (Fincham and Rhodes 1999, Handy 1999). Participation is assumed to have its effect because it increases an individual's perception of control and fairness in the process (Fincham and Rhodes 1999; 142). Increasing inspectors' participation in the VAC process is as important as it is in the legislative process. TFDA inspectors should be present in the VAC considerations. Their desire to see the cases through should be fulfilled. Knowledge of results or getting feedback about their performance can have considerable impact on both motivation and learning (Handy 1999). Participating in the VAC meeting would give inspectors the needed sense of control and fairness including feedback and help inspectors experience the meaningfulness of their work (Fincham and Rhodes 1999). Feedback can also improve relationships in organisation by breaking the compartmentalised authority structure (Fincham and Rhodes 1999). By opening the process, ambiguity will be minimised, and possibly avoid the feelings of mistrust as well as increase inspectors' willingness to send cases for the VAC consideration.

6.4.3.3 Discretion, code of practice and monitoring

Although centralisation is good in terms of uniformity, there are disadvantages – it can be resource consuming, make less immediate action, be less adaptive and less responsive. Discretion is essential in real world enforcement as indicated from the literature review and the results of this study. Site-level discretion could increase immediate deterrence effects imposed on offenders, increase bargaining power for inspectors, increase organisational efficiency and increase motivation of inspectors (Bardach and Kagan 1982, Morgan 1997).

Increasing discretion such as allowing inspectors to make on-the-spot fines would cause difficulties to the TFDA and inspectors due to the public mistrust of government officers. The pros and cons would have to be exhaustively weighed and explained. But without acknowledging the existing uses of discretion, measures to counterbalance misuse cannot be introduced in the system, which already has weak monitoring. By acknowledging it, organisations could use supplementary methods to prevent bias or misuse. There are many ways to monitor – such as re-inspection or joint inspection. However, with the limited number of personnel, inspectors' actions in the field are seldom monitored or supervised (Kelman 1981). In the absence of a strong monitoring system, the TFDA needs to build-up public

pressure, including the media, to help monitor violation and inspection in pharmacies. This can be done by informing the public of the problems or violation in pharmacies, their health impact as well as how pharmacies are regulated, that is increasing public awareness of the issues.

More transparency and accountability are required to ensure appropriate use of discretion both at the TFDA and at site-level. Increasing the role of outsiders, such as the media or non-governmental organisations, in the TFDA enforcement process would help counter-balance any interference and declare the TFDA neutrality and good intentions to protect the public. For example, the Royal Pharmaceutical Society of Great Britain has media participating in their disciplinary meetings at which offenders could be reprimanded as well as face more serious sanctions; the UK Food Standard Agency has media and the public participating in their meetings regarding food safety issues. Some agencies give discretion to inspectors but inspectors are required to make citations in all offences detected and be ready to clarify and justify their decisions (Kelman 1981).

Consideration to give inspectors discretion officially would be controversial and take a long time. In the meantime, the TFDA should devise remedial measures. The TFDA should establish a 'Code of Practice' to help inspectors interpret regulations in more precise actions to help their decision-making. A Code of Practice is often used in regulatory agencies. The UK Health and Safety Commission establishes an 'Approved Code of Practice and Guideline in relation to the Workplace' (Health, Safety and Welfare Regulations 1992). The TFDA, with input from inspectors, should develop, first, the criteria of '*weak evidentiary cases*', allowing these cases not to be charged officially but to be recorded in inspection records for the purpose of further follow-up. These cases are currently missing from the TFDA database because inspectors usually use their substituted measures and do not record the offences. Records of previous history are indicated in the study to prompt more serious legal action. Second, the TFDA should prioritise severity of offences. The Code should establish clear procedures telling what action needs to be taken in replacement of the legal action. The TFDA may be criticised as not following the Act, but there are examples of cases not prosecuted by courts, and minor cases that would not be worth the full prosecution process. The greater transparency would benefit the public as more cases are brought into the system and monitored.

6.4.3.4 Advancement, promotion and motivation

Career advancement would play a significant role in maintaining and motivating inspectors. Nevertheless, the TFDA system seems not able to provide enough advancement within the system. Currently inspectors are likely to fulfil themselves only through GMP inspection, which is perceived as more professional. Inspectors are regularly trained nationally and internationally, which increases self-growth – one motivational factor (Handy 1999). More thought needs to be given to enhance motivation regarding pharmacy inspection.

Specialisation in pharmacy inspection may be one consideration. The TFDA might need to revise the appropriate proportion between GMP and pharmacy inspection and allocate resources accordingly. A group of inspectors responsible mainly for pharmacy inspection is one possibility. Being specialists in one area is suggested as a way to increase self-esteem – one component of motivation (Collins 1994, Morgan 1997, Fincham and Rhodes 1999). The US Food and Drug Administration inspectors are encouraged to become specialists on some aspect of their work and to write about it or give cases for other inspectors (Bardach and Kagan 1982). There is much less advancement for pharmacy than GMP inspection, and the TFDA needs to bring the former into line with the latter.

6.4.4 Enforcement strategies

Results from this and independent studies show a high incidence of various breaches in the law, and the limitations of using legal authority. This suggests that the current TFDA enforcement policy and practice need to be reconsidered. The lack of inspectors' willingness to charge those committing widespread violations is clearly a result of using only inspection and punishment without support from executives to combine other supplementary measures. There are many enforcement alternatives. The appropriate enforcement style should be identified by considering number of staff, the Thai culture, business influence, problems in the health care system and other context. Having effective enforcement is complex, thus it is important to select a combination of strategies that would compensate deficits and fit with the context.

A co-operative enforcement style is one possibility that may fit the Thai system better than the punishment style. This style is used by many regulatory authorities in Sweden, Australia and Japan (Kelman 1981, Braithwaite et al 1987, Aoki 2000). Although co-operation between the TFDA and RPA seems to be established at a certain level, it has not been used systematically in the whole enforcement system. By using a co-operative system in a more

structured and official way, other measures could be introduced such as giving certificates, self-regulation, increasing community awareness. Meanwhile, mass education, reinforcing non-governmental organisations' participation in the TFDA processes would strengthen enforcement without increasing the number of inspectors. Other options include consultation with professional organisations. However, the TFDA needs to espouse more clearly its expectations of its inspectors, which will give clearer enforcement direction.

