Report on

Effectiveness of drugs control and regulating mechanism of the Drugs Control Department in Kerala State

Submitted to the Kerala State Planning Board

March 2021

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ACKNOWLEDGEMENTS

This report is based on data collection, analysis and my insights from the study entitled "Effectiveness of drugs control and regulating mechanism of the Drugs Control Department in Kerala State" funded by the Evaluation Division of the Kerala State Planning Board.

I wish to place on record my heartfelt gratitude to several people and organizations who played a pivotal role in the completion of this study and submission of this report.

This project report would not have been possible without the wholehearted and unstinting support of Dr. Jayakumar K., Director (In-charge), Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum.

I acknowledge the valuable inputs received from several eminent people including Dr B Ekbal and Dr V Ramankutty.

I thank the cooperation of the Drugs Controllers Shri Ravi S Menon (retired) and Shri K J John and all staff of the Kerala State Drugs Control Department approached for the purpose of the study. I also thank all experts/officers of the line departments Directorate of Health Services, State TB Office, Government Medical Colleges who gave their inputs for the study.

I thank the research support provided by the Centre for Public Health Protection, Kollam, Shri Rakesh Ramachandran, Dr Sophia Modi, Dr Rajalakshmi, Mr Subodh Satheesh, and Ms Juno S.

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05-03-2021

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LIST OF ABBREVIATIONS

CDSCO	Central Drugs Standard Control Organisation
DCA	Drugs and Cosmetics Act, 1940
DC	Drugs Controller
DI	Drugs Inspector
DPCO	Drug Price Control Order
IP	Indian Pharmacopoeia
KMSCL	Kerala Medical Services Corporation Limited
NABL	National Accreditation Board for Testing and Calibration Laboratories
NSQ	Not of a standard quality
NSSO	National Sample Survey Office
OOP	Out Of Pocket (expenditure for medicines)

Effectiveness of drugs control and regulating mechanism of the Drugs Control Department in Kerala State

EXECUTIVE SUMMARY

Background and rationale

Demographic and epidemiological transition patterns in Kerala have resulted in a state of high morbidity and pharmaceutical consumption in the state. It is imperative that drugs have to be safe and effective – but there exists an opacity on these attributes as far as the ultimate user, the patient is concerned. The main responsibility therefore of effective regulation over quality and safety of the drugs is thus the responsibility of the state. This is achieved in India (and Kerala) through relevant legislations and rules among which the Drugs and Cosmetics Act, 1940 and its amendments is central. The Drugs and Cosmetics Act, 1940, and the rules thereof provides the relevant definitions and stipulations. Thus, in India, the terms relevant to drug quality are (1) Spurious – this is the term used for counterfeit drugs; (2) Not of a standard quality (NSQ) – this is when the the drug falls short of the standards as prescribed by the Indian Pharmacopoeia (IP) which is maintained by the Indian Pharmacopoeia commission. At times reference may be made to other Pharmacopoeias as well; (3) Adulterated (4) Misbranded. The Acts and Rules mean that there is a duality in the control of drug quality and safety – the central system determines policy and strategy and the enforcement happens at the state level. The rapid expansion of the pharmaceautical industry in our country and evolution of different patterns of prescriptions and dispensing means that there is a pressing need to periodically review regulatory frameworks and practices to see whether they are able to cope with the expanding industry. This study primarily focuses on the state responsibility and approaches taken to ensure quality medicines in Kerala, through the Drugs Control Department.

Methods

The study was undertaken with the following objectives:

1) To review the structure and functioning of drug regulatory mechanisms in Kerala state Drugs Control department

2) To identify potential action points to improve the functioning of the department and to increase health care provider and patient trust of the regulatory mechanisms of the department

The study was undertaken in a two-stage processes. The first stage was largely desk study through review of scientific peer reviewed publications and other available documents and reports, proceedings of the legislative assembly, and available audit reports, and media reports. The second stage had key informant interviews with a variety of stakeholders. Based on emerging issues in the key informant interviews, in-depth interviews were carried out further in the form of three case studies. The proposal and tools were reviewed and cleared by the Institutional Ethics Committee of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

Results

Kerala state has very low manufacture but very high consumption of drugs - the reason why the state has been listed as a category II state in the Mashelkar committee report 2003. However, the state remains one with extensive private sector pharmaceutical activity. Hence much of the drugs consumed in the State will have to be obtained from manufacturers in other states. The main problem in India and Kerala is not spurious or counterfeit drugs, but one due to NSQ drugs. This has to be determined by regular testing based on Indian pharmacopoeia guidelines or equivalent ones. Other problems too are confronted at times, but to a minor degree – post-ban sales, licensing issues. The Drugs Control Department in Kerala performs commendably in these when compared to many other states in India. There is a robust electronic information system that has been effectively used for regulation and enforcement – the online licensing and notification.

However, there are several important issues in the functioning at present. A dominant theme of the findings was the imbalance emerging in enforcement side – the number of inspectorial staff. The laboratory capacity for testing and consequently the equipment and manpower have increased considerably. The number of licensees too has increased almost exponentially. Yet the staff strength in the enforcement side has not increased proportionately. Another theme that emerged was the need for better convergence –

the Drugs Controller being on the board of Directors of the Kerala Medical Services Corporation (KMSCL) offered a platform for convergence and bringing in drugs quality control and monitoring into many spaces within the public health system. Also, TB control activities demonstrated commitment from both sides, but in general with other line departments, there are gaps in convergence. Other issues identified included challenges in enforcing of schedule-based regulations; regulation of devices; online pharmacies; and differing perspectives so stakeholders. Some of these were explored as further case studies – (1) schedule H1 drugs with focus on anti TB Drugs (2) medical practitioners' perceptions on antibiotic quality (3) strengthening pharmacological jurisprudence in Kerala

Recommendations

(1) More number of Drug Inspectors are needed – in line with the Mashelkar committee recommendation of 1 Drug Inspector per 200 licences; accordingly supervisory posts also need to be increased

(2) Laboratory capacity for devices need to be developed

(3) Convergence with stakeholders need to be improved - Committees or working groups need to be formed. Such groups should be multi-disciplinary and should develop plans to prioritise areas of intervention and increased visibility of the regulatory mechanism at present – awareness programmes that reinforce trust in the system need to be rolled out

Additionally, at a policy level, the following approaches may be recommended:

- Move from a normative approach to a discursive approach: There is a need to emerge from being a normative institution (where the norms and rules shape action) to a discursive one where the institutional and social mechanisms are used to bring change. Evidence based approach: The regulatory system is not risk based – evidence generation through epidemiological and policy focussed research should be commissioned. Research should be preferably at the doctoral level and with close engagement with the Department.
- Newer technical and administrative approaches to identify and fill regulatory gaps in real time that are feasible in the Kerala context should be explored.

Conclusion

Like several other institutions in the state, the Department has evolved slowly and incrementally to its current situation, given the complex environment. Whether the changes are sufficient to keep up with the changing context where technologies and pharmaceutical products are becoming household items in almost every home is questionable.

CHAPTER I

INTRODUCTION

1.1. Background

In India, out-of-pocket (OOP) expenditures related to health care are very high, and a substantial part of this is the cost of drugs and remains a relentless problem. According to the report on healthcare expenditures in India based on System of Health Accounts 2011 and National Health Accounts Guidelines for India, 2016, 72.9% of all health care financing in the country comes from household revenues – 69.1% being out of pocket expenditure for health care. Pharmacies account for 35.7% of current health expenditure, thus indicating the large proportion of health expenditure incurred by drug purchase, despite this figure not including expenditure on drugs as part of treatment programmes and packages. (1)

Table 1.1: Morbidity and treatment seeking as per report of NSSO 71st round

		Rural			**Urban**		
		Male	**Female**	**All**	**Male**	**Female**	**All**
Number (per 1000) of ailing persons for each sex	Kerala	305	315	310	277	332	306
	India	80	99	89	101	135	118
Number (per 1000) of hospitalizations	Kerala			117			99
	India			44			49
Percentage of spells of ailment treated during last 15 days by Government Sources (%)	Kerala	32	40	36	31	31	31
	India	27	30	28	21	22	21
Percentage of cases of hospitalized treatment received from public sector hospitals (%)	Kerala			34.7			33.3
	India			41.9			32

Kerala accounts for about 1.18% of the landmass of India but is the 13th most populous state. It is also the state with the highest proportion of elderly persons. While Kerala

had achieved significant progress in health indicators by the 1970s, the fiscal response to economic liberalization meant a stagnation of development of the government health facilities. This led to almost unregulated growth of the private sector in the State. The 71st round report of the National Sample Survey Organization highlights the current paradigm in Kerala of high morbidity levels with a predominantly private provisioning of care. In mid-1980-s only 23% households regularly utilized government health facilities. However, the role of the public sector has been steady and slightly increasing over the last two decades. Looking across the 52nd (1995-96) and 60th (2004) round reports compared to the latest round (2014) – dependence on public facilities for non-hospitalized treatment increased from 28% to 37% and remained at 36% in rural areas, while it fell from 28% to 22% before going up to 31%. While demographic and health system changes must be considered while discussing this, the public sector remains the main resort to socially and economically disadvantaged sections of the population. As the case may be, the report gives the percentage of total expenditure for non-hospitalized treatment attributable to cost of medicines as 73.8% in rural and 74.6% in urban Kerala. (2)

Thus, drugs constitute an extremely important aspect of the health system and services today, public or private.

