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Formulating antibiotic policy: Analysis of India's ban on colistin use in food producing animals

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A R T I C L E I N F O

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A B S T R A C T

Antibiotics remain key tools for maintaining human health, and in many settings, food production. However, emergence of antibiotic resistance has become a global challenge, one that has resulted in multi-national calls for policy to improve antibiotic use. One such call has been to restrict the use of antibiotics deemed critically important for human health, such as colistin, during the production of food producing animals. Between 2016 and 2019 numerous countries, including India, implemented policies to heavily restricted the use of colistin in livestock. While this represents a key shift in the antibiotic policy landscape, other classes of critically important antibiotics continue to be used during food production. This paper provides a policy analysis of India's 2019 colistin ban to provide insight into how this came to be and to identify factors which could shape the development of future legislation. The analysis revealed that while antibiotic reform in food production had been in the background of India's policy agenda for some time, it took key-focusing events to shift the policy climate into a period of action. These focusing events included reporting of mobile colistin resistance genes in bacteria isolated from pigs in China and colistin resistant bacteria isolated from food samples in India. Consistent narratives had been built around colistin's role as a last resort antibiotic which, together with relatively low proportion of colistin resistance in bacteria isolated from human patients, framed legislation as a worthwhile endeavour for policy makers. In addition, India acted as a global player in antibiotic stewardship and followed the precedent set by several other countries in restricting colistin use during food production. As most colistin for animal use was imported into India from China, and viable alternative animal treatments existed, there was limited industry opposition that could block legislation. We suggest evaluation of these five critical factors (focusing events, consistent narratives, worthwhile endeavour, precedent for change, and industry opposition) should be part of the policy formulation process for legislation regarding the use of other critically important antibiotics in food production.

1. Introduction

Global and national action plans for antimicrobial and antibiotic resistance call for stewardship in both human health and during food production to mitigate the challenge of emerging resistance (FAO, 2016; OIE, 2014; WHO, 2014). Antibiotics have been used during the production of food animals to both treat and prevent[1] bacterial disease and as antibiotic growth promoters (Castanon, 2007; Collignon, 2004). Consequently, people can be exposed to both antibiotic residues and resistant bacteria from contact with the food system and consumption of

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[1] Antibiotic prophylaxis

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food (Samtiya et al., 2022). Both the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (WOAH) have called for cessation of antibiotics being used for growth promotion and a reduction in those deemed critically important for human health (Magnusson et al., 2019; OIE, 2014). One such critically important antibiotic (CIA) which has been under particular scrutiny is the polypeptide antibiotic, polymyxin-E, better known as colistin.

After its discovery in 1947 (Stansly and Schlosser, 1947) colistin was initially used to treat infections in both people and animals. In the following years, serious side effects in people (causing nephrotoxicity and neurotoxicity) led to it being largely abandoned in human medicine by the 1970s (Koch-Weser et al., 1970; Nation and Li, 2009). Subsequently, colistin has primarily been used during food production, particularly pork and poultry, to prevent and treat disease and to promote animal growth (Apostolakos and Piccirillo, 2018; Mazutti et al., 2016). As a broad-spectrum antibiotic, colistin is effective at treating common production related diseases caused by Gram-negative *Enterobacteriaceae* bacteria (Jansen et al., 2022). Over the last two decades, however, colistin's ability to treat multidrug resistant infections in people has led to a resurgence of use in human medicine (Falagas et al., 2005; Nation and Li, 2009b; Stein and Raoult, 2002). Consequently, there has been growing concern over colistin's role in food production as this is one of the driving forces for the development of resistance in bacteria affecting humans (Kumar et al., 2020). Between 2016 and 2019, numerous countries[2] across Europe, Asia, and South America, including India, implemented policy to restrict and reduce the use of colistin in non-human animals. While some countries implemented policy banning the use of colistin (e.g., in 2017 China banned colistin as an antibiotic growth promoter [Walsh and Wu, 2016]) other countries, such as Spain and Italy, implemented voluntary recommendations to encourage livestock sectors to decrease colistin use (Gagliotti et al., 2021; Miguela-Villoldo et al., 2022).

India has been described as a global hot spot for antibiotic resistance, both in human and animal populations (Murray et al., 2022; Taneja and Sharma, 2019; Van Boeckel et al., 2019). While surveillance data on antibiotic use in Indian livestock is lacking, it has been estimated India will experience a 7 % increase in antibiotic consumption from 2053 tonnes in 2017 to around 2190 tonnes in 2030[3] (Tiseo et al., 2020). This increase is expected due to adoption of intensive farming techniques (Van Boeckel et al., 2015) and sustained livestock sectoral growth, particularly poultry production (Vishnuraj et al., 2016). Responding to global calls for antibiotic governance, India produced its National Action Plan (NAP) for antimicrobial resistance in 2017 (Government of India, 2017a). Indeed, the NAP includes the objective of phasing out the use of CIAs in livestock. Despite this intention to change antibiotic use in India's food system, studies have described how other CIAs continue to be used in India, particularly within poultry production. For example, macrolides and fluoroquinolones are used as risk mitigation strategies during broiler production in the state of West Bengal (Arnold et al., 2021; Hennessey et al., 2025, 2023).

Through policy analysis of India's 2019 colistin ban we aimed to understand the development of this food production antibiotic policy focused on colistin. By assessing the context that influenced the ban and analysing the roles and power of actors involved in the policy process we sought to identify key factors that influenced and shaped the colistin ban. We then hypothesised how these factors would affect and shape future legislation of other critically important antibiotics used in food production.

[2] Italy & Spain (2016), China and Thailand (2017), Brazil and Japan (2018), and India, Argentina, Indonesia, and Malaysia (2019)

[3] It is estimated that by 2030 India will use 2.1 % of global antibiotics used in livestock, behind China (43 %), Brazil (7.9 %), the USA (6.5 %), and Thailand (4.0 %) (Tiseo et al., 2020)

2. Materials and methods

2.1. Analytical framework

The study incorporated both retrospective and prospective approaches. This allows analysis of "*why and how policy content was agreed upon (analysis of) as to better appreciate (and influence) the future trajectory of policy in the same space (analysis for)*" (Buse et al., 2023, p.279). Walt and Gilson's (1994) Policy Triangle Framework was used as an initial approach to the analysis. The Policy Triangle considers the content of the policy, the context within which the policy developed, and the actors involved in setting the agenda and formulating and implementing the policy (Fig. 1). Onto this, additional sequential frameworks were used to examine each element in greater depth. First, to examine the policy content we used Matland's (1995) conflict-ambiguity matrix. Here, Matland describes how the dimensions of policy ambiguity and conflict affect how policies are implemented and their likelihood of success (Table 1). Secondly, to analyse the policy context we used Leichter's (1979) description of contextual factors which include situational, structural, and exogenous aspects. Leichter argues that by considering these factors, policy analysts can assess how historical events, institutional frameworks, societal values, and external pressures impact policy feasibility and implementation. Additionally, within the analysis of contextual factors we identified 'key focusing events', which Kingdon (2013) describes as events which can cause a shift in the policy landscape. Kingdon describes how these events, such as crises, disasters or significant public issues can open policy windows for change, mobilise stakeholders, and create urgency for policy makers to act. Finaly, to examine the policy process we used Lukes' faces of power to assess how the various actors influenced the policy development (Lukes, 2005, 1974). Lukes describes three faces of power which can be utilised by policy actors; power in decision making (often overt), power in non-decision making (often covert), and power as thought control. Lukes describes this third face of power as being the most insidious as it changes people's preferences in a way that they no longer raise objections to issues which may not be in their best interests (Lukes, 1974).