To change the strategy is difficult especially when dealing with the pharmaceutical industry, which the global sales of prescription drugs and some OTC were £ 156 billion (Anon. 2002), and which is known to have a powerful influence in both international and domestic arenas (Dukes 1985, Drake and Uhlman 1993). The TFDA may need to identify the need for change and convince all parties involved to reinforce the changes. Participation from parties outside the TFDA would counter-balance business pressure as well as the TFDA instability due to frequent SG reshuffles. The TFDA should analyse successful conditions regarding the GMP strategy and adapt them to bring better compliance in pharmacies.

Analysing the magnitude of problems caused by violation in pharmacies compared to those of manufacturers and importers is suggested in order to allocate resources proportionally. Studies of harm, risk or health impact occurring in the field, suggested in 6.4.1, would not only be useful for inspectors' better decisions, but are also important to gain attention from policy-makers' and the public in order to mobilise more needed resources. In the area of traffic accidents, which has recently been on the national agenda, health and economic loss is addressed more clearly, such as how helmets can prevent death and injuries and save the MOPH budget (Chartbunchachai 1993). This strategy would comply with the principle of risk management, which is the new trend of regulatory control (Adams 1999, Braithwaite 2000, Francis et al 2001).

But as the problem is the result of a bureaucratic system, it is not easy to solve. Overcoming constraints within the TFDA, especially the desire to hold onto the power instead of decentralising to inspectors, will not be easy. The different enforcement attitudes between inspectors and managers who are not inspectors also requires some mutual understanding and acceptance. Although the change of the TFDA enforcement philosophy may not happen suddenly, it is necessary and this issue may require re-visiting in the future.

6.6 Limitations of the study

While every attempt has been made to comply robust and rigorous methods of design and analysis in this study, some limitations need to be acknowledged, not only for methodological overview (described in chapter 3) but to assist readers in determining the reproducibility and generalisability of these results in other countries.

The small number of interviewees is one weakness, although all those involved in TFDA pharmacy inspection in the TFDA were recruited. In compensation, they were interviewed until information was saturated. Also interviews will have been influenced by the Thai context, which may be different from other countries. Another limitation of this study, though part of its strength, was that it focused only on the role of inspectors of pharmacy, who are only one part of the whole pharmacy regulation. Inspectors were from the Drug Control Division of the TFDA and represented inspection of pharmacies in Bangkok only. Although this group of inspectors shares a number of commonalities with other types of inspectors, such as being civil servants, working in a government ministry, and working within similar context, some issues are specific to this particular group. Generalisation, therefore, while valid for all pharmacy inspectors in Thailand, will need to be cautiously applied to inspectors in other countries.

There are a number of stakeholders acting in the enforcement process, inspectors are only one group and are largely engaged in the implementation of regulations. The research did not explore other stakeholders' views of inspection such as pharmacists. This was a deliberate decision, largely based on pragmatic reasons of time and resources (see chapter 3). Nor did the research explore extensively the policy formulation process – the process by which the Drug Act 1967 was promulgated and amended. Greater understanding of the stakeholders in policy formulation as well as other groups involved, and how the different influences were exercised might have given greater explanatory power to the way inspectors perceived their role in the TFDA.

Being an insider researcher had huge advantages, in terms of rapport, gaining access to material, and acceptance among a small, relatively close group. However, I acknowledge that my own educational training as a pharmacist may have biased me in my interpretation of the data from interviewees, and also may have limited my understanding of social science and psychological perspectives in analysis. I may not have been sensitive enough to capture the hidden meanings in the interviews, which may be relevant for a greater understanding or

deep explanation of the problems. Attempts were made to overcome the possible weaknesses from training at the London School of Hygiene and Tropical Medicine (see chapter 3).

6.7 Contribution to knowledge

In spite of some limitations, this study has contributed to knowledge in a number of ways. It confirms other research that suggests that policy implementation should not be viewed as separate from the policy making process, and that where this occurs, implementation deficits result. Interaction between the many parties concerned is significant to the success of implementation. The study also shows that only having policy, even if supported by law, cannot guarantee successful implementation. Conducive conditions are essential.

There has been little research on the policy process in developing countries and this study therefore adds to the few studies that exist, deepening the understanding of such process in Thailand.

In relevance to enforcement studies in other countries, most studies found are conducted in developed countries and mostly in the areas of pollution, and occupational safety and health. This study adds empirical support that inspectors' decisions are multi-componented. A number of similarities are found in terms of inspectors' views and attitudes on their jobs, their authority and their views in using discretion as a useful tool to achieve their work. Professional knowledge and exhaustive information provided for inspectors are always important in making concrete enforcement decisions. The TFDA views on its inspectors are limited compared to the views of other regulatory authorities, which are likely to use inspectors as experts in bringing regulatory compliance through flexibility and various enforcement strategies.

In the area of enforcement in pharmacies, information generated by this study fills the gap of understanding of the role of pharmacy inspection and the problems inspectors encounter in their work. This study is the first in Thailand to provide this scientific analysis. The problems detected in the study will help policy makers to design and implement more appropriate and more scientifically accepted strategies for enforcing regulations. The greater understanding generated from this study will illuminate how various policy options can best be structured to achieve desired outcomes.

The research helps to point out factors possibly adversely affecting enforcement, that have been taken for granted and which hopefully will raise concern from policy makers. One outstanding example is the issue of inspectors' double role as enforcer and professional-in-charge. By raising this as a potential conflict of interest, this research may begin a process of re-constitution of laws regarding double-roles, especially since it comes with an insider's perspective.

The TFDA is currently undergoing decentralisation, passing its authority to the Bangkok Metropolitan Authority. Pharmacy inspection is one target of the decentralisation, and the TFDA will have only a supervisory role in the future. Based on interviews the study has concluded the salient conditions against imposing legal authority and the lessons learnt from this study will be useful in order to avoid problems in the future.