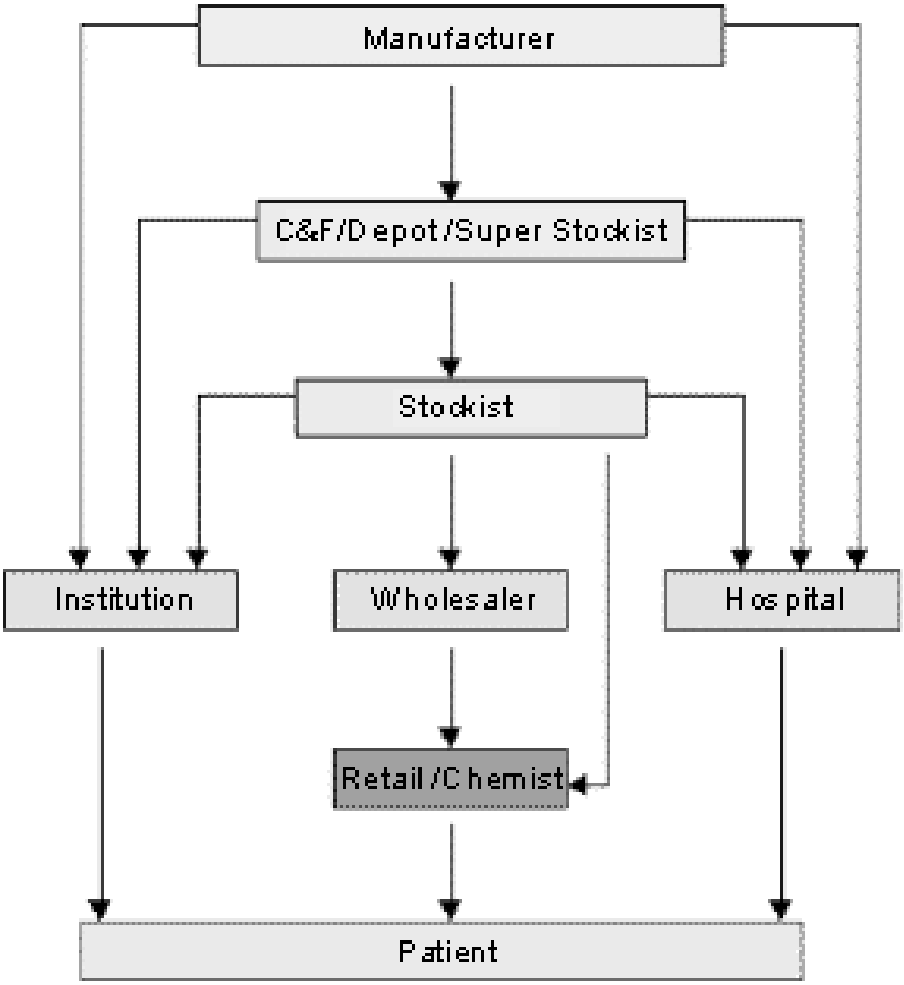

Figure 1.1. Conceptualization of drug distribution channel as reported by source: http://www.domain-b.com/industry/pharma/20000107distribution_channels.html (3)

Market forces and profit motives may dominate in this sector. Drugs are of any use only if they are safe and effective. Moreover, with a huge chunk of the population being poor, affordability is another extremely important facet regarding drugs. However, these aspects may not be dominant in all arguments around drugs. For instance, the McKinsey report on Indian Pharma 2020 calls for policy makers to "consider measures beyond price control" and mentions regulatory controls as an example of a pessimistic scenario. (4)

The citizens on the other hand usually have no information whatsoever on the quality of a drug that they receive or purchase. The case of health care providers too may not be much different as they handle packaged products and go by the information claimed by

the producer of the drug. Thus, there exists a major information disparity that is most compounded for the end-users, the patients, among all the stakeholders.

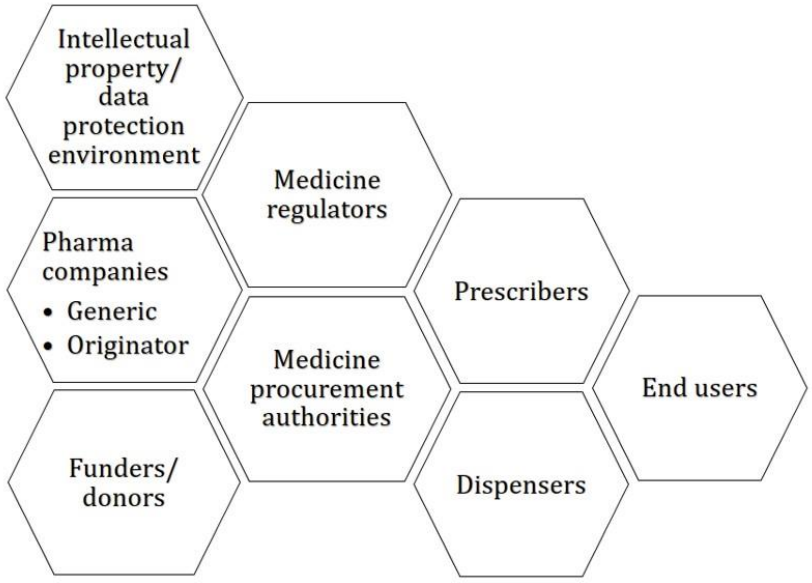

Figure 1.2: Schematic representation of stakeholders – the end users are the ones with least information.

1.2 Regulatory approach to drug quality and safety

Thus, it behoves upon the Government to take measures to protect the interests of citizens assure the citizens of safety and efficacy and affordability of medicines. These include regulatory approaches over the production and sale of drugs, affordability measures like listing of essential medicine and price control and related programmes like adverse effects documentation.

1.3 Legal framework for regulation

India has a hierarchical legislative processes characteristic of democratic constitutions. National or sub-national bodies create statutes – called Acts – that are binding and need to be enforced through various mechanisms. Various legislations and administrative regulations are put in place as part of the legislative mechanism for drug quality regulation. As per the constitutional provisions in India, health is a state subject. However, "drugs and poisons" figure in the concurrent list, thus creating a dual mechanism of control. The Drugs and Cosmetics Act, 1940, was given effect by the respective rules in 1945. This legislation and rules formed the legal basis for official

establishment of drug regulation in India and spell out the provisions and mechanisms of drug regulation in the country. At each state level, the State Drug Control department is responsible for drug control activities including regulation, manufacture, sale and distribution within the state. It is the responsibility of the Drugs Control Department to ensure availability of quality drugs to the public, with a market that is vigilant of and free from counterfeit, spurious and substandard or overpriced drugs. (5)

1.4 Counterfeit or Substandard drugs

Substandard drugs will be of little or no benefit, and may harm the patient who is the most unwitting stakeholder in the chain. Additionally, they may lead to emergence and compounding of public health problems, in the case of antibiotic resistance. While there are several classifications and definitions of counterfeit or substandard drugs, the definitions most used in India are those as given by the Drugs and Cosmetics Act, 1940.

1) Spurious – this is the term used for counterfeit drugs
2) Not of a standard quality (NSQ) – this is when the the drug falls short of the standards as prescribed by the Indian Pharmacopoeia (IP) which is maintained by the Indian Pharmacopoeia commission. At times reference may be made to other Pharmacopoeias as well.
3) Adulterated
4) Misbranded

1.5 Rationale

Kerala is currently undergoing a demographic and epidemiological transition with a heavy burden of non-communicable diseases (NCDs) as well as emerging and re-emerging infectious diseases. (6) E.g. Thousands of Dengue cases and several deaths (37) were reported in 2017; re-emergence of whooping cough is a big concern. (7) Acute respiratory infections and acute diarrhoeal diseases continue to occur, but mortality is very low for these conditions. The state is also grappling with other problems like mental health issues and road traffic accidents. Existing therapeautic practices are also facing new challenges like antimicrobial drug resistance through irrational prescriptions, self-medication practices and other reasons. The current

epidemiological context in Kerala has a large proportion of the State population being elderly or having non-communicable diseases warranting long term pharmacological treatment. This is concurrent with the rapid expansion of the pharmaceautical industry in our country. There is a pressing need to periodically review regulatory frameworks and practices to see whether they are able to cope with the expanding industry. This study primarily focuses on the state responsibility to ensure quality medicines for all needs to be reviewed, whatever the system of medicine people choose. This is to identify best practices of functioning and reliability and the mechanisms to increase physician and patient trust in medicine quality in the State. The report is made from a perspective that positions the places activities of the drug control department as a public good and necessary for the protection of public health interest.

The projected population of Kerala in 2019 was 36241000. (8). In 2016, the proportion of Keralites over the age of 60 years was estimated to be 13.2%. Projections of life expectancy were 74.2 years for men and 78.1 for women (2016-20). As per the study report of prevention and control of NCD in Kerala by the Achutha Menon Centre for Health Science Studies, among people aged 18-60 in Kerala, 11.2% were on medications prescribed by a doctor for hypertension; similarly, 9.2% were on medications for diabetes mellitus. (9) Considering just one condition – hypertension - a proportion of 11.2% means that over 4,00,000 lakhs people in Kerala are on hypertension medications daily. Only about a third of hypertensives are on treatment - the proportion would go up significantly if actual drug needs of persons were fully met, and if other chronic conditions and the elderly were also considered. Given the demographic and epidemiological transition, the new health care challenges, high health care seeking behaviour, high requirement of interventions for trauma and other surgical situations, the need for ensuring the safety and quality of medications and blood products cannot be underrated. Assessing the safety and efficacy of a medicine is not something that can be done at the point of consumption either by the prescriber, dispenser or the consumer. It is the responsibility of the state to ensure this.

CHAPTER II

METHODS

2.1 Objectives

The study was undertaken with the following objectives:

3) To review the structure and functioning of drug regulatory mechanisms in Kerala state Drugs Control department
4) To identify potential action points to improve the functioning of the department and to increase health care provider and patient trust of the regulatory mechanisms of the department

2.2 Study setting:

The study will be based primarily on data, reports and key informant interviews from Drugs Control Department, relevant academia, programme managers and relevant stakeholders in the state of Kerala.

2.3 Methodology

The study was undertaken in a two-stage processes. The first stage was largely desk study and the second stage was a circulation of the desk study report to get the inputs and guidance of key stakeholders.

(1) Scientific review

A systematic review of peer reviewed literature pertaining to drug quality regulation in Kerala was conducted. A search in PubMed and Google scholar was attempted. Search terms initially were “drug quality” and “Kerala”. Later “drugs control” was also added.

(2) Document review

This activity included archival review of multiple document reviews including print and electronic reports and secondary data sources from governmental sources, reports of proceeding from courts, and reports by professional organizations. Media reports were also scrutinised to identify any report or publication cited by the popular media. The objective was to explore reports for policies primarily of a regulatory focus for drug

quality assurance. The study explored formal organizational structures related to the drug quality control regulation in Kerala, the main actors in the State, their powers and roles stated and exercised (as evidenced from the documents) and the outputs of the policy implementation process. The in-depth analysis of strengths and weaknesses that evolved from this were discussed with key stakeholders.