2.2. Data collection

A literature review was conducted to allow a documentary analysis to be performed which was supported by data collected through in-depth stakeholder interviews.

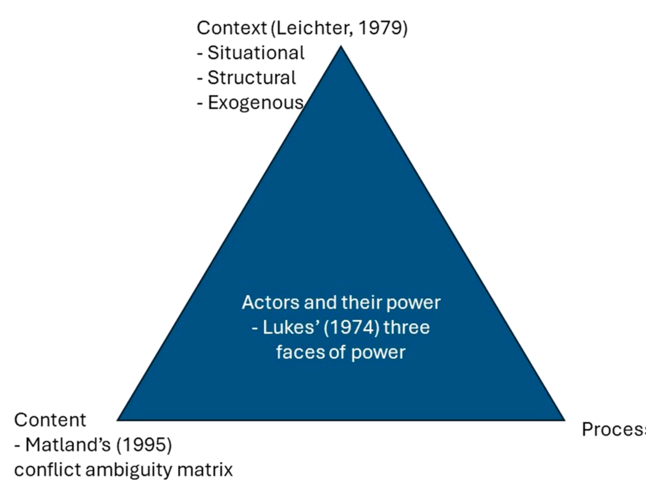

Fig. 1. Walt and Gilson's Health Policy Triangle (1994), incorporating elements from Matland's (1995) conflict ambiguity matrix, Leichter's (1979) contextual factors, and Lukes' (1974) three faces of power.

Table 1
Matland's conflict-ambiguity matrix (1995). Matland considers policies across two dimensions (ambiguity and conflict) which creates four types of policy implementation, each with different factors for success.

		Conflict	
		Low	**High**
Ambiguity	**Low**	*Implementation type* Administrative *Key factor for success* Resources	*Implementation type* Political *Key factor for success* Power
	High	*Implementation type* Experimental *Key factor for success* Contextual conditions	*Implementation type* Symbolic *Key factor for success* Coalition strength

2.2.1. Documentary analysis

To generate a comprehensive analysis, a wide range of documents were included (Buse et al., 2023) including grey literature (e.g., reports, evaluations, press releases, editorials, minutes of meetings, and memoranda), media articles, published literature, and policy supporting statistical data (Fig. 2). Documents were included if they were written in English, and provided information relating to the ban itself, historical livestock antibiotic use policy, and colistin use or resistance. Starting with the amendment to the Food Safety and Standards Regulation which operationalised the 2019 colistin ban (FSSAI, 2019), a retrospective snowballing technique (whereby any referred to documents were searched for and examined) was used to identify relevant documents relating to the ban, until dead ends were met.

Google searches and Indian government websites were used to identify literature written by both governmental and non-governmental sources. Twenty-three documents were included in the analysis, a summary of which is provided in Appendix 1 (Tables 1 & 2).

Databases Scopus and Web of Science were used to conduct a rapid search for published scientific literature to provide an overview of the research landscape. The search was limited to the 10 years up to the ban (i.e., July 2009 to July 2019) searching the article topic with the Boolean terms "India" AND "colistin". Of the 369 non-duplicate articles, 146 contained information relevant to the ban and were included for analysis (Appendix 2).

A similar search using Google and the Boolean terms "India AND colistin AND livestock" a search for media articles was conducted. Results were screened on page title and meta description and fourteen documents were included in the analysis (Appendix 1, Table 3).

In addition to reports from individual research studies, antibiotic resistance data were obtained from the Indian Council of Medical Research (ICMR) Antimicrobial Resistance Surveillance and Research Network (AMRSN). A similar network for livestock was established in 2017, the Indian Network for Fisheries and Animal Antimicrobial Resistance (INFAAR). This national network of veterinary laboratories is a programme of the Indian Council of Agricultural Research supported by the FAO and United States Agency for International Development (USAID) to coordinate surveillance of antibiotic resistance in animals (Rathore et al., 2020). However, INFAAR did not publish any surveillance data before the introduction of the colistin ban.

2.2.2. Interview data

Documentary analysis was supplemented with data from in-depth stakeholder interviews (n = 19) conducted in 2021 at the start of the primary author's PhD research. Stakeholders were defined as people with anticipated high-level knowledge of broiler production and antibiotic use in India and included academics, those working directly with the industry, and government representatives (Appendix 1, Table 4). Participants were contacted through two research projects, the One Health Antibiotic Stewardship in Society (OASIS) and the One Health Poultry Hub. Interviews were conducted online due to COVID-19 restrictions (April to June 2021). An interview guide was constructed around antibiotic use and misuse in poultry and covered: 1) regulation of antibiotic use in poultry, 2) guidelines for antibiotic use, 3) relevance of the Indian National Action Plan to poultry, and 4) barriers to implementing antibiotic stewardship (Appendix 3). Questions probed into antibiotic use in general rather than focusing solely on colistin to provide a deeper perspective into antibiotic use and misuse. Most respondents, however, talked about colistin use and the ban, indicating this topic was a major recent event influencing antibiotic use in broiler production. Interviews were conducted under ethical approval granted by the London School of Hygiene and Tropical Medicine's Observational Research Ethics Committee (ref. LSHTM-IECHR-01–2019), West Bengal University of Animal and Fishery Science (ref. IAEC/190(xvii)/B), and by the Royal Veterinary College's Social Science Research Ethical Review Board (ref. URN SR2021–0095). All interviewees were given an information sheet (Appendix 4) and consent obtained to record the interviews.

3. Retrospective analysis: policy content, context, and actors

3.1. Policy content

On the 8th of August 2019, the Food Safety and Standards Authority of India (FSSAI) issued an amendment to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 (FSSAI, 2019). This amendment was to operationalise a notification from the Ministry of Health & Family Welfare prohibiting the manufacture, sale, and distribution of colistin in food producing animals (The Gazette of India, 2019). Colistin labels now had to contain the text "*Not to be used in food producing animals, poultry, aqua farming and animal feed supplements.*" (ibid, p2).

As India's colistin ban applied to all livestock species, it can be considered to have low ambiguity – its content is clear and there are no exceptions for using it in livestock. This has less ambiguity than, for example, the EU, China, Thailand, Japan, and Malaysia's legislation which prohibits colistin as an antibiotic growth promoter but still allows it to be used in animals for therapeutic purposes. The ban can also be considered to have low conflict. Both ministries from the human and animal health sectors agreed to ratify the ban and though it was reported there was some pushback from the pharmaceutical and poultry industries (The Times of India, 2019) there appears to have been little public opposition. Thus, India's colistin ban can be considered to have an administrative style policy implementation (Matland, 1995). This is considered the least complicated form of policy to implement. Should there be sufficient resources available to deliver the policy it should not require excessive political force thus increasing the likelihood of it being successful (Buse et al., 2023).

3.2. Policy context

3.2.1. Exogenous context

Since its discovery in 1947 (Stansly and Schlosser, 1947), colistin has transitioned from being a novel antibiotic used in both humans and animals, to one primarily used in animals, to now, one kept in reserve for use in people. Fig. 3 outlines the timing of key events relating to colistin use in livestock in India.