6.8 Direction for future research

This study is only a piece of the whole enforcement picture. There are a number of potential areas that could throw further light on problems in using legal authority entailing more in-depth research. The study result should be used to build up more in-depth research. Studies of other groups of stakeholders such as drug sellers, professionals-in-charge and customers would give a deeper understanding of the issues around violation and regulation from different angles. Issues of corruption should be explored. Constraints raised by inspectors should be tested with other groups. It may also be useful to compare other groups of inspectors who use different regulations to see if there are lessons from other fields.

Problems or constraints suggested by this study should be investigated in more detail. For example, the Drug Act 1967, which is often raised as conflictual, should be explored in relation to the appropriateness of its criminal nature, types of sanctions and level of penalty. The advantage and disadvantage of the VAC closed consideration should also be an issue of further study. Some of the recommendations suggested may need to be tested first through small studies and convince policymakers to gather more evidence.

The limitation of primarily using inspectors to enforce regulation indicated from this research could be used as a starting point to investigate the possibility of moving enforcement in pharmacy to a broader perspective, for example, by enhancing public awareness, increasing education or introducing incentive enforcement measures. Research would be needed to explore the most efficient model.

This study shows conflict within the organisation and a weak communication system. In this situation participatory action research might be an appropriate method to conduct research to test various methods of improving communication. The method would bring together officers having antagonistic or different views, consultation would be brought in through the research process and compartmentalisation would be broken down. Consequently, the study results might be more accepted through mutual recognition and understanding and thus would be easier to implement.

Pharmacy inspection by the TFDA inspectors has been conducted for more than 20 years. Problems regarding enforcing the Drug Act 1967 have been subject to complaint by inspectors but with no systematic review. This study investigated problems preventing inspectors from using their legal authority fully. However, this is only a preliminary step for such a highly-impact issue like enforcement. Further research in each component raised in this study is essential to bring more in-depth and concrete evidence in order to communicate with policy-makers for changes. Further research could bring mutual recognition and understanding among parties concerned for developing solutions to solve the problems from within.

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Annex 1

The current DCD staff (30 June 2001)

| Section and sub-section | Number of staff | |
|------------------------------------------------|---------------------|--------------------------------|
| | Pharmacy background | Non-bachelor degree background |
| 1. The Research and Development Section | 9 | 2 |
| -Planning and evaluation | 2 | - |
| -Research | 2 | - |
| -System development | 1 | - |
| -Regulation development | 1 | - |
| -Product classification | 2 | - |
| -Information and database | 1 | - |
| 2. The Pre-marketing Control Section | 30 | 10 |
| -New drugs | 5 | - |
| -Generic drugs | 11 | - |
| -Biological products | 4 | - |
| -Traditional drugs | 5 | - |
| -Advertisement control | 5 | - |
| 3. The Post-marketing Control Section | 19 | 3 |
| -Supportive team | 2 | - |
| -Evidence compilation | 2 | - |
| -Premises licensing | 3 | - |
| -Inspection | 12 | - |

Annex 2

Document Pro Forma

1. Regulations

- The Drug Act 1967
- The Penal Code 1956
- The Drug Act Revision Working Group meeting minutes
- MOPH ministerial and TFDA orders

| Issues | Check list items | Description |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------|
| 1. The Drug Act 1967 | | |
| The pharmacy licensing system | Legal requirements | detail |
| The scope of the regulations required for pharmacy practice stated in the Act | Issues regulated identified by clauses of the Act e.g. quality of medicinal drugs, manner of practices | detail |
| Clarity of the Act | All technical terms are defined | yes/no- detail exceptions |
| | No contradiction between any controlled issues | yes/no – detail exceptions |
| Logic of the Act | All the regulations are still in practice (will be checked also at interview) | yes/no, detail |
| Loopholes in the Act | All actions are regulated consecutively | yes/no |
| | All offences have penalty | yes/no |
| Authority given to officers regarding pharmacy inspection | Legal authority of officers in charge | detail |
| | Authority given is the same for all officers | yes/no |
| | Authority given covers all regulated activities, including related activities | yes/no |
| | Authority is given to issue verbal warning | yes/no |
| | Authority is given to issue warning letters | yes/no |
| | Authority is given to collect data and then proceed to the police authority | yes/no |
| | Authority is given to assign community work | yes/no |
| | Authority is given to assign continuing education | yes/no |
| | Authority is given to seize offenders | yes/no |
| | All authorities given can be exercised fully by inspectors themselves | yes/no |
| | All authorities given can be exercised by inspectors directly when violations are found | yes/no |
| | Inspectors are protected by the Criminal Law in the same way as policeman | yes/no |
| Sanctions | Range of sanctions | detail |
| | Characteristics of sanctions | detail |
| | Maximum imprisonment sentences handed down | detail and case |
| | Minimum imprisonment sentences handed down | detail and case |
| | Minimum fine issued | detail and case |
| | Maximum fine issued | detail and case |

| | | |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------|
| | Matching of violations and sanctions; then analyse how the measures are used in various types of violation | detail |
| | List measures to encourage compliance | detail |
| | List measures to deter offenders | detail |
| 2. The Penal Code 1956 | | |
| The scope that relates to the Drug Act 1967 | Find out issues that would hinder or facilitate the use of inspectors' authority | detail |
| 3. The Drug Act Revision Working Group meeting minutes | | |
| How the regulations are drafted | Composition of the working group | detail |
| | Inputs used in the drafting process | detail |
| 4. MOPH and TFDA orders | | |
| Contents of the orders | Explanation of rationale: adequacy and clarity | detail |