(3) Engagement with stakeholders

Exploratory interviews were conducted with key informants. The sampling for interviews was be purposive. The State Drug Control Department was approached first, followed by the other stakeholders. The perspectives of stakeholders outside the Drugs Control Department, an aspect insisted upon by the Institutional Ethics Committee of the SCTIMST was explored by interviewing pharmacists in institutions registered for morphine stocking and dispensing, pharmacists in private sector and medical and pharmacy academia. Based on deliberations about the project, three sub-components were also explored – the perception of medical practitioners regarding drug quality in the state (specifically antibiotics and antibiotic resistance), the perceptions of Drug Inspectors about the practical aspects of monitoring sale of anti-TB drugs over the counter and the perceptions of experts in the field of Pharmacy on the role of the discipline and scope for policy research in pharmaceutical jurisprudence in Kerala in future.

(4) Case studies

Based on the themes emerging from the in-depth interviews, three case studies were conducted. These were:

i. Perceptions of antibiotic quality control – This cases study explored perspectives of physicians regarding drug quality of antibiotics, patient related aspects influencing choice, preference of generic or branded drugs. The perspectives of hospital and community pharmacists and the enforcement staff were also explored.
ii. Feasibility of proper maintenance of Schedule H1 register with a focus on anti-TB drugs – this case study explored the perspectives of pharmacists and enforcement staff about maintaining a separate register for Schedule H1 drugs,

the issues around computerised register generation. The issue of linking TB notification through this was particularly probed.

iii. Strengthening pharmacological jurisprudence in Kerala – Pharmacists from academia, enforcement, industrial side and experienced community pharmacists were consulted for perspective on pharmacological jurisprudence. Additionally, clinical and public health professionals were also consulted.

2.4 Ethical considerations:

This was a low-risk study. However, officials were anxious of the implications of the study and might have experienced some discomfort when answering questions on their professional space and activities. Written informed consent was be taken. In case of senior officials willing to participate, but not ready for signed consent, oral consent was be taken, with a witness for the consent process and documentation thereof. The use of witnessed consent for interviews in this mode were permitted by the Institutional Ethics Committee of the Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum, through clearance letter dated 30/08/2019.

CHAPTER III

RESULTS

3.1 Summary of data collection processes

This section provides a brief summary of the data collection processes.

3.1.1 *Scientific literature review*

A search in PubMed using the mentioned terms did not give any reports, show how neglected the field of drugs control is in Kerala. Replacing "drugs control" with "drugs regulation" too did not yield any papers. Using "rugs and cosmetics" instead gave one paper that was not relevant to the topic under study in this report. Replacing "Kerala" from the search terms with "India" provided five papers for the term "drugs control" – these too were not relevant from a public health or policy perspective. "Drugs regulation" and "India" gave 37 results of which 13 were about AYUSH formulations and four were related to chemicals in general and not specific to pharmaceutical preparations. The remaining twenty papers were read and their references were checked, and the findings of the relevance to the report were incorporated.

Searching Google Scholar with the terms "drugs control" and "Kerala" gave 195 results including scientific papers and dissertation reports relevant to policy. Forty-six were pertaining to AYUSH systems or complementary or alternative therapies. Five were on essential medicines, 19 were on antibiotics (10 about TB) – predominantly about resistance, three were on spurious on NSQ drugs and two were on price control. Three papers were on policy and regulation systems and were incorporated into this report. Others were about multiple topics not directly related to the functioning of the drugs control department – e.g. agricultural or botanical drugs, laboratory procedures etc.

3.1.2 Document review

Archived reports available in the public domain or for review from government departments including Kerala State Planning Board, the Kerala State Drugs Control Department, the Kerala Medical Services Corporation Ltd, Kerala Pharmacy Council were reviewed. In addition, audit reports, proceedings of Kerala state legislative assembly, and a sample of published judgements where the Drugs Controller or Drugs

Inspector was one of the parties were reviewed. In the search engine "India kanoon", the search term "drugs controller" and "Kerala" gave 782 items and the terms "drugs inspector" and "Kerala" gave 307 items, many of which were overlapping. From each list, 10% items – i.e. 78 from the first list and 31 from the second list - were randomly selected and reviewed.

3.1.3 Key informant interviews

The key informant interviews conducted were:

1. Enforcement side – 10 in-depth interviews –
    a. seven drugs inspectors – data saturation was achieved after this, and no new themes were emerging
    b. Three senior staff
2. Analytical side – 3 in-depth interviews – no new themes emerged
3. Price monitoring unit – 1 in-depth interview
4. Other stakeholders – two from Public health, seven from Pharmacy (two from academic/ registration authority, two from registered medical institutions with opioid license, three from community pharmacies), and two from clinicians. All public health stakeholders, one from the Pharmacy field and one clinician were working in the State Government service.

3.1.4 Case studies

Three case studies were conducted based on selected recurring themes emerging from the in-depth interviews.

1. Schedule H1 register – the practical difficulties around maintaining Schedule H1 registers. Thirty interviews were envisaged and twenty five were conducted as part of this case study.
2. Doctors perspectives on drug quality with focus on antibiotics – doctors' prescription preferences and perceptions on drug quality and risk of antibiotic resistance. Fifteen interviews were envisaged and conducted.
3. Pharmacy experts' perceptions of achievable levels of pharmaceutical jurisprudence, the current gaps, and possible actions for the situation in Kerala were explored. Twelve interviews were envisaged and ten conducted.

3.2 Synthesis of findings

This section unifies the findings of all study components in an attempt to summarize the findings in line with the study objectives.

3.2.1 Kerala state has very low manufacture but very high consumption of drugs

The movement of pharmacological products within the state is very high, but drug manufacturing is relatively lesser than that in some other states – the reason why the state has been listed as a **category II** state in the Mashelkar committee report 2003. (10) A more recent report listed Kerala as the 14th rank in the list of states according to number of drug manufacturing units. (11) However, the state remains one with extensive private sector pharmaceutical activity. The State and its health care system is relentlessly working to address these issues and striving to attain equity through democratic processes and decentralization to increase people's participation. The quality and scope of health care services also are being revamped through the *Aardram mission* to create a responsive system that treats every patient with dignity. For instance, medicines for the management of COPD have been included in the list of essential drugs with the roll out of the SWAAS component of the mission. (12) Kerala is primarily a drug consuming state. As per the list of WHO Good Manufacturing Practices (GMP) Certified Manufacturing Units for Certificate of Pharmaceutical Products (COPP) in various States of India as received from the States / UTs through Zonal / Sub-Zonal Offices of CDSCO as on May 2019, Kerala had 8 manufacturing units while India had 2006. Gujarat with 684, Maharashtra with 229 and Himachal Pradesh with 202 were the States with the highest number of manufacturing units. While the number in most states had gone up from a 2015 report of CDSCO, the number in Kerala came down from 10 to 8. (13) Hence much of the drugs consumed in the State will have to be obtained from manufacturers in other states.

3.2.2 High need for regulation

Most reports indicate the regulatory system in Kerala as one of the strongest in India. However, the need for regulation cannot be understated. A study on post-ban sales of selected pharmaceutical agents found that sale continued in Kerala despite the ban. Post-ban sale of Cisapride and Tegaserod were highest in Kerala among Indian states – 78% and 30% respectively. This was from a study that looked as sale of Gatfloxacin,

Sibutramine, Simethicone + Cisapride, Letrozole and Rosiglitazone in addition to the two mentioned drugs. The researchers used data from the All India Organization of Chemists and Druggists (AIOCD) and its own subsidiary marketing research firm, AIOCD AWACS Pvt. Ltd. (14) Departmental reports reflects the attempts by the Drugs control department to stop the sales of the drugs after the ban was notified.
However, it must be noted that the main problem in India is not one of spurious or counterfeit drugs but one of Not of Standard Quality (NSQ).

Table 3.1. Results of CDSCO survey in the Indian market

	2003-04	2007-08
Spurious	0.3%	0.17%
NSQ	7.5%	6.3%

3.2.3 Imbalance in the regulatory approach

3.2.2.1 Legislations relevant to pharmaceutical regulation in Kerala

The historical evolution of such legislations and policies till 2006 at the national level has been describe by Parvathy K Iyer (2007) as depicted in the figure 2. (15) Drugs are declared as essential commodities as per the Essential Commodities Act, 1955. Drugs are products that are extensively commodified and the drug industry is modular and fragment. India has a chequered legacy of attempts to regulate the drug industry in the country. The Drug Prices Control Order (DPCO) was first implemented in 1966. However, the Drug Prices Control Order 1987 kickstarted private sector expansion in drug production in India and the pharma industry in India is one of the a largest in the world with a market size of around 20.03 billion US dollars. (16). Since 2013, however, the DPCO 2013 is governed by the National Pharmaceutical Pricing Authority and this marks a departure from the earlier approach governed by the Essential Commodities Act.