After the realisation in the 1970s that colistin could cause serious side effects in people such as nephrotoxicity and neurotoxicity (Koch-Weser et al., 1970; Nation and Li, 2009a) it became primarily an animal antibiotic. During the last 20 years, however, numerous bacterial species, such as Enterobacteriaceae, *Pseudomonas aeruginosa*, and *Acinetobacter* species emerged as being multidrug resistant and began causing serious infections in humans (Ventola, 2015). Subsequently, medical practitioners began to look for alternative treatment options and colistin became increasingly relied on to treat these multidrug resistant infections (Falagas et al., 2005; Spapen et al., 2011). Consequently, at the level of global governance, colistin was prioritised as a

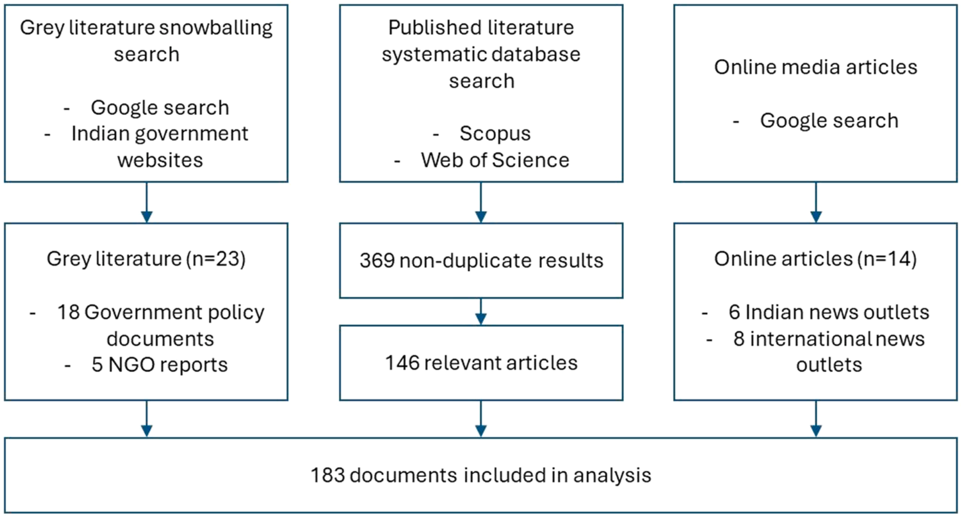

Fig. 2. Summary of literature searches (grey and published literature and media articles), screening, and inclusion for documentary analysis.

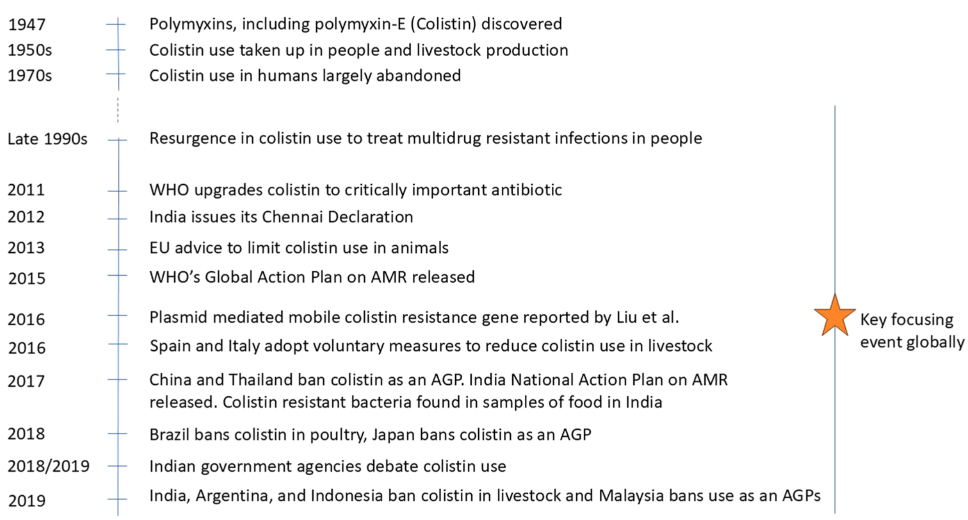

Fig. 3. Timeline of key global events (from the discovery of colistin in 1947 to the 2019 bans) relating to colistin use, highlighting the time of the key focusing event at a global scale.

critical antibiotic for human health. In 2011 the WHO upgraded colistin's prioritisation status from highly important to critically important antibiotic (WHO, 2012). This level of concern was further supported by the European Union Medicines Agency that issued advice to limit colistin use in animals. This occurred following concerns over the development of antibiotic resistance and its potential impact on human health (EMA, 2013).

In 2016, the mobile (i.e., between bacteria) colistin resistance gene *mcr-1* was discovered in bacteria from a pig in China (Liu et al., 2016) and colistin use in animals became a major public health issue. Subsequently, colistin was upgraded by the WHO to a highest priority critically important antibiotic in 2016 and its use in animals became much more of a concern than it had previously been. This upgrading occurred as colistin now satisfied all three of the WHO's prioritization criteria. First, the antimicrobial was needed to treat serious infections in people. Second, there was high frequency of colistin use in human patients with serious infections. Third, it was used in treatment of "*infections in people for which there is evidence of transmission of […] resistance genes from non-human sources*" (WHO, 2017a, p.12). Soon after the Chinese discovery, *mcr-1* carrying bacteria were reported from other countries across the world (Wang et al., 2018) including India (Marathe et al., 2017; Sanjay et al., 2018). Thus, the discovery of the *mcr-1* gene can be considered a key focusing event on the global antimicrobial resistance (AMR) policy landscape.

At a similar time, in the WOAH list of important antibiotics for animal health, colistin classed as a highly important antibiotic for animal treatment, i.e., in the second highest category, below critically important antibiotics[4] (OIE, 2018). Therefore, at the time the colistin ban was being debated in India, while colistin had been prioritised globally at the highest level in human health it was still classed as highly important for animal health (WHO, 2017a; OIE, 2018). This represents a potential conflict between two sectors with both vying to maintain the priority of colistin in their therapeutic arsenal.

Meanwhile, in China, further research into the *mcr-1* gene, by teams such as Shen et al. (2016), suggested that the use of colistin in animal

[4] Veterinary critically important were defined as (1) those antibiotics that the majority of OIE member respondents identified as important and (2) antibiotics essential for specific infections which lack suitable alternatives (OIE, 2018). Veterinary highly important are those antibiotics which satisfy one of these two criteria.

feed probably promoted dissemination of *mcr-1* genes in animals and humans. Consequently, China's National Centre for Food Safety Risk Assessment drafted a colistin ban which the Chinese Ministry of Agriculture subsequently ratified (Walsh and Wu, 2016). As the world's largest producer of colistin, however, China continued to export this relatively cheap antibiotic[5] to other countries, including India (Kumar et al., 2020; Umair et al., 2023). However, China's colistin ban appeared to produce a domino effect and over the following three years several other countries[6] introduced colistin regulation in livestock.