2. Inspection records 1980 – 1996

| Issues | Check list items | Description |
|--------------------------------------------|----------------------------------------------------------------------------------------------------|-------------------------------------|
| The records where violations are found | Range, minimum and maximum time spent by inspectors on each type of violation | time spent |
| | Describe the written actions identified from those records by type of violations | detail by types of violations |
| | Describe evidence needed identified from those records by type of violations | detail by types of violations |
| | Were all records written in the same pattern? | yes/no |
| | Did all records contain all the necessary information? Compare with manuals or handbooks, if any . | yes/no |
| | Cases that prosecution decisions did not comply with the prosecution guideline | detail/number |
| | How often were inspectors' decision reversed? | statistics and detail |
| The records where violations are not found | Range, minimum and maximum of time spent on those cases | time spent |
| The records required for follow-up | Action furthering the orders to make follow-up | cases that corrections are not made |
| All inspection records | Find irregularities, special orders, special cases | detail |

3. Prosecution process and prosecution profiles

- VAC Guideline.
- VAC meeting minutes. 1995 –2000. The Regulatory Affairs Unit, TFDA, MOPH
- Prosecution reports. 1990 –2000. The Regulatory Affairs Unit, TFDA, MOPH and the Inspection Division
- The TFDA Order regarding the Violation Adjudication Committee Appointment. TFDA, MOPH.
- The TFDA Order on Violation Adjudication No. 0701/RAU 80 dated 13/01/1992 authorising inspectors to issue official warnings
- NDC meeting minutes 1988-1999. TFDA, MOPH.

| Issues | Check list items | Description |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------------------------|
| 1. The VAC Guideline | | |
| How offences are dealt with | Describe processes involved in prosecuting offences | detail of processes by violation cases |
| | Describe who are involved in prosecution process | officers involved in violation cases |
| | Time spent on the prosecution process | time spent in each step |
| 2. The VAC meeting minutes 1995 –2000 | | |
| Meeting minutes | Number and composition of the committees | detail |
| | Presidents (chairs) of the meetings | detail |
| | Secretaries of the meeting | detail |
| | Any evidence of conflict in the meetings | detail |
| | Duration of the meetings | detail |
| | Conflicts in the meetings | detail |
| | Content of the meetings | detail |
| | Data from fieldwork were used | yes/no |
| | Issues considered in the meetings | detail |
| 3. Prosecution reports. 1990 – 2000 from the Regulatory Affairs Unit, the DCD and the Inspection Division TFDA, MOPH. | | |
| Prosecution reports | Number and types violations prosecuted | statistics |
| | Number and types of sanctions used by type of violations | statistics |
| 4. The TFDA order regarding the Violation Adjudication Committee Appointment and the TFDA order on Violation Adjudication No. 0701/RAU 80 dated 13/01/1992 authorising inspectors to issue official warnings | | |
| The TFDA orders | Rationale of the orders | detail |
| | Content of the orders | detail |
| 5. NDC meeting minutes 1988-1999. TFDA, MOPH. | | |
| Meeting minutes | Number and composition of the committees | detail |
| | Presidents (chairs) of the meetings | detail |
| | Secretaries of the meeting | detail |
| | Any evidence of conflict in the meetings | detail |
| | Duration of the meetings | detail |
| | Conflicts in the meetings | detail |
| | Content of the meetings | detail |
| | Data from fieldwork were used | yes/no |
| | Issues considered in the meetings | detail |

4. The TFDA goals, policies and activities 1979 –2000

- The Royal Gazette.
- The 6th (1987-1991) and 7th (1992-1996) Consumer Protection Programme Evaluation, TFDA, MOPH.
- The 7th (1992-1996)and 8th (1997-2001)National Health Development Plan, MOPH
- The TFDA Annual plans 1989 –2001
- The TFDA Annual reports 1989-2001

| Issues | Check list items | Description |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| 1. The Royal Gazette | | |
| The official organisational structure and responsibility | Main roles and responsibility of the TFDA and its divisions | detail |
| | Whether the roles and responsibility changed over time | detail |
| | Main roles and responsibility of inspectors indicated | regulator, educator etc. |
| | The overall goal of TFDA and in relation to enforcement | detail |
| | Do conflicts exist between roles and responsibilities? | yes/no |
| | How well matched are the roles and responsibilities indicated in the royal gazettes and the authority given by regulations? | detail |
| | How relevant are the roles and responsibilities to TFDA policy and plans? | detail |
| | How well matched are the roles and responsibilities with the suggested authority in WHO guideline? | detail |
| | How have the roles and responsibilities developed or changed over time since the enactment of the Thai Drug Act 1967? | detail |
| | How well matched are the roles and responsibility with the authority given by the Drug Profession Act? | detail |
| 2. The 6th (1987-1991) and 7th (1992-1996) Consumer Protection Programme Evaluation, TFDA, MOPH. | | |
| 3. the 7th (1992-1996)and 8th (1997-2001) National Health Development Plan, MOPH | | |
| 4. the TFDA Annual plans 1989 –2001 | | |
| TFDA policies and projects related to pharmacy and pharmacy inspection in the last five years. Such as: -the Self-regulating policy -Compliance Policy 1995 -Standard Pharmacy 1994-5 -Pharmacy for community 1997-1999 | What is the proportion of these projects compared to other projects? What is the content of the projects and directions given? | ratio, detail |
| | What is the frequency of appearance of issues about problems in pharmacies and their content? | number and detail |

| | | |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Aims of the policies | detail |
| | Statements of what are the problems in pharmacies | yes/no |
| | Statements of what are the violations in pharmacies | yes/no |
| | Statements about using authorities to tackle problems | yes/no |
| | Describe support for each policy | detail |
| | Which issues have been targeted in policies : enforcement or education? | choice |
| | Matching of policies and violations recorded | detail |
| | Were data used as main sources of information? | yes/no, detail |
| | Calculate manpower needed to fulfill policy goals about pharmacy inspection, if nature of policies permits | number of inspectors to fulfill policy goals |
| | Enforcement goal | existence |
| | Budget spent on TFDA activities over time | budget used in each activities |
| 5. TFDA Annual Reports 1979-2000 | | |
| Activities highlighted in annual reports | The highlighted issues that related to pharmacies and pharmacy inspection compared to other activities | number and detail |
| Activities reported in annual reports | Matching of activities with policies and plans | detail |
| | The reported issues that related to pharmacies compared to other reported activities | number and detail |
| | Calculate ratio of violation cases to total number of pharmacies inspected by type of violation | annual ratio by type of violation (to be baseline data to compare with data at interview about the perception of inspectors regarding the incidence of violations) |
| Achievement of policies | Statements showing failure or achievement; and reasons | yes/no, detail |
| | Statement about problems in pharmacies | detail |
| 6. TFDA Annual Action Plans 1990-2000 | | |
| Inspection activities in the last five years | Matching of activities stated in roles, responsibilities, policies and plans | detail |
| | Coverage of pharmacies and manufacturers | statistics |
| | Compare activities set in plans and in annual reports | differences |
| | The use of authorities was specified in plans and/or rationalised | yes/no |
| | Activities supporting the use of authorities existed | yes/no |
| | The extent to which targets related to policies | detail |
| | The extent to which targets related to enforcement | detail |