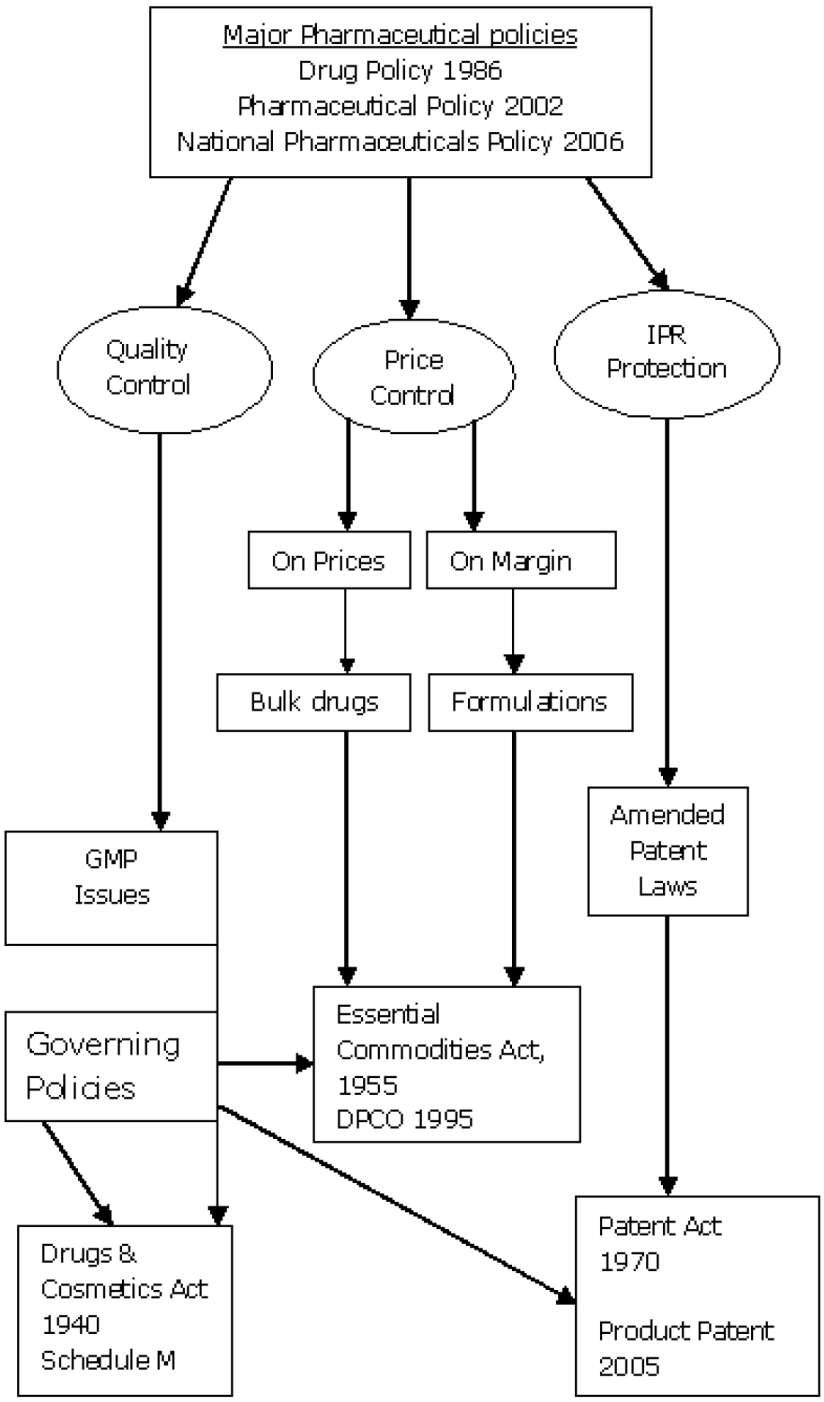

Figure 3.1: Regulatory control of the pharmaceutical sector – reproduced with permission from Iyer PK (2008)

At present, the most relevant legislations to the functioning of the Department are

1. The Drugs and Cosmetics Act, 1940 and the Rules 1945
2. The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954
3. The Kerala Drugs and Other Stores (Unlawful Possession) Act 1971
4. The Drugs (Prices Control) Order 1995
5. The Kerala Poison Rules 1996
6. The Narcotic Drugs and Psychotropic Substances (Amendment) Act, 2014 and Rules
7. The Medical Devices Rules 2017

Although health is a state subject and the Department is under the respective state ministry, both central and state agencies that have a role in how the Department works. The sources of revenue for the Department include plan funds, non-plan funds and revenue generated through the respective regulatory instruments.

The Kerala State Drugs Control Department (hereafter called Department) is a statutory body. It started to function in the year 1961. The stated vision of the Department is "Health for all where use of drugs are minimal" and the mission is "to make available Drugs and Cosmetics of standard quality at controlled prices." The Department website acknowledges the information asymmetry where the persons has limited awareness about the drugs they consume and thus it is for the Department to ensure drug quality as well as protect persons from counterfeit, spurious and substandard drugs as well as ensure price control. The main role of the agency is regulatory in nature. The regulatory functions are described in the sections that follow. The faith of the whole health system and community is thus largely dependent on the Department and its regulatory activities.

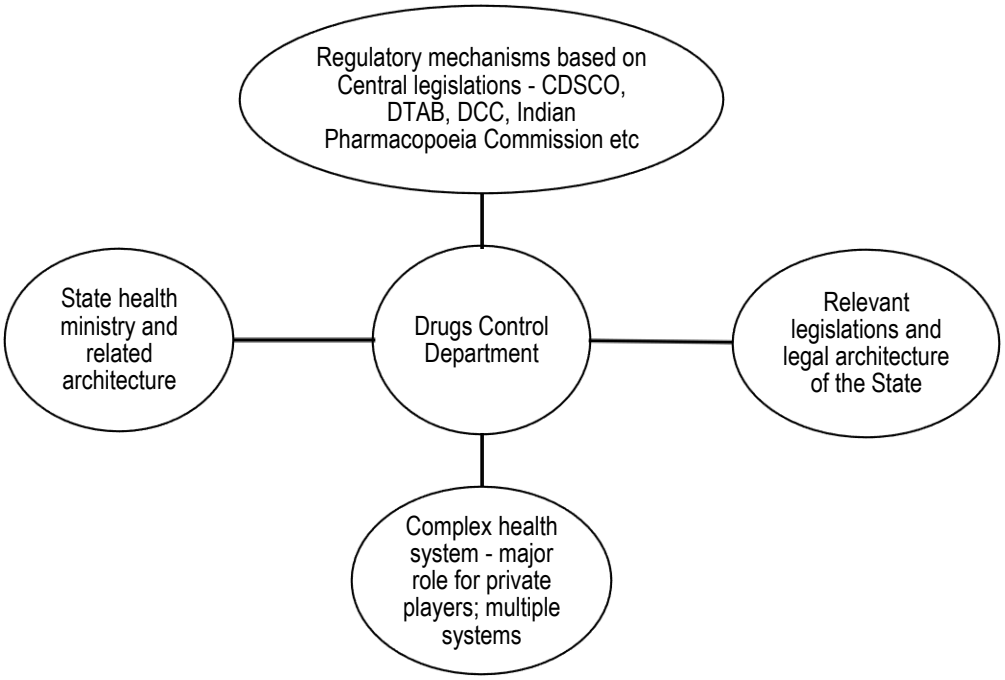

Figure 3.2. Nature of regulatory space in which the Drugs control department works

The main regulatory instruments include those that prescribe standards, instruments to decide on and distribute licences, instruments to inspect for compliance and other digressions subject to which the legal architecture is depended on for corrective action, which is also expected to be a deterrent. Drug license issuance procedures, pharmacy store Inspections, drug sampling, poison storage permit issuance, actions against rule violations and measures to address quality issues and Court related responsibilities of the Department constitute the forms of instruments in use. The relevant aspects of these are incorporated under respective portions of this chapter.

The health system as mentioned has public and private players, wholesale and retail seller and products that are branded or generic. While Drug Inspectors felt that the preference for branded and generic drugs in the state was somewhat similar, pharmacists felt that the preference of practitioners was still more for branded drugs than generics. Certain pharmacists also said that up to 50% patients come request medications without prescriptions, often making them the first point of care.
The Department has human resources to support the office of the Drugs Controller, intelligence and legal units, inspectorial staff, laboratory staff and other support staff. The detailed staff pattern in given in the Appendix.

3.2.2.2. Functioning of the Drugs Control Department of the state and main issues

The Drugs Control Department has two wings the enforcement wing and the analytical wing, headed by the Drugs Controller of the State. The detailed organizational structure is given in the appendix.

Enforcement wing and licensing

The enforcement wing has two deputy controller, and 1 assistant controller. The Assistant controller is the Licensing authority who issues Sale License. Assistant Drug Controller under Intelligence branch in Thiruvananthapuram basically investigates general complaints and no power of licensing authority, but can issue poison license. Some licenses like manufacture and blood banks need dual license, and these comes directly under the State Drug Controller. So does license to stock and dispense Essential Narcotic drugs. Ayurveda has a separate division under Enforcement Wing with one Deputy Drugs Controller and one Assistant Drug Controller comes in this. There are six divisions – Thiruvananthapuram (for Thiruvananthapuram district), Kollam (for Kollam, Pathanamthitta and Kottayan districts), Ernakulam (Alappuzha, Ernakulam and Idukki districts), Thrissur (Thrissur and Palakkad districts), Kozhikode (Malappuram, Kozhikode and Wayanad districts) and Kannur (for Kannur and Kasargod districts). The basic unit office in a district is the Drug Inspector, where the district is divided into different zones, often Taluk wise. Manufacturing activity is very less in Kerala and the related responsibilities also are less. With around 60 manufacturing licenses in Kerala, manufacturing units are very less in Kerala.

Regulation of manufacture, storage and transport was largely restricted to available legal guidelines. Documentation is mainly in the form of applications for licences and inspection reports. Routine checking was mainly as part of inspectorial visits and for meeting the mandatory sampling targets of inspectorial staff. There are 47 Drug Inspectors in the State for inspectorial duty of sales licences, and seven Senior Drug Inspectors for drug manufacturing units and blood banks. The main problem in the state is that of Not-of-Standard-Quality (NSQ) drugs and presence of spurious drugs seem very low in the state.

Staff shortage: Staff shortage is a major issue being faced in the enforcement side. Some statements made included:

> "Before 2000, only Trivandrum office was there. Ernakulam office came in 2013 and Thrissur in 2019. So the testing capacity is high so there is a need to collect more samples. Also, shop numbers have considerably increased. But the inspectorial staff numbers have not increased proportionately"

> "The last new post creation of Drug Inspector in Kerala was in 2000 while the analytical side has seen creation of additional 41 posts in the same period. Since then the number of sales units have gone up to over 20,000 in the State"

The drug inspector to license ratio recommended is 1:200 as per the Mashelkar committee but the actual number is much higher for each inspector. In areas where the number is relatively lower, access is difficult – e.g. Attappady in Palakkad.

A main problem repeatedly mentioned by Department staff is the bulk of pharmacies in the State. As seen in table 3.2, ten taluks in Kerala have over 500 pharmacies, of which four have over 500 wholesale pharmacies. **The average pharmacies per inspector is 438.** Given the high load of licences per inspector, much in excess of the Mashelkar committee report recommendation of 200 licences per Inspector, inspectorial staff reported that it is almost impossible to meet the target of annual inspection pertaining to all licences at least once, and recommended even 300 licences per inspector should be feasible, but not the current numbers that were around 1000 for some Inspectors. Those Inspectors with less licences were functioning in areas with difficult terrain like Idukki or Wayanad. There proportions of pharmacies without pharmacist varied from taluk to taluk – with highest in Perinthalmanna at 4.04% and 33 taluks having no such pharmacies as per the records with the Department. The system of registering pharmacists is helping to curb the name of a pharmacist to be shown against multiple pharmacies.