3.2.2. Indian structural context

Previously, legislation governing the use of antibiotics in livestock in India concerns the legitimacy of medicine prescriptions and prescribers, including veterinarians (Ministry of Health and Family Welfare, 2016) and regulation of medicine residues in food producing animals (FSSAI, 2017). However, research into antibiotic use in India has described how antibiotics are readily available without prescriptions and from those actors who lack legal mandates to prescribe (Gautham et al., 2021; Hennessey et al., 2023). Furthermore, before the ban in 2019, no restriction existed for what types of antibiotics could be used in terrestrial food producing animals. However, the Food Safety and Standards Regulations 2011 contained a list of antibiotics prohibited in aquaculture including glycopeptides (the class to which colistin belongs) and fluoroquinolones (FSSAI, 2017) demonstrating the states' ability to regulate.

India was a major importer of colistin from China (Kumar et al., 2020; Umair et al., 2023). In 2019 Indian experts estimated that approximately 95 % of colistin, and the active pharmaceutical products needed to formulate colistin, used in animals was imported from China (The Times of India, 2019). The 1940 Drugs and Cosmetics Act upholds the government's power to prohibit the import of medicines should there be concerns that "*the use of any drug or cosmetic is likely to involve any risk to human beings*" (Ministry of Health and Family Welfare, 2016, p. 12). Thus, stopping imports of colistin products was a potential route to address use in food production without adversely affecting the domestic pharmaceutical industry. India's pharmaceutical industry is a major industrial sector, it is the third largest in the world in terms of volume (Bjerke, 2022) and thus could have been an opposing force should domestic business have been affected.

3.2.3. Indian situational context: scientific research and surveillance

Before the colistin ban in 2019, there was a marked increase in published research concerning colistin use and resistance in India in the human sector (Fig. 4). However, during the same time published research focusing on animals and the environment remained low.

Many of the human focused studies described how colistin is one of the few antibiotics which effectively treats multidrug resistant (MDR) infections in vulnerable human populations.[7] This evidence reinforced the narrative of colistin as a '*last resort*' antibiotic and confirmed its importance to India's human medical sector (for example Kaur et al., 2018; Mathur et al., 2019). Data from Indian national surveillance showed that between 2015 and 2018 the proportion of colistin resistance in bacteria (*E. coli*, *K. pneumonia*, *P. aeruginosa*, and *Acinetobacter* species) isolated from people was increasing but remained below 10 % (ICMR, 2021; Walia et al., 2019a). Ad hoc studies of food producing animals revealed variable levels of colistin resistance in zoonotic bacteria of animal origin (Table 2). The variation in colistin resistance is likely due to a number of variables, including geography, production type, and antibiotic use practice. Importantly, colistin resistance had been documented as high as 100 % in *Salmonella* from poultry (Singh et al., 2010), 80 % in *E. coli* from cattle (Bandyopadhyay et al., 2012), and 100 % in *Vibrio* from shellfish (Sudha et al., 2014).

While precise national surveillance data on the use of colistin in animals was lacking, some non-governmental organisations and experts highlighted the indiscriminate use of antibiotics, and colistin in particular, in poultry and aqua farming for growth promotion (CSE, 2013; Stockton et al., 2018). Stakeholders from India's poultry sector also reported how colistin use had been widespread in poultry due to it being effective, cheap, and easy to administer:

> "One of the good things was that colistin could be given in the water, oral doses. But other antibiotics need injections, [which] requires manpower. You have to inject and repeat the doses. It is some problem. That is why colistin was the best choice." 210506_1543, Government veterinarian.

Thus, in the years leading up to the colistin ban there was a growing body of scientific evidence documenting low level but increasing colistin resistance in people amid high prevalence of colistin resistance in animals. We suggest this represented a window of opportunity for policy makers to act to protect colistin effectiveness, i.e., during this time a colistin ban in livestock was worth pursuing.

3.2.4. Indian situational context: antibiotic policy environment

As with many other countries, there has been a steady increase in AMR interest within state and non-state institutions in India over the last decade, reflecting the importance the issue has received at the global stage (Podolsky, 2018). In their scoping report, Gandra et al. (2017) argue AMR came to the attention of policy makers in India after the 2009 discovery and reporting of NDM-1 resistant bacteria and subsequent controversy over the naming of the organism.

Several national and state level policy documents recognised and clearly articulated a need for reducing the use of human antibiotics in animals (Appendix 1). Three declarations (Jaipur 2011, Chennai 2012, and Delhi 2017) have been issued by the Indian government to highlight its commitment to tackling AMR (Ghafur et al., 2013; Government of India, 2017b; WHO, 2011). The Chennai Declaration (2012) has been hailed as an important milestone in creating widespread awareness of AMR in India, changing the way the medical community and policy makers engaged with the issue (Moudgil et al., 2018; Singh et al., 2019). As Kapoor (2023) notes, declarations such as these "*encapsulate the work of multiple ministries, member countries, and knowledge partners […] sending out a message to the world. […] to make common commitments towards issues of global concern*" (p.1). Thus, these declarations not only display the intention of the Indian government to act on AMR but also demonstrate the states' interest in being a global player on the issue.

While India's National Action Plan to tackle AMR does not mention colistin specifically it does renew calls for control on the use of antibiotics in livestock (Government of India, 2017a). However, in the years leading up to the ban, colistin began to be mentioned specifically within national policy documents including the Indian Council of Medical Research and the Indian Council of Agricultural Research's draft antibiotic stewardship initiatives (Walia et al., 2019b) and Kerala's state Strategic Action Plan for AMR (Kerala State, 2018). This focus on colistin within India's AMR policy follows the first detection of *mcr-1* in livestock in China, i.e., after the key-focusing event on the global antibiotic policy landscape.

3.3. Policy process and actors involved

Examination of the colistin ban context shows how efforts to reform antibiotic use in livestock have occurred over the last decade, both at global and national levels. As Lukes (2005) noted, when conducting policy analysis, it is important to examine what does not happen as much as what does. We therefore consider the policy process in two phases. A period of background activity followed by a period of policy action. Here, we examine each of the actors involved and consider how

[5] Around $17 USD per kg (Walsh and Wu, 2016)

[6] Thailand 2016, Japan & Brazil 2018, Malaysia, Argentina, & Indonesia 2019

[7] Such as neonates, surgical, transplant, cancer, intensive care patients, and people with chronic illnesses.