| | | |
|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|---------------|
| Resources allocation in the last five years | Analyse time input vs. manpower vs. violation prevalence | adequacy |
| | A trend of total budget given for inspection | annual amount |
| | A trend of proportion of resources used for pharmacy inspection compared to manufacturers inspection | number |
| 7. Inspection reports 1985 – 1996 (Inspection Division) 1998-2000, DCD, TFDA, MOPH. | | |
| Activities carried out | Inspection of manufacturers, importers, pharmacies | detail |
| | Type of inspection | detail |
| Violations detected | Types and number of offences detected | detail |

5. Evaluation and job appraisal

- The TFDA Performance Appraisal Guideline 1997.
- The Civil Servant Performance Appraisal Order No. 10/1995 dated 29 June 1995. Bureau of Civil Servant.

| Issues | Check list items | Description |
|-----------------------|-----------------------------------------------------------------------------------------------------|--------------------|
| Process of evaluation | Describe evaluation processes | detail |
| | Describe composition of the evaluation committee | detail |
| | Describe the extent to which inspectors are involved in the evaluation processes | detail |
| | Explore the subjectivity of the process | detail |
| | Describe what happened when plans were not achieved | detail |
| | Were all inspectors evaluated? If not, why not? | detail |
| | Were any steps taken to improve the inspection process as a result of evaluation? Describe | detail |
| Process of appraisal | Job appraisal procedures are written | yes/no |
| | Issues indicate that enforcement is given special consideration | yes/no |
| | Who appraises inspectors? | detail |
| | How often are inspectors appraised? | detail |
| | What is objectivity of the appraisal? | detail |
| | Is there a mechanism to address under-performance and to reward good performance? | |
| | Is there evidence that actions were taken to address under-performance and reward good performance? | |

6. Independent studies related to enforcement in pharmacies

- Tonteerawongs, B., Sri-aramrourngroeng, P., Yoongtong, W. and Taengtai, N. 1997. Situation Analysis of Consumer Protection in Thailand 1997. TFDA, Ministry of Public Health. (in Thai)
- Saorumnee, P. and Bunyarat, D. 2001. Situation Analysis on Consumer Protection in Thailand 2001. TFDA, Ministry of public Health.
- Oonhalekagha, A. 1999. The 1998 Consumer Protection Survey. TFDA, MOPH.
- Tanasit, P., Praweenwongwut, W., Kraisin, K., Srisung, S., Wongyai, S., Sooksriwongse, C., Lawanprasert, Y., Tephasadin Na Ayuddhaya, N., Assawakitwiree, W., Rienjaroen, T. and Janpraparb, S. 1996. Modernizations of Regulatory Measures Regarding Medicinal Drugs, Biochemicals and Herbs. TFDA, Ministry of Public Health.
- Loven, B. 1994. A Consultation Report on Improving GMP Compliance. Inspection Division, TFDA.
- Bowarnwattana, P. and Siripan, A., 1992. Enhancement of the TFDA Effectiveness. Epidemiology Board of Thailand.

| Issues | Check list items | Description |
|---------------------------------------------------|--------------------------------------------|-----------------|
| Incidence of violation by types of violation | Matching of studies and inspection records | comparison data |
| Management problems regarding pharmacy inspection | Content from the studies | detail |

7. The TFDA field operational manual and/or handbooks on pharmacy inspection

- Inspection Manual . 1979. TFDA
- Inspection Manual. 1989. TFDA
- Inspection Manual. 1999. TFDA
- Inspection SOP 1996 (Standard Operation Procedure)

| Issues | Check list items | Description |
|---------------------------------|-------------------------------------------------------------------------|-------------|
| Official enforcement procedures | Procedures of pharmacy inspection are specified | yes/no |
| | The inspection procedures are written in a practical manner | yes/no |
| | The written inspection procedures cover all aspects of inspection | yes/no |
| | Procedures of investigation are written | yes/no |
| | The investigation procedures are written in a practical manner | yes/no |
| | The written investigation procedures cover all aspects of the procedure | yes/no |
| | Procedures of compiling evidence – is written | yes/no |
| | The compiling evidences procedures are written in a practical manner | yes/no |
| | The written compiling evidences procedures cover all aspects | yes/no |
| | Procedures of note-taking are written | yes/no |
| | The note-taking procedures are written in a practical manner | yes/no |

| | | |
|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| | The written note-taking procedures cover all aspects | yes/no |
| | Reporting procedures are written | yes/no |
| | Reporting procedures are written in a practical manner | yes/no |
| | The written reporting procedures cover all aspects | yes/no |
| | Publication year of the manual – any revisions? | year |
| | Matching processes written in manuals and what are done checked from inspection records | detail |
| Working procedures | Who arranges inspection schedules | detail |
| | How are the schedules arranged? | contingency/ daily/weekly/ monthly |
| | How are the jobs prioritised? Who ensures that the jobs are actually carried out? If jobs are left undone, is there a procedure for addressing this problem? | criteria to prioritise jobs |
| Complexity of prosecution process (e.g. compiling evidence, submitting reports, committee meetings, going to court etc.) | Describe steps to be taken when violations are found | detail |
| | Describe time spent on each step (use data from operation manuals) | detail |
| | Describe status of officers involved in each step | detail |
| Practicality in using authority | Matching of violation types and evidence compilation process | detail |
| | Matching of evidence needed to the process of compiling evidence and the penalty | detail |
| | Matching of violations and evidence needed for prosecution | detail |
| | Guidance for making decisions | detail |