Table 3.2 Taluks in Kerala with more than 500 pharmacies

District	Taluk	Wholesale outlets
Ernakulam	Kanayannur	>500
Kozhikode	Kozhikode	>500
Kollam	Kollam	286
Kannur	Kannur	246
Kottayam	Kottayam	266
Malappuram	Eranad	203
Malappuram	Tirur	186
Palakkad	Palakkad	267
Thrissur	Thrissur	>500
Thiruvananthapuram	Thiruvananthapuram	>500

Transport: Vehicles for conveyance is another issue. Most of the office vehicles are very old. Some pertinent statements made were:

> "Confiscated vehicles from excise dept is taken over as department vehicle, it is already in a bad condition when it is acquired. In Idukki, 1086 medical shops are there, and there is no office vehicle. So, inspections are very less and the officers use public transport. Joint inspections are done only in case of any issues."

> "Most areas have good access and we can manage somehow. But licenses are there even in difficult to access areas – like Neeliyampathy."

Sampling – cost issues and increase in number of products being tested: Quantity of sample, in case of tablet was 200 numbers, which is divided into 4 portions. One portion, should be retained by the shop owner, one portion held with govt analyst for testing, one portion kept with govt, and one portion send to the manufacturer. Since lab accreditation by National Accreditation Board for Testing and Calibration Laboratories (NABL) 240 samples are to be collected and divided into four parts of 60 each; 30% is to be from the Government sector and the from the private sector. The statutory sampling target for drugs seems arbitrary and there was no document to suggest risk-based sampling strategies. Checking was also based on complaints received by the Department. The large quantum of drugs required for sampling and the huge number of

retailers meant that most of the sampling happens at wholesale dealers rather than retail ones.

Sample target per month at present is 13 samples. Each sample requires about one to two hours for processing and labelling – any defect would mean the testing would not stand in court. Target in sample collection also includes a requirement that 30-40% samples should be collected from government institution. There is also a target that 1% should be cosmetics. The samples collected must be sent through registered post or by hand. No other method is acceptable as per the stipulations of the Drugs and Cosmetics Rules. The Department reportedly has better infrastructure and capacity as compared to some other states. For instance, regarding cold chain, refrigerators are available in DI offices and there is sufficient cold chain equipment for transport of samples that require cold chain. The main problem reported was that funds were inadequate for purchase of adequate samples of costly drugs – the state-wide ceiling of Rs 4,00,000 (2018) for purchase of drugs from private sellers meant that costly drugs could not be purchased. The target of the number of samples to be collected by DI is increasing – this is inline with increased testing capacity in the State. While the testing capacity has increased, the number of Drug Inspectors has not. If the target keeps increasing, achieving them will become more challenging.

This study did not find any reported corruption from the stakeholders such as community pharmacists or pharmacists at registered medical institutions (under the NDPS Act). DIs did mention that regulatory attention was more on drugs that are perceived as more important. This was reflected in the key informant interviews where the participant stressed on particular attention to third generation cephalosporins and anti-TB drugs.

Feasibility of mobile testing was not acknowledged by DIs mainly due to legal constraints.

> "If there is a procedural lapse, the case will not hold in court."

This has also been mentioned as a major limitation in expanding regulations to online / e-pharmacies.

Table 3.3 Comparison of enforcement – Kerala with Gujarat and India based on available reports in 2019

Name of Functionality	**Gujarat**	**Kerala**	**Total**
Retailers / Wholesalers	42241	24496	175590
Online Applications	143642	87621	391629
No of D.I / L.A	92	50	467
Monthly Samples	205	453	819
Monthly Application	1397	1266	6097
Monthly Disposal	1199	1276	5083
Monthly Inspection	536	439	2368
As on Date Pending	2165	971	16026
Shops per Staff	459	489	
Inspection Per D.I	5	8	
Disposal %	85	100	
Pendancy %	2	1	
RTS Violation %	52	6	
R.P More then 1 Firms	204	314	
Retailers With No R.P	381	176	

Analytical wing and testing

There are currently three Drugs Control Laboratories in the State. The ones at Thiruvananthapuram and Ernakulam are full-fledged and functional, at about optimal capacity for 5000 samples to be tested annually, but with far more tests needing to be done. These two laboratories are accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL). A new Laboratory has started functioning in a basic way at 50 cents of land allotted in Medical College campus, Thrissur in a three storied building. Land (1 acre) has been allotted in Pathanamthitta at Konni. In Kozhikode, 15 cents in Medical college campus was earmarked for a new laboratory, but this is insufficient for a laboratory if it is to have all the required divisions. Each lab is

headed by the Chief Government Analyst, except Thrissur that has only a Government Analyst post, which was created from 2019. There are seven sections in each laboratory, except in Thrissur which does not have a microbiology section. The time period to submit report for a sample by the Government analyst is 60 days. if not done so the manufacturer can challenge it. In any case, there has been significant increase in the testing capacity in the state over the last two decades as shown in the table below. The interactions with laboratory staff revealed that drugs which has pharmacopoeia preparation are easy for analysis, while for those outside it, are followed the in house method which the manufacturer specified is used for analysis. The problem came with certain combinations when clear guidelines may not be identifiable easily.

Table 3.4 Slow and deliberate expansion of testing

	2003	**2019 (6 months)**
Retailers / Wholesalers	11315	22368
Total licences		46513
Total inspections		30402
Samples entered	3359	34146
NSQ declared	124	338
Cancel / StopSale / Suspend		2282

No significant delay in results: DIs have a time of two months to finish the process - one month for completion of enquiry, one month for other process before filing. Issues in functioning of laboratories include occasional delays (over 60 days) for analysis and reporting and return of samples due to some instances due to failure to meet recommended guidelines, but these are a minority and the overarching theme that emerged from the interviews suggested the need for more importance to be given to strengthening existing labs to State-of-the art level rather than investing in new laboratories. The reasons cited for this was that at times it was not possible to perform testing as per standard pharmacopoeia guidelines. Nevertheless, of the sub-standard batches reported in the national portal (14 states of the country report on this portal), all in all 81 batches were identified, of which 27 were detected from Department laboratories in Kerala (22 from Thiruvananthapuram and 5 from Ernakulam) –

suggesting reasonably superior functioning with respect to other parts of the country. The table below gives details of notification of substandard batches at national and state level.

Table 3.5 Online notification of substandard batch

	2016	**2017**	**2018**	**2019**
All India	836	830	559	246
Kerala	40	87	91	83
Laboratory				
TVPM	36	68	61	64
EKM	4	19	30	6
TSR	-	-	-	13
State of manufacture – Himachal Pradesh	HP-9	HP-12	HP-14	HP-14

Legislative considerations and court duty determine functioning

The DCA and rules clearly states that procedures to be followed and any lapse in this would result in failure to enforce regulation. Thus, sample collection and recording processes take a lot of time. Also, a lot of time is consumed by court duty There is pendency of cases – sometime for years. The provisions are for giving time for the accused to attend, and they are from other states. A recurring theme was the time the inspectorate staff of the Department have to spend for court duty and the time away from technical work. There is no designated court in Kerala for addressing cases related to Drugs Control and related laws. Reports also suggested legal delays resulting from time taken by Inspectors to file full complaints and also problems due to documentation or hostile witnesses. Pendency of cases exist but do not seem to be a major issue. Analysis of 395 judgements reviewed suggested only few cases were of action for serious violations and others were for procedural and minor digressions. Acquittals

have been questioned as an indicator of Departmental failure in the past. A theme from this review suggested that the system exerted caution when dealing with pharmacies on the notion that they are distributors of life saving medicines, unlike legal action with respect to issues like narcotics abuse where the action was based on the same set of legislations.

Harnessing ICT for effective regulation and enforcement

Since 2012, the Department uses existing smart information sources and e-services for licence issue/ renewal and documentation of sample collection in the web portal (https://xlnindia.gov.in/). The latter function also facilitates avoiding duplication of sample collection by other Inspectors. E-services facilitate traceability and timely communication to all stakeholders for monitoring of action taken on recall procedures initiated, returned products. The current software and data management system, online licensing systems etc were was generally appreciated by all DIs and other relevant stakeholders. For the DIs, development of a legitimate mobile app was anticipated to be useful – one in which at least some tasks like a photo of documents may be taken, attached and uploaded. It would also help to have a list of NSQ from any part of India. A positive step towards effective enforcement was the website and timely information uploads. The 59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha reported the state of Kerala as having taken the initiative to upload information on spurious and sub-standard drugs on the websites on a monthly basis. Currently there exists a data bank and the Departmental website as well as the Drug Information Portal website https://drugsip.blogspot.com/ updates regularly the list of banned drugs and batches of NSQ drugs, thus serving to increase public confidence in the system. Automated SMS notices to doctors and pharmacists also help in action on NSQ/ spurious drugs.

The responsibility of other stakeholder, particularly pharmacists is clearly delineated as follows: “He/she will constantly visit the website of the Drugs Control department, procurement authority and disseminate the information of sub-standard drugs, banned drugs etc to all the concerned and take steps to block the flow of those items in the pipeline. He/she should explore the possibility of using the Information Technology in tune up with the time.”

XLN (Extending Licensing Node for laboratory) which is an eGovernance enabling tool towards effective, speedier & accurate monitoring of issuance of Sales Licenses for drugs, developed by NIC, Gujarat, is one of the applications being replicated in many other states including Kerala. It is the online licensing system software that is adopted by the State. (https://xlnindia.gov.in/FDCA_details_by_type.aspx)

Medical Devices

A lot of efforts are on to bring medical devices under the ambit of Drugs and Cosmetics Act, 1940 and the Drug Price Control Order, 2013. A landmark moment was the implementation of the Medical Devices Rules, 2017. Steps taken included identification of Medical Device Officer (MDO), Medical Device Testing Officers (MDTO) and Medical Devices Testing Laboratories (MDTL) – NABL accreditation for naming MDTL was also done. Based on complaints, devices are collected to test. Specific devices are tested at specific labs; thus checking is done at that places only. The lab does not get notified but the Drug Inspector gets notified. For instance, it is Kolkata for cotton, Guwahati for condoms or syringes and so on.