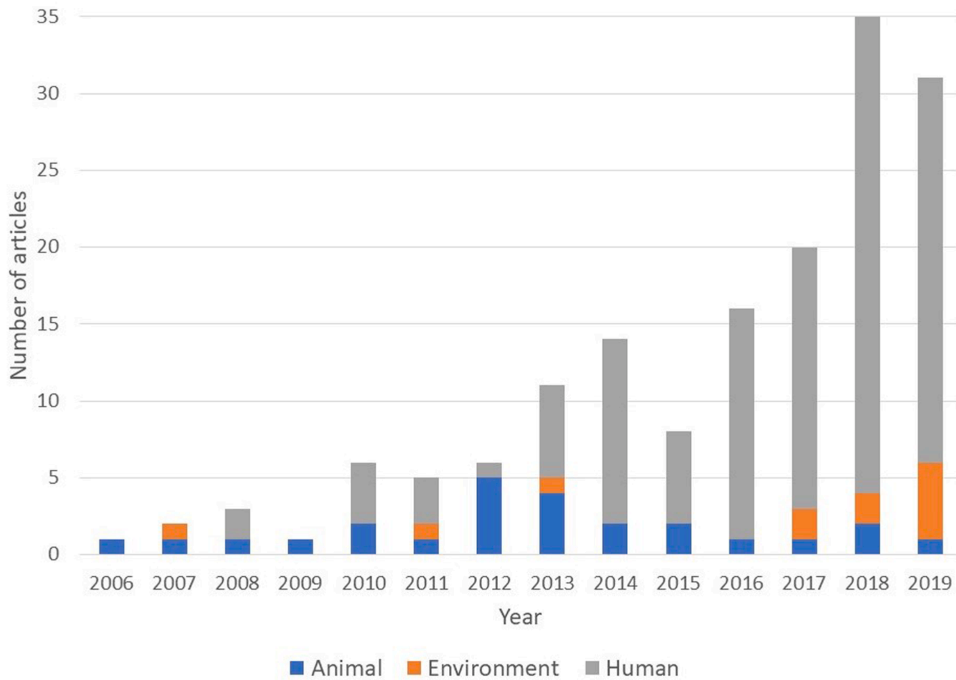

Fig. 4. Published scientific articles identified through a rapid literature review (Scopus and Web of Science) reporting on colistin use and resistance in India 2013–2019 by year and sector of focus.

Table 2
Summary of all studies containing data on colistin resistance in bacteria from animals in India identified through a rapid literature review (using Scopus and Web of Science) published from 2009 to 2019.

Authors & Year	Livestock type	Source (number of isolates)	Bacteria	Colistin resistance %
Singh et al. (2010)	Poultry	Eggs (27)	*Salmonella*	100
Taddele et al. (2012)	Poultry	Various (22)	*Salmonella*	11.2
Singh et al. (2013)	Poultry	Various (24)	*Salmonella*	0
Samanta et al. (2014)	Poultry	Various (22)	*Salmonella*	75
Mir et al. (2015)	Poultry	Faecal (32)	*Salmonella*	47
Waghamare et al. (2018)	Poultry	Various (42)	*Salmonella*	4.8
Arya et al. (2008)	Cattle	Faecal (46)	*E. coli*	12
Bandyopadhyay et al. (2012)	Cattle	Faecal (75)	*E. coli*	~80
Ghatak et al. (2013)	Cattle	Milk (8)	*E. coli*	0
Sharma et al. (2015)	Cattle	Milk (27)	*Staph. aureus*	55
Batabyal et al. (2018)	Cattle	Milk (22)	*E. coli*	0
Sudha et al. (2012)	Fish	Various (82)	*Vibrio parahaemolyticus*	77
Kumar and Lalitha (2013)	Fish	Various (265)	*Vibrio*	84
Sudha et al. (2014)	Shellfish	Various (72)	*Vibrio*	95–100
Silvester et al. (2019)	Shellfish	Various (280)	*Vibrio*	100

NB. Source refers to where samples were collected for microbial testing and number of isolates indicates how many bacteria isolates were included in the antibiotic sensitivity tests.

they exerted power and influence in the development of India's colistin ban.

3.3.1. *A period of background activity*

First, we question why action on this issue did not occur until recently? Colistin had been classified as a critically important antibiotic since 2011 and there had been numerous calls, both internationally and within India, for reform. We hypothesise that prior to the ban becoming actively debated there were sufficient forces at play in opposition to changing the status quo and introducing legislation, otherwise change could have occurred earlier.

3.3.2. *Poultry and pharmaceutical sectors*

Even though overt evidence of opposition is not available, limited anecdotal evidence suggests that there was some resistance from the poultry and pharmaceutical industries (The Times of India, 2019). Ministry departments concerned with food production and economics may also have been wary. Colistin was commonly used to improve production performance[8] and to a lesser extent to as a therapeutic agent to treat bacterial disease in poultry. India's livestock sector contributes 4.11 % to GDP (Islam et al., 2016) with poultry being one of the main sources of meat. Thus, we hypothesise that the poultry industry could have been in opposition to potential antibiotic reform. Here, the industry may have used its power as an influential agricultural sector to keep antibiotic reform off the policy agenda, an example of Luke's second face of power in non-decision making. Development of India's poultry sector has been rapid over the last two decades, (Gulati and Juneja, 2023; Tak et al., 2022) and rapidly increasing (Scudiero et al., 2023).Thus, any antibiotic reform which potentially threatened poultry production is likely to have been controversial, both within the sector and the state.

[8] Products such as Colimex 10 % (produced by Vetmex Animal Health) were available which contained colistin sulphate (as well as vitamin B12 and dextrose) and claimed the product "promotes growth [and] increases feed utilization."

However, given the lack of restrictions on other antibiotics being used in livestock, the poultry industry was able to react to a colistin ban by using alternatives, such as enrofloxacin, as indicated by this technical manager of an animal health company:

> "For treatment you can go for quinolone group. It is not as bad as colistin sulphate, this was needed for humans. […] Quinolones are very safe [and effective] against bacterial disease like E coli [which] is very rampant." (210427_1851, Veterinarian, technical manager animal health company)

The presence of viable antibiotic replacements for colistin might explain the lack of opposition from the poultry industry for the colistin ban.

Similarly, India's pharmaceutical sector, which contributes 1.5 % to GDP (World Bank, 2023) is likely to have had a relatively large amount of influence in policy debate concerning antibiotic use, a situation known to occur across the sector globally (Jorgensen, 2013; Kapczynski, 2023; Rickard and Ozieranski, 2021). However, as most animal grade colistin was imported into India, a potential ban was unlikely to have a major negative impact on domestic production and may have even created an opportunity if antibiotic use switched from foreign to domestic sources. Furthermore, it is possible that the pharmaceutical industry could look favourably on such a ban if it were to improve India's reputation in global markets. Thus, for colistin, we consider the pharmaceutical sector a relatively neutral actor in this policy debate.

3.4. *Ministry of Fisheries, Animal Husbandry and Dairying*

Initially, reference to antibiotic use in livestock by the Ministry of Fisheries, Animal Husbandry and Dairying had mainly concerned antibiotic residues in animal source foods. Consequently, the dominant narratives coming from this sector focused on food safety rather than AMR (AMR being the dominant narrative from the health sector). This may have prevented sufficient agreement from being achieved between sectors and contributed to the period of inaction during which antibiotic reform did not occur. In their analysis of antimicrobial policy development in Denmark, Wielinga et al. (2014), detail how conflicts of interest between state sectors occurred due to uncertainty about resistance transmission from livestock to humans. The authors describe how conflicts between the agriculture, health, and commercial sectors complicated and delayed antibiotic stewardship interventions (Wielinga et al., 2014).

3.5. *Ministry of Health and Family Welfare*

In the years leading up to the ban, the Ministry of Health and Family Welfare put numerous documents and declarations into the public realm calling for antibiotic reform in livestock, though not focusing specifically on colistin (App. A, Table 1). Here, the Ministry used its authority and position as a key Indian state actor to reinforce a human health focused narrative. We consider this an example of Lukes' third face of power, power through thought control.