8. Training programs on pharmacy inspection 1979 – 2000

- Inspection Training Curriculum. 1992-1999.

| Issues | Check list items | Description |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Training programs | Are there specific training programs for pharmacy inspection within the overall Thai FDA training program? | yes/no |
| | Explore the contents and types of programs inspectors have attended and how often (e.g. Technical, management, problem-oriented, public health, regulations) in the last five years. | types and number of training programs |
| | How many training programs are specific for inspectors compared to the overall program? | percentage |
| | Explore objectives of the training programs. | detail |
| | If there were training programs on pharmacy inspection, how often were they provided? | yes/no |

9. Feedback information system

| Issues | Check list items | Description |
|---------------|--------------------------------------------------------------|--------------------------|
| Process | A written system exists | yes/no |
| | Frequency of information given in the last five years | number |
| | Information is given directly to inspectors or to supervisor | inspectors or supervisor |
| Content | Statements showing information given in the last five years | Detail |

10. Morale support schemes for inspectors

| Issues | Check list items | Description |
|----------------|-------------------------|--------------------|
| Morale support | insurance scheme | yes/no |
| | special promotion | yes/no |

11. The Retail Pharmacy Association Magazines 1979 –2001.

| Issues | Check list items | Description |
|--------------------------|-----------------------------------|--------------------|
| Content in the magazines | Issues related to law enforcement | detail |

Annex 3

A list of interviews

| No. | Date of interview | Job title |
|--------------------------|--------------------|------------------|
| 1 | 27 – 02 – 2001 | Inspector |
| 2 | 28 – 02 – 2001 | Inspector |
| 3 | 1, 22 – 03 – 2001 | Inspector |
| 4 | 2 – 03 – 2001 | Inspector |
| 5 | 6 – 03 – 2001 | Non-Inspector |
| 6 | 9 – 03 – 2001 | Inspector |
| 7 | 12 – 03 – 2001 | Inspector |
| 8 | 12, 15 – 03 – 2001 | Non-inspector |
| 9 | 14 – 03 – 2001 | Inspector |
| 10 | 16 – 03 – 2001 | Inspector |
| 11 | 19 – 03 – 2001 | Inspector |
| 12 | 21 – 03 – 2001 | Inspector |
| 13 | 26 – 03 – 2001 | Inspector |
| 14 | 2 – 04 – 2001 | Inspector |
| 15 | 3 – 04 – 2001 | Inspector |
| 16 | 5 – 04 – 2001 | Non-inspector |
| 17 | 9 – 04 – 2001 | Non-inspector |
| 18 | 11 – 04 – 2001 | Inspector |
| 19 | 12 – 04 – 2001 | Inspector |
| 20 | 17 – 04 – 2001 | Inspector |
| 21 | 19 – 04 – 2001 | Inspector |
| 22 | 20 – 04 – 2001 | Non-inspector |
| 23 | 26, 29 – 04 – 2001 | Non-inspector |
| 24 | 2 – 05 – 2001 | Non-inspector |
| 25 | 9 – 05 – 2001 | Non-inspector |
| 26 | 14 – 05 – 2001 | Inspector |
| 27 | 17 – 05 – 2001 | Inspector |
| 28 | 22 – 05 – 2001 | Non-inspector |
| 29 | 23 – 05 – 2001 | Inspector |
| 30 | 25 – 05 – 2001 | Inspector |
| The first group meeting | 15 – 06 – 2001 | Four inspectors |
| The second group meeting | 22 – 06 – 2001 | Three inspectors |

Annex 4

A semi-structured interview questionnaire for the TFDA SG and ex-SG

Introduction I am conducting research related to inspection as a part of my doctoral study. I am particularly interested in pharmacy inspection, so your work experience is a crucial part of the study. The research is an effort to collect and analyse existing data scientifically. Without your contribution, the study is not possible.

All information given will be treated confidentially. Data will be presented anonymously. The study is approved by TFDA but this is an independent study. Summarisation of the interview will be presented to you. The London School of Hygiene and Tropical Medicine, University of London will academically approve the analysis.

Please consider the following section as an introduction to an exchange of experience rather than a formal interview. For analysis purposes, it would be greatly appreciated if you would allow me to tape-record the interview. Please feel free to tell me at any time if you want your interview off-record.

1. What do you think about enforcement on the Drug Act performed by the TFDA?
2. In your idea, what are measures or strategies to gain regulatory compliance?
3. In your view, what are appropriate roles for the TFDA to carry out effective consumer protection?
4. Violations in pharmacies have been rampant. For example, selling outside of the duty hour, selling without supervision of professionals-in-charge, selling non-registered drugs, selling drugs other than permitted, selling drugs without licence.
5. What is your view about hazards caused by those violations?
 - when compared to violations conducted by manufactures and importers?
 - when compared to other problems under the TFDA?
6. The Drug Act 1967 has been enacted for a long time, why there are still high violations?
7. Why is it good in using a warning measure performed by the TFDA?
8. In your idea, what should the TFDA do to reduce those violations?

Annex 5

A semi-structured interview questionnaire for regulatory officers

Introduction I am conducting research related to inspection as a part of my doctoral study. I am particularly interested in pharmacy inspection, so your work experience is a crucial part of the study. The research is an effort to collect and analyse existing data scientifically. Without your contribution, the study is not possible.

All information given will be treated confidentially. Data will be presented anonymously. The study is approved by TFDA but this is an independent study. Summarisation of the interview will be presented to you. The London School of Hygiene and Tropical Medicine, University of London will academically approve the analysis.

Please consider the following section as an introduction to an exchange of experience rather than a formal interview. For analysis purposes, it would be greatly appreciated if you would allow me to tape record the interview. Please feel free to tell me at any time if you want your interview off-record.