Price monitoring unit

The Kerala State Pharmaceutical Price Monitoring and Resource Unit Society was the first such unit in the country. The Price Monitoring and Research Unit is headed by the State Health Secretary as the Chairman and the Drugs Controller as the Member Secretary. The society has an executive committee headed by the DC. The members include representatives of the State Government, private pharmaceuticals, and consumer protection fora. The current state of price monitoring and enforcement is through market-based surveillance and coordination with other departments of the State and with the National Pharmaceutical Pricing Authority. It functions with 5 staffs – 1 Project Coordinator, 2 Field Investigators, 2 Data Entry Operators. Training of Senior Officers and Drug Inspectors was done.

Other aspects of functioning and issues

Enforcement / Coordination within the public sector: The Kerala Medical Services Corporation Limited (KMSCL) is the central procurement agency for drugs and equipment in the state of which the Drugs Controller is a member of the board of Directors. The KMSCL has its own drug quality checking mechanism and has empanelled private laboratories for drug quality checking, with the Department as the appellate authority. The KMSCL is a company but fully government owned. The DC is on the board of Directors and there is good coordination of relevant activities. As far as quality testing is concerned, it is mainly at the stage of procurement. For the KMSCL tendering process, DC is the Directors board member and has inspectional function and licensing authority power. Empanelled Drugs Testing Laboratory of KMSCL require Good Laboratory Practices (GLP) certificate. These are issued by the DC who is the competent authority under the Drugs and Cosmetics Rules. Drugs through public outlets are procured through KMSCL, even the drugs purchased by local self-government institutions with their funds.

Problems arise when certain other aspects in the government sector. Line departments have failed to meet the requirements in a timely manner occasionally in the past – for instance the blood bank at the W&C hospital Alappuzha and blood storage units at THQH Sultan Battery were functioning without license, while THQH Tirurangadi blood storage unit was not functioning citing the lack of requisite license. In such instances, when confronted with a license renewal issues in government blood banks, it is difficult to take immediate action as the care of needy patients may be affected.

Lack of convergence: One DI pointed out the lack of convergence that existed in the state. Some convergence existed between the institutions in the Health Department and ICDS. DIs have to work with Government hospitals, DMO, the Collectorate - depending on who forwards complaints. Also, the DI is a member of the condemnation committee of KMSCL – e.g. NSQ drugs that need to be condemned. MO in charge of government programmes may request verification of drug quality of programmes like Mass Drug Administration. ICDS drugs too are examined periodically for quality. According to one DI, the most challenging part was the diversity within the pharmacy professionals.

> "If we are to have a model of drugs quality assurance in the state, there is a need for community pharmacists, hospital pharmacists, Pharmacy professionals, Industrial pharmacists and Enforcement Pharmacists to work together if we are to have… However, this is lacking at present."

Traceability of pharmaceuticals flowing into the state: As such this was a challenge. This has become more problematic post-GST implementation. DIs reported difficulty in tracking drug movement channels in the GST system.

> "Some issues exist because of GST implementation – earlier it was easy to track the channel of drugs and changes from expected stocks could be examined. However, now, purchase can be made from anywhere and this sort of tracking is difficult."

Expired drugs: Recently there was a programme for collection of expired drugs was a standalone project – collected drugs were sent to Mangalore for proper disposal, as IMAGE, Palakkad refused to handle them. The PROUD scheme was a project for collection of expired medicines. Although it was initially understood as a one-time activity the State Budget 2020-2021 mentioned it and the Clean Kerala project also addresses this issue. The DC reported several logistic issues with the storage and transport for disposal of expired drugs.

Schedule based enforcement: Schedule drugs are those where the inventory and sale, regulation of scheduled drugs, misuse of any medicines, proper purchase bill maintenance, tally of sale and purchase, presence of pharmacist are checked. Drugs with addictive potential and drugs with problem of drug resistance get more attention than other drugs even when they are in s specific schedule that needs prioritization. For instance, Schedule H1 has 46 drugs and many brands – it is cumbersome for pharmacists to maintain the register. This is despite the details asked for being simple - name and address of prescriber, name of patient, drug and quantity issued. Some pharmacists use a software that permits a print out of list of dispensed schedule H1 drugs. A daily print out that is signed could be considered as the register. However, the software is private and there may be many related issues. A government sanctioned software would probably be dependable.

Contradiction between Drugs and Cosmetics Act rule 55(2) [OR 65(2)], section K – chapter IV and Pharmacy Act: Academic pharmacists found this very problematic. However, pharmacists on the enforcement side were more pragmatic in their observations. According to a senior DI:

> "when we consider the whole country and different parts where health manpower is extremely limited, it is not good to be too strict with drug dispensing. The situation in Kerala and South Indian states may be different, but the provisions of the legislation will have to consider the situation of the whole country."

Neglected areas – Cosmetics, Poisons, Phytopharmaceuticals: Cosmetics remain neglected in terms for regulation as well as laboratory testing facilities. Phytopharmaceuticals have been notified, but as yet there are no products that have been approved from the central level. Another neglected area was poisons under Section II of the relevant act, including acids.

Online pharmacies: This was reported as a great challenge that was emerging; there are many loopholes in the guidelines and rules, even if the rules pertaining to a brick-and-mortar pharmacy was applicable here too. It is licensed from Central government and there are no rules to monitor or cross check it. So chances of psychotropic drug misuse, quality of drugs are a problem. It just requires a retail shop license and no further details are required.

COVID-19 related issues and responses: Special efforts were taken by DIs during COVID-19 restrictions to continue uninterrupted supply of drugs like chemotherapeautic agents. In some places, physicians, DIs, and suppliers worked together to ensure that certain treatments like chemotherapy cycles were not interrupted due to the restrictions. Hand sanitizers came into focus following the pandemic. Sanitizer and Handwash manufacturing units have increased considerably in this COVID situation. Hand sanitiser samples can be collected from any place where it is stocked or sold. Samples are sent to Ernakulam laboratory. Several DIs mentioned feeling happy at the appreciation received for their efforts. Appreciation exists in usual times, but is not very remarkable and may be in the form of best DCI, or from the Kerala Pharmacy Council to the All India Drugs Control Officers' Confederation.

3.3 Summary of case studies

3.3.1 Case study I – Case study on schedule H1 drugs with focus on anti TB Drugs

Technical Collaborators: Rakesh PS, WHO NTEP Technical Support Network, Rakesh Ramachandran, Centre for Public Health Protection, Kottarakara, Kerala, Shibu Balakrishnan Regional Team Lead (South), NTEP, World Health Organisation, India

Background

Through gazette notification GSR 588 (E) dated 30-08-2013, an amendment was included into the Drugs and Cosmetics Rules by way of inclusion of the schedule H1, effective from 01-04-2014. The purpose of this was to regulate the dispensing of certain drugs with important public health implications like drug resistance or addictions. The drugs include certain anti-microbial drugs, anti-TB drugs and certain other habit-forming drugs. Currently, 46 drugs including 24 antibiotics have been placed under this restricted category. Guidelines include those relevant to packaging, dispensing and documentation in a separate register. Documentation includes identity of the patient, contact details of the prescribing doctor and the name and dispensed quantity of the drug in a register that has to be retained for at least three years. The State Drugs Control Department is the regulatory authority for enforcement of the order. Government drug inspectors can conduct surprise checks on these registers and monitor sale of the drugs under Schedule H1. A focus on anti TB drugs is added as it is a point of convergence between the Drugs Control Department and the State TB Cell and the TB programme has a specific notification system, the Nikshay portal. The register thus could be a process of tracking movement of important pharmaceutical agents in the private sector, a dominant player in curative services in Kerala. As the state gears up for good electronic data management systems like e-health, documenting the process will help policy makers and managers to plan and strengthen the implementation of schedule H1 more effectively and envisage utilising the system to facilitate regulation of certain drugs across government and private sector. The current case study documents the implementation of schedule H1 regulation in Kerala state, the facilitators, challenges, best practices and suggestions for improvement.

Methodology

In depth Interviews (IDI) were conducted among the field officers from enforcement wing of drugs controller's department, chemist shop owners and key staff of TB Elimination department. Participants were selected based on discussions with higher officials of drugs controller department, chemist's association leaders and State TB officer. Participants from a mix of 'good performing' districts and 'districts with reported challenges' for implementation of schedule H1, based on the perceptions of higher officials were included. A total of 25 participants were interviewed.

Themes were identified deductively from formative research and initial interviews. Major themes identified were current practices, challenges faced, good practices and suggestions for improvement regarding maintenance and monitoring of schedule H1 registers. All the interviews were conducted in the local language Malayalam. All IDIs were moderated by persons who had experience in conducting qualitative studies and who were fluent in the local language. The interviewer ensured that the themes were fully discussed and that all participants were given a chance to express their views fully. One researcher recorded the proceedings, noting key themes and monitoring verbal and nonverbal interactions.

Results

Current practice: Most chemist shops are maintaining schedule H1 register, at times electronically, but the register is generally incomplete. Only habit-forming drugs and anti TB drugs are documented in schedule H1 register by most of the chemist shops. The practise is almost similar in all parts of the state.

Challenges in maintenance: Time constraints were the main one reported. Others were lack of clarity in prescriptions by doctors.

Challenges in enforcement: The quality of the information is too poor for effective enforcement. A tally with the reported stock is the most fool proof option rather than the register alone, but it is time consuming.

Potential solutions: billing software often have inbuilt mechanism to incorporate the schedule H1 drug dispensing register. Others included training/ information provision

at the time of licensing, and arrangement of schedule H1 drugs such that the pharmacist may remember that drugs from a certain shelf are to be entered in the register.

Monitoring of anti-TB drug dispensing: Key TB staff visit and use the schedule H1 register for enhancing TB notification in the State. The TB programme has actually printed and provided registers to chemists in the state that dispense Anti-TB drugs, along with state-wide campaigns. Instances of failure to maintain the register were due to entry of incorrect name, and contact number of patients often explained as efforts by the patients to maintain their confidentiality due to perceived stigma.