3.6. *NGOs, media agencies and the research community*

Media stories generated through NGOs and the general media and articles from the research community produced consistent narratives concerning antibiotic use and resistance. Here, narratives from Indian studies describing colistin as '*the last resort antibiotic*' in human health (for example Kaur et al., 2018; Mathur et al., 2019) supported global narratives. In this sense, the research community can be considered to have used its intellectual capital and prestige to influence policy debate. Similarly, medical professionals, including infectious disease specialists and microbiologists, had been championing AMR as a policy issue using platforms such as the Chennai Declaration of 2012 to call for the regulation of antibiotic use in livestock (Ghafur et al., 2013). Several non-governmental organizations[9] (NGOs), some working in collaboration with overseas organisations also pushed for antibiotic regulation in livestock in India. As with the state actors, these groups made repeated calls for phasing out non-therapeutic use of antibiotics such as for growth promotion. Some of these NGOs brought a critical voice to India's AMR policy debate, suggesting India had been late in recognising the role of livestock antibiotic use in promoting antibiotic resistance (Ganguly et al., 2011) and calling out the double standards of multi-national companies operating in India (Khurana and Tewari, 2017; Stockton et al., 2018).

3.6.1. *A period of policy action*

The period of background activity ended after the discovery and global awareness of the *mcr-1* gene and shortly after other countries had acted to limit colistin use in livestock. Now, formulation of India's policy to ban colistin took place in a relatively short space of time (Fig. 5). During this time a coordinated process between private sector advocates and government ministries and their agencies took place to move the policy from a request for action to official regulation.

3.7. *Advocates from the human health sector*

In 2017, bacteria isolated from food samples in Chennai were found to be resistant to colistin (Ghafur et al., 2019). This can be considered another key focusing event at the national level. Here, evidence of colistin resistance in bacteria found in food provided the impetus for action and calls for reform from medical professionals. Here, we consider private sector advocates to be using their power through Lukes' first face, power of decision making by successfully getting colistin use in livestock onto the policy agenda. As the national antibiotic coordinator, Dr Ghafur took this new evidence to the Central Drugs Standard Control Organization (CDSCO) and requested an urgent ban on colistin use (DTAB, 2018).

3.8. *Coordination between government ministries and agencies*

Once the request for a colistin ban was received by the CDSCO the Ministry of Health & Family Welfare and Ministry of Animal Husbandry, Dairying and Fisheries, along with their departments and agencies, worked together to coordinate a period of policy activity in a relatively short period of time. Here, the ministries and their relevant departments and agencies had the institutional power legal authority to move the request through to a regulation in less than two years (Fig. 5). However, the process to develop the colistin ban does not appear to have been in consultation with stakeholder groups outside of ministries and private sector advocates. Importantly, we did not find evidence that representatives from the livestock sector, particularly poultry stakeholders where colistin was heavily used, and the pharmaceutical sector were part

4. Prospective analysis of other CIAs used in livestock

The retrospective analysis identified several factors which facilitated the colistin ban reaching India's policy agenda and going into law (Fig. 6). Despite a national commitment to restricting antibiotic use in livestock over the last decade policy change in India was initially slow and we argue reliant on 1) key focusing events, 2) consistent narratives, 3) a worthwhile endeavour, 4) precedent for change, and 5) lack of substantial opposition. We now consider how these factors relate to two other classes of antibiotics commonly used in livestock in India, fluoroquinolones and macrolides. Both these classes of antibiotics are

[9] Including the Indian public interest group Centre for Science and the Environment, the international Global Antibiotic Resistance Partnership, and the Indian and USA collaboration Centre for Disease Dynamics, Economics and Policy

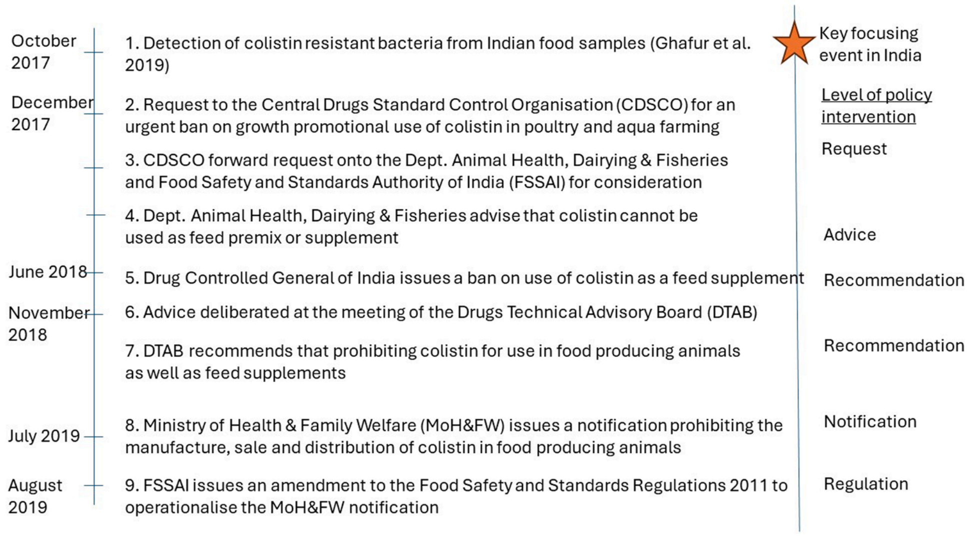

Fig. 5. Timeline of the series of events within India during the period of policy action from the key focusing event in India through to the implementation of the ban. The right-hand column indicates the level of policy intervention for each stage of the process.

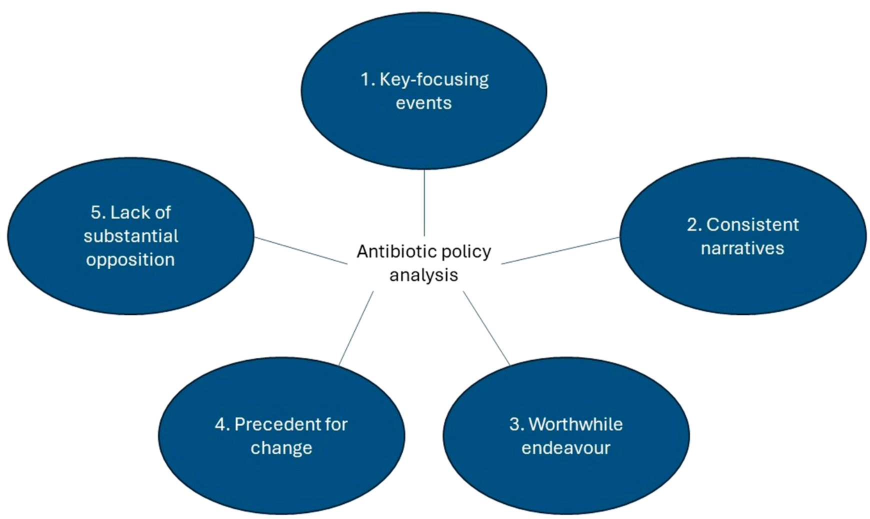

Fig. 6. Five critical factors the authors consider relevant for a prospective antibiotic policy analysis.

deemed critically important for human health by the WHO (WHO, 2019) and thus according to India's NAP should be restricted and phased out from use in food animals (Government of India, 2017a). Previous research, however, has indicated use of these antibiotics remain a key risk mitigation strategy in broiler production systems (Hennessey et al., 2025)suggesting further policy change, beyond the colistin ban, is required to reform usage in India's food producing animals.