- 1.How are the contents and penalties of the drug regulations obtained, including penalty level and sanctions?
- 2.What is the participation from inspectors in drafting, revising or proposing the regulations?
- 3.In your view, how do inspectors agree with the rationale or penalty level of the regulations?
- 4.The drug regulations are often commented as too idealistic or not practical for the Thai context. What is your idea about the comment?
- 5.In your idea, what makes the regulations, e.g. selling out of the duty hours, not fully enforced?
- 6.Why is the VAC allowed to give warnings without authorisation from the Drug Act? Should this be assigned to field inspectors who face the real situation and to shorten the prosecution process?

Annex 6

A semi-structured interview questionnaire for managers and ex-managers

Introduction I am conducting research related to inspection as a part of my doctoral study. I am particularly interested in pharmacy inspection, so your work experience is a crucial part of the study. The research is an effort to collect and analyse existing data scientifically. Without your contribution, the study is not possible.

All information given will be treated confidentially. Data will be presented anonymously. The study is approved by TFDA but this is an independent study. Summarisation of the interview will be presented to you. The London School of Hygiene and Tropical Medicine, University of London will academically approve the analysis.

Please consider the following section as an introduction to an exchange of experience rather than a formal interview. For analysis purposes, it would be greatly appreciated if you would allow me to tape record the interview. Please feel free to tell me at any time if you want your interview off-record.

1. Could you please explain your job and responsibility?

2. In your idea as a manager responsible for consumer protection,

What are pharmacies expected to be?
How would inspection help to achieve the expectation?
What is the support from the TFDA?

3. About pharmacies in Bangkok,

What is the compliance situation regarding pharmacy?
What are the main offences (main problems)? Why they are selected?
How serious are the offences in terms of health hazard compared to those of manufacturers and importers; and to the rest of TFDA responsibility?
How are the problems recognised by executives in terms of violation degree and risks?
In your idea, what are causes of violation?

4. About inspection performed by inspectors,

What is your view about enforcement in pharmacy? How satisfactory is it?
What are the problems and causes of problems on enforcement?
What is the impact of violation regarding pharmacy practice?
In your idea, how can enforcement be made more effective?

5. Whose responsibility is it to increase regulatory compliance in pharmacy?

6. What do you think are appropriate and effective strategies to gain or maintain compliance regarding pharmacy? How can enforcement support this?

7. In terms of management....

What are the main management problems about inspection and enforcement regarding pharmacy inspection?
What do you need from the TFDA to support better enforcement?

Annex 7

A semi-structured interview questionnaire for inspectors and ex-inspectors

Introduction I am conducting research related to inspection as a part of my doctoral study. I am particularly interested in pharmacy inspection, so your work experience is a crucial part of the study. The research is an effort to collect and analyse existing data scientifically. Without your contribution, the study is not possible.

All information given will be treated confidentially. Data will be presented anonymously. The study is approved by TFDA but this is an independent study. Summarisation of the interview will be presented to you. The London School of Hygiene and Tropical Medicine, University of London will academically approve the analysis.

Please consider the following section as an introduction to an exchange of experience rather than a formal interview. For analysis purposes, it would be greatly appreciated if you would allow me to tape record the interview. Please feel free to tell me at any time if you want your interview off-record.

1. How long have you been an inspector?
2. What did you do before becoming an inspector, and for how long?
3. What motivated you to become an inspector?
4. What do you like about being an inspector; and what do you dislike?
5. As you are both a civil servant and also the authorised officer according to the Drug Act, is there any conflict between these two roles? Are you assigned the same roles and responsibilities regarding pharmacy inspection?
 - 5.1 In your idea, what is pharmacy inspection for?
 - 5.2 What do you think
 - are roles and responsibility according to the Act?
 - are roles and responsibility according to the position?
 - your authority according to the Act is for?
 - 5.3 How do you know what is expected of you?
 - 5.4 How is your work regarding pharmacy inspection supported by TFDA?
 - 5.5 What do you normally do during pharmacy inspection?
 - How long does it take per inspection: offence found, offence not found?
 - How many pharmacies do you visit per week?
6. How often are offences found in pharmacy inspection?
 - 6.1 In your view, how serious are the majority of the offences in terms of health hazards?
 - 6.2 Are all offences prosecuted?
 - When are offences likely to be prosecuted?

- When are they unlikely to be prosecuted?
- Why don't you apply your authority to all offenders?

6.3 What do you do when offences are found and you do not want to prosecute to ensure consumer protection?

6.4 Why do you think those alternative methods are as good as formal measures?

6.5 Why are you not afraid of being accused of corruption for not applying your authority?

7. The following offences are found in pharmacies, one offence in one pharmacy. Please indicate your actions on those offences with reasons and how your decisions will be changed if you are informed of the following information

| Topics | How your decision would change if..... |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Pharmacist absence during the registered period | If there is a policy |
| Antibiotics tablets are found in Type B pharmacy at the front counter | If drugs found are four items of prescription drugs and six items of injection |
| Ten tablets of fake antibiotics are found in a small grocery | If they are found in type A pharmacy |
| Non-registered contraceptives pills are found on a working desk | If they are traditional Thai drugs |
| A dozen of expired eye drop are found at the front counter | If it is diabetes drug expired according to its label |
| A grocery with 10 tubes of steroid cream and 4x 30 tablets of non-OTC cold remedies | If they are antibiotics and non-OTC anti-inflammatory drugs capsule |
| Sale of low back pain drugs by non personnel-in-charge | If you are informed of 100 million baht loss due to irrational dispensing by those non-pharmacist counter attendants |

8. How far do you feel you work autonomously? What management support or procedures would be helpful to improve enforcement of good pharmacy practice?

9. Finally, in your view, how would it be possible to reduce violations regarding drug selling? What role is there for enforcement?

10. Would you change your decision to be an inspector, if you could?

Annex 8

The school's letter



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To Whom It May Concern:

Duangtip Hongsamoot is a DrPH student in the Department of Public Health and Policy at the London School of Hygiene and Tropical Medicine (LSHTM), University of London. She is carrying out research into pharmacy inspection, which is funded by the World Health Organisation as part of her DrPH. In earlier parts of his research, she has carried out documentary analysis concerning the specified issues. She now wants to interview managers/inspectors/regulatory officers on that matter. The interview is likely to take no more than one hour. The contribution is greatly useful to the research.