Reflections

Some efforts at maintenance and enforcement of the schedule H1 register is in place in Kerala. However, there are several gaps and limited utility to the activity at present. Yet, as shown by the experience from the TB – Drugs Control convergence activity, there is an opportunity to scale up this system for better regulation and enforcement that includes the private sector prescriptions as well. Digital capacity enhancement of individual chemists and information systems may be the way forward for utilizing this regulatory approach effectively.

3.3.2 Case study II – Case study on medical practitioners' perceptions on antibiotic quality

Technical Collaborators: Dr Sophia Modi, Assistant Professor, Dept of Pharmacology, Govt Medical College, Kollam; Dr Rajalakshmi S, Achutha Menon Centre for Health Science Studies

Background

Substandard or spurious drugs can result in life threatening issues, financial loss and consequent loss of trust in health system. Lax pharmaceutical control as well as profits to be made from selling fraudulent drugs and counterfeit brands have been assumed to be the reason for substandard quality of drugs. In Kerala, the Drug Control Department is responsible for ensuring the quality of drugs available in market as well as availability of the drugs at controlled prices. While low quality of any pharmaceutical preparation is problematic, when it comes to antibiotics, the situation is compounded by the additional public health problem of drug resistance. Use of suboptimal doses of antibiotics contribute to selection pressure for drug-resistant organisms. Incompletely treated infections consequent to poor-quality drugs results in use of more expensive higher agents to treat resistant organisms. We therefore undertook a qualitative study in order to examine the perspectives of medical practitioners in Kerala on the effectiveness of monitoring of drug quality. In this case study we brought in a specific focus on antibiotic quality and their opinions were obtained on achieving safety and efficacy of antibiotics received by patients.

Methods

In-depth interviews were conducted with fifteen medical practitioners in Kerala during the period of December 2020 to January 2021.

Participants: The study participants were purposefully sampled till saturation was achieved and included junior doctors as well as senior specialists in the fields of General medicine, General surgery, ENT, Ophthalmology, Pulmonary medicine, Obstetrics and Gynaecology, Paediatrics, Dermatology and Orthopaedics practising in government and private health care institutions in Kerala.

Data collection: An interview guide was developed based on review of previous literature on the topic. The interviews were conducted over phone and were audio recorded after obtaining informed consent from the participant. No personal information was recorded. Each interview lasted between 15 to 30 minutes. The interview guide used is included in appendix.

Analysis: All interviews were transcribed, transcripts coded and analysed deductively.

Summary of findings

Perceived quality of antibiotics: In Kerala, the government supplies generic medicines to all government health care institutions through a central purchase and distribution system. Most of the doctors practicing in government institutions prescribe only the generic medicines available at the institution and were satisfied with the quality of generic medicines available to them. Branded medicines were bought from outside medical stores only if the medicine is not available in the institutional pharmacy. Most of the private health care institutions have a pharmacy attached and doctors are expected to prescribe only the drugs available in the pharmacy. The general opinion was that even though low-quality drugs are still available in market, quality of antibiotics including generic medicines available in Kerala has considerably improved in recent years. But, even though most generic medicines seem to be "okay",

> "some generic medicines are not up to that of the brands what we are using".

What constitutes good quality? Doctors were of the opinion that there are differences (in the effectiveness) between "good companies" and "other companies" and same antibiotic manufactured by a different company may be less effective. "Good quality" antibiotics are chosen primarily by brand name followed by opinions of colleagues, clinical experience and early personal experience. When prescribing branded medicines, the doctors always chose a 'good brand'. The explanation offered for such a choice was "good brands" have fewer side effects as well as good 'effect'. These choices were informed by clinical and personal experiences rather than through a quality monitoring system.

> "Earlier I have consumed Ciprofloxacin, and Pefloxacin … similarly Augmentin … amoxicillin, clavulanic acid also, I have consumed…. If I have taken the bad tablet

which is provided from hospital, I have experienced severe diarrhea. On the other hand, when I consumed a good brand, the kind of problem did not come. Bad taste, gastritis…such small problems are less common for good brands, in my personal experience."

Perceived definition of low quality: Low quality medicines were assumed to be stemming from profit making motives of manufacturers and the resultant "lack of sufficient quantity of active ingredient in the product" or due to the "things added to preserve it" or due to 'incomplete purification' resulting in more impurities in the drug, use of 'low-quality preservatives' etc.

When is low quality suspected? A suspicion in effectiveness of prescribed antibiotic usually arises by second or third day after starting an antibiotic course, when the infection is not reducing or the total leucocyte count is not coming down. The reason for lower effectiveness is usually assumed to be antibiotic resistance. Low quality of the antibiotic prescribed is considered as a thing of past and hence almost never considered as a differential diagnosis even though some doctors had experiences to the contrary. Any reduction in efficacy is usually noticed only when it is something significant.

Substitution of prescribed medicines by pharmacists: Doctors working in government hospitals viewed substitution of prescribed "good" brands by the pharmacists as inappropriate as the substitutions were usually with brands of "lower quality" "for which they (pharmacies) are offered with higher profits" and hence fail to "get the desired effect". Such substitutions were viewed as "something that promotes a bad company" and often result in the prescriber advising the patient to change the medicine. Such substitutions seem to be common with antihistamines. One senior doctor who had many such experiences said "Most of the times, when they (patients) say that they did not get any use, we will come to know…we will understand that they (pharmacy) have provided the medicines from a "chaathan" company". The brand names that the doctors had not heard before were the brands referred to as "chaathan" companies and were assumed to be manufactured under poor quality regulatory conditions.""Chaathan" means one that is not very branded, but are promoted a lot to write (prescribe) these (medicines) frequently, medicines with a lot of promotion work." But "the drug may not

be of good quality...not for all of them, but with some, there will not be quality inside the drug".

"For them (patients) all medicines are equal": A senior doctor opined that patients do not know much about quality of medicines and "for them all medicines are equal". Only when the medicine is not effective, patients will convey it to the treating doctor otherwise minor side effects are not reported by patients. Side effects reported by patients were observed to be more with certain brands. Awareness of patients about quality was limited to checking expiry date of medicines, but this was notable.

Consequences of low-quality medicines: Other than less efficacy and more adverse effects, the use of low-quality medicines were opined to increase the cost of treatment as a consequence of

> "adding some other medicines on seeing that a proper effect was not obtained"

loss of daily wages of the patients due to more hospital visits and might lead to friction between doctor and patient due to ineffective medicines.

Lack of convergence with regulatory processes: When encountered with suspected low-quality medicines or adverse drug effects, participants refrained themselves from prescribing those brands again but do not resort to any corrective measures including cautioning the authorities. The reasons for not reporting seemed to be diverse.

> "In our place, if we report or complain to anyone, at last we will become the guilty person."
> "If something significant comes up, we usually inform RMO or whoever are buying…will inform them personally these rather than complaining…."
> "Whom should we report to? If there is some interaction, I can report. Other than that, if the quality is less, who to report it to, I do not know. I don't think we have a system to report such things. Based on just observations whether we can even report, I do not know."
> "Nobody is monitoring it. Who is monitoring this in Kerala?"

Reflections

Antibiotics are considered as scarce resources with high economic value. Tackling antibiotic resistance requires not only the judicious use of antibiotics by prescribers and consumers but requires adequate monitoring from drug quality monitoring agencies too. Since drugs are money-spinning merchandises, the continued availability of low-quality medicines in the market should alert the policy makers towards adopting a much more stringent policy in ensuring the quality of drugs available in market. Use of low-quality antibiotics can increase the selection pressure on bacteria and can contribute to rapid emergence of antibiotic resistance. Even though prescribers in Kerala seem to be generally satisfied with the effectiveness of drug quality in general, they mentioned possibility of quality issues, but mainly from a position of a detached prescriber or at times a consumer themselves. It is very evident that cautiousness and choice of antibiotic brands based on prior experiences has also played a significant role in such a positive depiction. Yet, the awareness of existing drugs control mechanisms was generally low, indicating how drugs quality control remains a somewhat invisible public health function to some of its most crucial stakeholders – providers as well as patients.

3.3.3 CASE STUDY III - Case study on strengthening pharmacological jurisprudence in Kerala

Technical Collaborators: Juno S, Assistant Professor, Kerala Academy of Pharmacy, Neyyattinkara; Subodh S Satheesh, Assistant Professor, Sree Krishna College of Pharmacy and Research Centre, Parassala

Background

The study was conducted on the current situation and the need to strengthen Pharmaceutical jurisprudence in Kerala. The field of pharmaceutical jurisprudence deals with the laws and acts involved in the pharmacy profession of India. It is significant in running a pharma business and it proposes and exercises a system surveillance over the quality of pharmaceuticals in the realm of health care. This case study focused on the perceptions regarding analysing the quality of drugs available in the market and the need for ensuring efficacy and safety of drugs.

Methods

The study participants were persons with expertise on regulatory affairs, drug control, pharmacy, industry and experienced academicians. A total of 10 persons from above mentioned fields of pharmacy were interviewed and their opinions and suggestions were transcribed. The duration of each interview was in the range of 15-20 mins. Telephonic interviews were conducted and the time of interview were fixed as per the convenience of the study participants. A detailed description of the study was given prior and the oral consent with electronic documentation of the process was obtained. The interviews were recorded after obtaining permission from the participants. A semi-structured interview guideline was used to interview the participants and probes were used to delve further into their view points and perceptions. The interview guidelines were developed based on existing literature reviews and expert opinions of eminent persons in this field.

Results

The narratives focused on the problems related to the availability of substandard drugs in the market, the need for safety and efficacy of these drugs and the concerned departments and personnel associated with it. In addition to this, the narratives were

also about the various methodologies adopted for maintaining quality control of drugs and the prospect of regulations and inspections in identifying inferior quality drugs.

A dominant theme was the perception that the drugs supplied from the government have an inferior quality when compared to those available in market. Drugs supplied from government hospitals may be compromised both in quantity and the proportions of active pharmaceutical ingredients which hinders the desired pharmacological action. Presence of adulterants and the related risks was another concern raised. Observations included that these drugs exhibited a delayed therapeutic action and even resulted in toxicity and kidney disorders in consumers.