4.1. Key focusing antibiotic events

As Kingdon (2013) described, key focusing events elevate policy problems from being matters of concern to arriving on official policy agendas. Certainly, the discovery of the *mcr-1* gene in 2016 (Liu et al., 2016) and evidence of colistin resistance in bacteria found in Indian food (Ghafur et al., 2019) appeared to be pivotal moments in the development of India's colistin ban.

Plasmid-mediated quinolone resistance has been reported since 1987 (Jacoby et al., 2014). Around two decades ago fluoroquinolone resistance in bacteria from livestock and associated human infections was reported Denmark (Mølbak et al., 1999) and in the United States of America (USA) (Collignon, 2005)). While this reporting appears to have been a focusing event for change in antibiotic use policy within both Denmark and the USA, it did not cause a flurry of other countries to follow suit. Thus, it seems that for fluoroquinolone resistance there has not been a recent key focusing event comparable to the *mcr-1* gene discovery in the last decade (i.e., not since the WHO's Global Action Plan on AMR). Should this have occurred, then attention of the international community may have been focused and fluoroquinolone use in livestock pushed onto policy agendas in a similar way to colistin.

Similarly, the use of macrolides in animals has been linked with the development of erythromycin (a critically important antibiotic for human health) resistant bacteria in food animals for some time (Aarestrup et al., 2001; Jackson et al., 2004). This type of evidence was used by the EU to ban the use of the macrolide tylosin as an AGP in 1999 (Casewell et al., 2003). More recently, a publication by Suzuki et al. (2022) reported pig farms in Taiwan as the origin of novel mobile antibiotic resistant genes. Whether this type of discovery has the significance or traction to cause similar international concern as the discovery and reporting of the *mcr-1* gene remains to be seen.

4.2. Consistent narratives

Colistin belongs to the polymyxin class of antibiotics (colistin is polymyxin-E) and is the main active compound in that class. Consequently, most research investigating bacterial resistance to polymyxins focuses solely on colistin. As a result, clear and consistent narratives developed over colistin being a 'last resort antibiotic' (for example Kaur et al., 2018; Mathur et al., 2019). This narrative has permeated research, media, public discourse, and ultimately policy debate. The fluoroquinolone class, however, contains several generations of antibiotics each containing numerous compounds. While messaging from the WHO stipulates that all fluoroquinolones are deemed critically important antibiotics (WHO, 2017b) complicated by several compounds existing which are only used in veterinary medicine (enrofloxacin[10] and marbofloxacin). Despite evidence existing for bacteria developing cross compound resistance within a class of antibiotics (Bhatnagar and Wong, 2019) animal healthcare professionals continue to justify the use of what they deem to be 'animal' fluoroquinolones. This ambiguity was communicated by one veterinarian when talking about which antibiotics should be used to treat poultry:

> "For treatment, you can go for quinolone group, it is not as bad as colistin sulphate, this was needed for humans. Enrofloxacin is not used for humans, ciprofloxacin and levofloxacin to some extent. I think quinolones should not be banned as a treatment antibiotic."
> 210427b - Veterinarian, animal health company technical manager

Similarly, numerous antibiotic compounds exist within the macrolide group, several of which are not used in human medicine. Two of these compounds, tylosin and tilmicosin, are commonly used in poultry. This is concerning, as with the fluoroquinolones, cross-resistance between members of the macrolide class can occur (Leclercq and Courvalin, 2002).

Neither the fluoroquinolones nor macrolides have reached the status of being described as 'last resort', or similar terminology, antibiotics. Thus, it appears more difficult to generate consistent narratives for introducing restrictions for classes of antibiotics with numerous compounds, especially when several of them are licensed only in animal species.

4.3. A worthwhile endeavour

Before 2019, colistin resistance in key pathogenic bacteria in human health (*E. coli*, *K. pneumonia*, *P. aeruginosa*, and *Acinetobacter* species) in India remained below 10 % between 2015 and 2018 (ICMR, 2021; Walia et al., 2019a). This indicated that taking action to preserve the effectiveness of colistin in bacteria from humans could be worthwhile.

While further work is needed to properly evaluate how India's colistin ban has been implemented and its effectiveness on reducing the prevalence of antibiotic-resistant bacteria such studies have been conducted in China. These studies show significant reductions in the prevalence of colistin resistant and *mcr-1* positive bacteria in pigs, poultry, and people (Liu et al., 2020; Shen et al., 2020; Wang et al., 2020) indicating a beneficial effect of China's colistin ban.

Looking at fluoroquinolone (ciprofloxacin and levofloxacin) resistance of *E. coli* and *K. pneumonia* in India tells a different story. For *E. coli* in people resistance rates are in the region of 72–75 % and for *K. pneumonia* 63–71 % (ICMR, 2021, p68), equally high. Similarly, macrolide (erythromycin) resistance of *Staphylococcal* species in human bacterial isolates is between 54 % and 88 % (ICMR, 2021, p101, p112). While these levels of resistance in humans are concerning, it should be noted that mechanisms for resistance against antibiotics can carry a biological cost for bacteria (Périchon and Courvalin, 2009)). Indeed, studies have shown that rates of bacterial resistance can decrease once the selection pressure of antibiotic use is removed (Aarestrup et al., 2001; Dunai et al., 2019). Thus, there may still be benefit from reforming fluoroquinolone and macrolide use in livestock to safeguard use in human health. However, whether restricting antibiotic use in animals will result in a reduction in resistance in bacteria isolated from people is more complex and requires a longer-term approach with human and animal health sectors working together to monitor the problem.

Additionally, studies in human bacterial isolates have identified the co-selection of fluoroquinolone and extended-spectrum beta-lactamase (ESBL) resistance (Febrianti et al., 2023; Katsandri et al., 2008). This suggests that allowing the ongoing use of fluoroquinolones in livestock production may also threaten use of other critically important antibiotics such as third and fourth generation cephalosporins, though further studies of livestock bacterial isolates are needed to investigate such resistance dynamics.

4.4. Precedent for change

Before India's colistin ban, several other countries introduced similar legislation. This suggests India was receptive to what was happening on the international antibiotic governance stage. In their analysis of AMR policy development, Wielinga et al. (2014) note that food safety risk strategies taken up by early adopter countries result in similar strategies in other countries. Given the international nature of the AMR policy debate, with organisations such as the WHO, FAO, and WOAH contributing to antibiotic stewardship, it is unsurprising that member states are observant and reactive to policy actions taken by others. Indeed, in the Delhi Declaration, India had confirmed its commitment to being a global player to tackle the challenge of AMR (Government of India, 2017b).

Regarding fluoroquinolone policy change, legislation restricting use of this antimicrobial class in livestock has been sporadic over the last 15 years. In 2002 the Danish government passed legislation severely limiting use of fluoroquinolones in food animals (Heuer et al., 2005) and in 2005 the United States banned the use in poultry (Collignon, 2005). Currently, India does regulate fluoroquinolone use but only in aquaculture to protect the food export industry (FSSAI, 2017).

Globally, there has been even less legislation regarding use of macrolides in livestock. As previously discussed in 1999 the EU banned the macrolide tylosin from being used as an AGP (Casewell et al., 2003) and in 2020 Brazil did the same for pork production (Dutra et al., 2021).

Thus, at an international level, while there has been some precedent set to restrict the use of fluoroquinolones and macrolides in livestock, this has not yet been adopted for terrestrial livestock in India. Here, it may be that India's current position as a negligible exporter of livestock meat into global markets (Kumar, 2010; Kumar et al., 2022) has given the Food Safety and Standards Authority of India little cause to implement the type of restriction the aquaculture industry is subjected to.