Complete confidentiality will be maintained throughout. The provider of any information will not be identifiable. This study will, we hope, prove valuable to pharmacy inspection practice.

Yours sincerely,

(Professor Gill Walt, the supervisor)

(Duangtip Hongsamoot, the research student)

Annex 9**Format Data Sheet for Documentary Analysis**

-Code of the document

-Title of the document

-Source of the document

-Division

-Person

-Date/month/year of the document

-Types of the document

-Length of the document

-Date of data collection

Annex 10
Interview documentation sheet

General information about the interview and interviewee

Interviewee's name :

Date of interview :

Place of interview : (Indicate situation)

Duration of the interview: (indicate interruption , if any)

First/second/third time interviewing : (indicate situation)

Sex :

Age :

Marital status :

Education background :

Job title :

How long the interviewee has been an inspector :

Previous job/how long :

Have job with any pharmaceutical company or not :

Annex 11

Detail of MOPH staff and their profiles

| Department | Number of staff | | 1999 Budget (million baht) |
|---------------------------------------------------------|-----------------|------------------|--------------------------------|
| | Professional | Non-professional | |
| 1. Permanent Secretary Office | 149,141 | 37,441 | 48,730.2 |
| 2. Medical Department | 7,572 | 3,087 | 3,307.4 |
| 3. Health Department | 2,626 | 2,586 | 877.0 |
| 4. Communicable Disease Control Department | 4,216 | 4,757 | 5,098.7 |
| 5. Medical Science Department | 1,158 | 376 | 3,713.5 |
| 6. Mental Health Department | 3,332 | | 1,438.1 |
| 7. The Thai Food and Drug Administration | 376 | 134 | 480.2 |
| - Secretary – General Office | 20 | 25 | 20.1 |
| - The Food Control Division | 59 | 16 | 34.9 |
| -The Drug Control Division | 58 | 17 | 33.2 |
| -The Narcotic Substance Control Division | 37 | 15 | 21.8 |
| -The Cosmetic Control Division | 32 | 12 | 19.1 |
| -The Medical Device Control Division | 30 | 7 | 18.0 |
| -The Toxic Substance Control Division | 29 | 6 | 14.4 |
| -The Technical Division | 30 | 11 | 110.5 |
| -The Advertisement Control and Public Relation Division | 23 | 13 | 189.1 |
| -The Inspection Division | 48 | 7 | 10.2 |
| -The Regulatory Affairs Unit | 10 | 5 | 8.9 |

NB: 40 baht = 1 pound until April 1997 then devalued to 65 baht = 1 pound, the minimum daily wage for non-skilled labour is 150 baht (2001).

Annex 12
Inspectors' profile

| Topic | Number | |
|---------------------------------------------------|---------------|--------------------|
| | Ex-Inspectors | Current Inspectors |
| 1. Sex | | |
| - Male | 6 | 9 |
| - Female | 1 | 3 |
| 2. Degree | | |
| - Bachelor | 5 | 9 |
| - Master | 2 | 3 |
| - Have lawyer degree (as well as) | 2 | 3 |
| 3. Experience as inspector | | |
| - ≥ 15 years | 7 | 8 |
| - 3 – 14 years | - | 4 |
| - less than 3 years | - | None |
| 4. Inspector is the first job | 4 | 4 |
| 5. The first job | | |
| - hospital | | 2 |
| - medical representative | 1 | 2 |
| - registration work at the TFDA | | 3 |
| - laboratory work | | 1 |
| - run family business (pharmacy) | 2 | - |
| 6. Families have pharmacy business | 2 | 3 |
| 7. Work part-time in pharmacies or drug importers | 5 | 4 |
| 8. Work part-time in hospitals | - | 4 |

Annex 13

Comparison of penalties between the two Drug Acts

| Offence | Penalty 1967 | Penalty 1950 |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| 1. Sale without license | Imprisonment not more than 5 years and fine no more than 10,000 baht | Imprisonment no more than 6 months or fine < 1,000 or both |
| 2. Sale of fake drug - knowingly - not knowingly | Imprisonment 1-20 year and fine 2,000 – 10,000 baht fine 1,000-5,000 baht | Imprisonment < 10 year or fine <10,000 or both Fine 2,000 baht |
| 3. Sale of substandard drug - knowingly - not knowingly | Imprisonment 6 months – 3 years and fine 1,000 – 5,000 baht. Fine no more than 5,000 baht | N/a N/a |
| 4. Sale of expired drug - knowingly - not knowingly | Imprisonment no more than 1 year or fine no more than 3,000 baht or imprisonment and fine Fine no more than 3,000 baht | Imprisonment no more than 1 year or fine no more than 3,000 baht or imprisonment and fine N/a |
| 5. Sale of non-registered drug | Imprisonment no more than 3 years or fine no more than 5,000 baht or fine and imprisonment | n/a |
| 6. Sale without supervision of personnel in charge | Fine 1,000-5,000 baht | N/a |
| 7. Sale drugs other than allowed | Fine 2,000-5,000 baht | Fine < 2,000 baht |
| 8. Sale of mixed drugs in one container | Imprisonment < 5 years or fine < 50,000 baht or both | N/a |
| 9. Sale prescription drugs with out prescription | Fine 2,000-5,000 baht | N/a |
| 10. Sale withdrawn drugs. - knowingly - not knowingly | Imprisonment 6 monthes to 3 years and fine 1,000-5,000 baht Fine no more than 5,000 baht | N/a Fine <2,000 baht |
| 11. Sale drugs with incorrect labeling | Fine 2,000-10,000 baht | N/a |
| 12. Do not show or show incorrect sign plate | Fine 1,000-10,000 baht | N/a |
| 13. Conduct incorrect entry record | Fine 1,000-10,000 baht | N/a |

NB: 40 baht = 1 pound until April 1997 then devalued to 65 baht = 1 pound, the minimum daily wage for non-skilled labor is 150 baht (2001).