4.5. Lack of substantial opposition

As Lukes (2005) noted, the examination of power requires the identification of a conflict of interests. Through our analysis we have postulated how the most likely stakeholders to be opposed to change are those benefiting most from the current status quo of antibiotic usage in animals, the livestock (particularly poultry) and pharmaceutical sectors.

For the livestock sector, it appears that the ready availability of treatment alternatives meant there was little opposition to the colistin ban. However, as stakeholders have reported enrofloxacin replacing colistin in poultry production, it seems logical that additional policy to further restrict antibiotic use would now be more challenging and meet greater resistance from the industry. Clearly, any future antibiotic policy development needs to consult with stakeholders from the livestock sector (which did not appear to happen to much extent for the colistin ban) to ascertain their concerns and mitigate the potential externalities

[10] Enrofloxacin is largely metabolised into ciprofloxacin

of further restrictions. Here, mitigation strategies could include measures to reduce the need for antibiotics in livestock production (e.g., biosecurity measures) and alternatives to antibiotics (such as pre- and pro-biotics).

Similarly, for the pharmaceutical sector, it appears the colistin ban would have had little industrial impact given most colistin was being imported from China. However, many other antibiotics being used in livestock are produced within India by both domestic and multinational pharmaceutical firms. For example, internet searches for enrofloxacin producers in India reveal two international companies, the French Vetoquinol (producing Meriquin) and the USA Zoetis India (Enrocin), and at least 16 domestic manufacturers.[11] Recently, it has been reported that one of India's largest poultry producers, Venky's,[12] is selling a medicated poultry feed mix Tylomix (containing tylosin, a macrolide) as an antibiotic growth promoter (Rahul et al., 2024). Thus, it seems likely that should the Indian government introduce legislation restricting the use of fluoroquinolones or macrolides in livestock, this would go against the interests of many stakeholders.

Given the findings of this prospective analysis, it may be necessary for the Indian government to adopt several strategies, or policy instruments, to enact change in antibiotic use in livestock to align practice with global (WHO, 2019) and national (Government of India, 2017a) targets. Such policy instruments could include further regulatory measures, economic incentives, and voluntary guidelines and agreements, or the use of multiple instruments in tandem (Bennear and Stavins, 2007). Antibiotic bans regarding other critically important antibiotics would appear challenging given the therapeutic reliance of these antibiotics in animal health. Furthermore, bans have potential to cause system shocks on livestock sectors currently reliant on antibiotics. Such shocks could threaten both food security and incomes of smallholder farmers. Economic incentives such as taxes and subsidies may be alternative solutions and have been used in some settings to influence antibiotic use. Denmark, for example, introduced differential taxes on antimicrobials in 2013, with higher taxes on critically important antibiotics to discourage their use, an approach which contributed to a significant decrease in antibiotic consumption in livestock (DANMAP, 2018). Modelling of global antibiotic taxation systems by Morgan et al. (2023) suggest that such differential systems would maintain better antibiotic availability compared to single and flat taxation strategies and generate the highest potential revenue. Revenue generated could be used to fund other antibiotic stewardship interventions, such as surveillance, or to subsidise antibiotic alternatives. Indeed, as indicated in a study of broiler farming in India (Hennessey et al., 2025) poultry companies are beginning to move to antibiotic alternatives (such as pre- and pro-biotics) but these are often considered cost prohibitive. Voluntary agreements, such as industry led initiatives have been used successfully in some sectors to reduce antibiotic use. In the UK, for example, the British Poultry Council (BPC) implemented a comprehensive stewardship programme that has significantly reduced antibiotic use in poultry production. Since 2012 BPC members have reduced the use of critically important antibiotics by 98.7 %, and fluoroquinolone use has almost stopped entirely (BPC, 2023). In India, given the prominent role of the corporate sector in broiler production through contract farming (Hennessey et al., 2025), poultry firms have capacity to instigate change by addressing technical challenges to the way broilers are reared to move away from a reliance on antibiotic use. However, such collective action requires a great deal of coordination and as such will likely need support from the state.

As Lhermie et al. (2019) highlight in their analysis of policy instruments to reduce antibiotic use in American beef production, instruments have different advantages, disadvantages, and requirements for use. Further research considering these factors and modelling of what Bennear and Stavins (2007) describe as the three criteria of assessment (efficiency, cost-effectiveness, and non-economic criterial) would therefore be beneficial for future antibiotic policy development in India.

[11] Birhans, DotcomPharma, Globion, Vetsfarma, Zydus, Leo Bio-Care, Newlife Pharmacy, Shushima Laboratories, Zenex Animal Health, Sun Remedies, Omni Protech, Hester Biosciences, VetPlus, Neospark, International Health Care, Allchem

[12] Venkateshwara Hatcheries Pvt Ltd

5. Limitations

When assessing the power of actors involved in policy development it can be difficult to know what has occurred behind the scenes and regarding those actors who are difficult to engage with. This analysis is therefore reliant on information that is available in the public domain and from actors who were willing to talk with us and share their experiences and opinions. We were unable to interact with stakeholders from the pharmaceutical sector and information regarding state actors was largely obtained from publicly available documents. Thus, there are likely to be additional factors which influenced the colistin policy debate and which could affect development of future antibiotic stewardship policies.

6. Conclusion

Our policy analysis has shown that India's colistin ban was a reactive process in response to key focusing events, as it was in other countries. India followed suit on the international stage, an action which was aligned with its stance of being a global player, as described in the Delhi Declaration on antimicrobial resistance. Over the last decade, medical gatekeepers of human health, including numerous advocates supported by both the state and international agencies, have used their power to keep a focus on antibiotic use in livestock in the public debate. Within this debate, colistin had a unique position, being hailed as one of the key 'last resort' antibiotics for human health. Given that most colistin was being imported into India, and suitable antibiotic alternatives available to replace its use in livestock, there was limited opposition from the pharmaceutical and poultry industry to a proposed ban. This may not be the case for future legislation which seek to further limit antibiotic use in food producing animals and are needed to fully operationalise the goals of national and international action plans against antimicrobial resistance. Such pro-active actions need to be considered to prevent just waiting for the emergence of new resistant organisms or genes which compound the global threat of bacterial resistance. Introduction of the colistin ban, however, demonstrates India's willingness to take affirmative action to tackle antibiotic stewardship during food production. Currently, further research is needed to evaluate the effectiveness of the colistin ban, both in terms of policy implementation and the longer-term effects on bacterial resistance. We argue any further policy development should be in collaboration with key stakeholders, particularly the pharmaceutical and livestock sectors (who stand to be most affected), to understand and help mitigate any potential negative externalities of new antibiotic regulation.

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CRediT authorship contribution statement

Papaiyan Kumaravel: Writing – review & editing, Investigation. **Paleja Haidaruliman:** Writing – review & editing, Investigation. **Fournié Guillaume:** Writing – review & editing, Supervision. **Samanta Indranil:** Writing – review & editing, Supervision, Investigation. **Gautham Meenakshi:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Alarcon Pablo:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Funding acquisition, Formal analysis, Conceptualization. **Hennessey Mathew:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare no conflict of interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.prevetmed.2025.106534.

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