Another theme was concern on logistics - industries that involved in government drug supplies were limited in numbers which often created a delay in procurement, distribution and availability of medicines. Lack of well-established manufacturing and production units in Kerala further had implications on the drug supply. Adulteration is another alarming concern related to the drugs supplied in government hospitals.

A third theme was concern was the capacity for production of safe pharmaceutical agents that had dose accuracy and efficacy. The productions units in the government had several issues that needed to be explored – such as the competence of personnel, conditions of production, and need for stringent actions to regulate quality.

Reflections

The perceptions emerging in the case study raised several questions on the pharmaceutical jurisprudence in Kerala pertaining to issues of production, logistics and assurance of safety and quality of pharmaceutical agents. These need to be explored and analysed further to identify potential areas for intervention and the role of key stakeholders for the same.

CHAPTER IV

DISCUSSION, RECOMMENDATIONS AND CONCLUSION

4.1 Discussion

The main purpose of this evaluation was to identify possible ways to improve the functioning of the Kerala State Drugs Control Department. The methodology used is a standard approach in evaluation of the pharmaceutical regulation framework. (17) The Department clearly functions in what can be considered as a command-and-control framework – a regulator sets standards, other stakeholders follow these, and the regulator inspects for compliance. This approach has been often criticized has a high cost low efficiency model based on the high investment needed for technical knowledge, infrastructure and human resources and the tendency to focus on larger players rather than smaller players.12 This was suggested in this study as sampling happened mainly at wholesale pharmacists rather than retail ones. The federal nature of India with important roles for the Centre and State and the complexity of the legal and health care environment adds to this conundrum. In this context, the shortfall of personnel and infrastructure sceptical take on the functioning of the Department. While this analysis has not attempted an evaluation in strict economic terms, given that simple market rules do not explain the pharmaceutical industry, it is safe conclude that an evaluation pure economical terms will not do justice to the peculiarities of the epidemiological, institutional and technological contexts in which the Department functions in. However, this also points out that regulatory regimes need to change over time when contexts change.

The fundamental purpose of any drug quality control mechanism is protection of public health. The guiding principles should be – safety, efficacy, purpose, risk/benefit, quality – ultimately all these should be balanced in such a way that they enhance public health. The approach however is predominantly through legislative frameworks - legal definitions define the scope of the regulations. Policy and programmatic attention is also determined by the risk perception that exists around certain drugs. Highly regulated drugs tend to be those perceived to have abuse potential. Some restrictions are enforced when other risks are perceived. Another study also mentioned that regulations are stricter depending on the schedule to which the drug belonged (18)

Kerala is a high morbidity and high pharmaceutical product consumption state but drug production is very low. We need to depend on manufacturing that happens in other states. There is a need to match surveillance and research for drug quality in line with the expansion of products moving in Kerala – sound data acquisition and analysis should be followed by dissemination of the data to those who need it. This would imply macro-economic research into movement of molecules and other products, epidemiological research into high-risk products and policy and operational research into rescaling governance mechanisms in line with actual needs.

4.1.1 What do the findings reflect?

The guiding principles for state control over drug marketing and prices in a country should ideally be epidemiological situation, economic consideration, values beyond economic considerations. Epidemiology of diseases in resource poor settings needs to be a factor in drug availability and affordability –health systems are increasingly having to deliver long term pharmacological care and this requires placing medicine availability and accessibility as a high priority.[4] The National Institute for Health and Clinical Excellence (NICE in the United Kingdom carries out technical as well as financial evaluation of new drugs in that country. For the latter type of evaluation, they use a method of computing cost per QALY gained by use of the new drug. However, economic criteria alone do not determine the decisions made to purchase drugs through the National Health Services (NHS) – NICE maintains values beyond economic ones such as the removal of the economic threshold for purchase of end-of-life care drugs in 2009.(5)

A larger context where drug quality is conflated with other issues like intellectual property and price: Substandard drugs and medicinal products always do harm – the best case scenario is one where the patient does not get the intended relief and the worst case scenario is death. The debate on quality should always be the first policy priority even though pricing issues and intellectual property issues are important. The conflating issues should not become the priority over compromised drug quality. (19) This would mean administrative provisions for more financial and technical strengthening and interdepartmental fora to address emerging relevant issues.

A successful digitization model: The shift to a digital mode has brought several advantages to the Department as mentioned in the results section. These advantages

help is better utilization of resources by avoiding duplication of sample collection, better timeliness by streamlining licencing systems, and better transparency – this may explain pharmacists reporting very low levels of corruption and need for a good department. The web and SMS based notifications have improved enforcement as well as potential public engagement with the Department, as evidenced by the websites for interaction with the public. Yet, there is a perceived need for smart applications that can ease further the current administrative processes around licensing and filing requests or complaints.

A scope for better convergence and synergistic role with other departments: The formal and informal liaising of the Department with procurement agencies, professional regulatory bodies like the Kerala State Pharmacy Council and independent professional associations reveal the synergistic role and at times appellate role the Department plays in drug quality control beyond its immediate organizational boundaries. The role is best displayed in the regulatory aspects happening in the the KMSCL and to a certain extent in the TB control programme. There is however a need for premiership of the Department given the changing landscape of the health system in the state. This can only be achieved by improving the technical capacity of the Department. There is also the need and possibility to extend the Departments role to prompt ethical questioning in other Departments - by health professionals of the review of pharmaceutical promotional material they receive; or by prompting careful audit of drug promotion expenditure.

Need to reinforcing the enforcement role: In the immediate circumstance, the biggest reported problem that emerged was undoubtedly the shortage of Drug Inspectors and the Mashelkar Committee report recommendation was the most commonly cited justification for this. (10) A credulous move in this direction would mean more than doubling the number of Drug inspectors in the Department, a move that is not pragmatic at present. Critically speaking, it is clear that the State has a low risk of spurious drugs and it may be more judicious to focus resources to reinforce the inspectorial role. A surveillance mechanism to bring more focus to the inspections and sampling should be considered – with more electronic data available, exploring patterns of NSQ may help identify “risky” drugs and licences to monitor closely. A lot of time is spent for legal duties – the Department has a legal cell, unlike in some other states in the

country and that is commendable. But a legal analysis may help find causes for delays and how more time may be spared for inspectorial duties.
Functioning of laboratories is commendable given the load, but by no means exemplary. Separate lab specific recommendations need to be made in the context of the findings of this study. Creation of new labs should not take the focus away from strengthening existing lab infrastructure. Overall, there is also a need to think of enforcement functions beyond just inspectorial aspects. According to the World Health Organization, existence and use of sub-therapeautic medicines are unethical and corrupt and Inspections are an important function in the medicine chain that spans from R&D and clinical trials to dispensing, pharmacovigilance and ethical promotion. (20)

4.1.2 Does the Department achieve its stated mission?

The mission statement and values of the Department is frequently cited and consistent with organizational purpose. However, there strategies to link the mission and values to day-to-day action are determined by the legislative framework, primarily of the Drugs and Cosmetic Act, 1940, as well as based on the mandates and requirements from central level. Strategies are based on assumptions rather than epidemiological evidence of need. The lines of authority and accountability are regularly updated and consistently used, and governance and communication mechanisms are optimal when compared to the rest of the country. However, while drug quality and patient safety is clearly a political priority in Kerala, for further political commitment is needed by way of redefining the role of all stakeholders – the Drugs Control Department, the line departments, the private sector, manufacturing units etc.

In reality, the spectrum of products is simply too diverse for the Department to handle. Cosmetics is a very broad term and cosmetic treatments are booming. Cosmetics may have limited or no medical purpose; but they may harm -physically or financially. Products that make nutritional and health claims are also another contentious area. Legal definitions now include drugs and devices but cosmetics and nutritional products remain grey areas. Important stakeholders like physicians and pharmacists are not always aware of regulatory mechanisms unless they are directly engaged in a regulatory function. However, they are not to blame and they seem to be behaving rationally within a system that moulds them in a certain way. At times the Drugs Control Department is

perceived as an oppressor. It is the context of high demand and consumptions in a situation of low manufacture that creates a situation of the drugs control department being perceived as the oppressor.

4.2 RECOMMENDATIONS

4.2.1 Short term recommendations

The existing infrastructure, though very respectable compared to most other states in India, is still inadequate to perform the functions in line with the changing situation and need for drug, blood and equipment control in the State

(1) More number of Drug Inspectors are needed – in line with the Mashelkar committee recommendation of 1 Drug Inspector per 200 licences; accordingly supervisory posts also need to be increased

(2) Laboratory capacity for devices need to be developed

(3) Convergence with stakeholders need to be improved - Committees or working groups need to be formed. Such groups should be multi-disciplinary and should develop plans to prioritise areas of intervention and increased visibility of the regulatory mechanism at present – awareness programmes that reinforce trust in the system need to be rolled out

4.2.2 Long term recommendations

1. Move from a normative approach to a discursive approach: There is a need to emerge from being a normative institution (where the norms and rules shape action) to a discursive one where the institutional and social mechanisms are used to bring change. The state can be a leader – a model of pharmacological jurisprudence for the developing world.
2. Evidence based approach: The regulatory system is not risk based – evidence generation through epidemiological and policy focussed research should be commissioned. Research should be preferably at the doctoral level and with close engagement with the Department.
3. Newer technical and administrative approaches to identify and fill regulatory gaps in real time that are feasible in the Kerala context should be explored.

4.3 CONCLUSION

Pharmaceutical products exist at the intersections of several spaces – the therapeutic spaces in public and private health system, the industry, the legal world and the political and economic spheres of society. As expected, the interests of people and organizations in each of these spheres will be different and that has implications on what drug quality control and regulation actually means today in Kerala. The Drugs and Cosmetics Act,1940 and Rules 1945 and the central and state institutions set up for implementation of provisions of these dominate the regulatory space in Kerala. The Drugs Control Depart of the state has evolved slowly and incrementally to its current situation, given the complex environment. The performance in generally creditable with respect to licensing, testing, timeliness and enforcement, but the pharmaceutical sector is undergoing many changes in a rapid pace. Whether the changes are sufficient to keep up with the changing context where technologies and pharmaceutical products are becoming household items in almost every home is questionable. Moreover, the discourse on drug quality and regulations varies between stakeholders like physicians, pharmacists and regulatory authorities. There is therefore an immediate need to rectify immediate shortcomings within the existing framework so that functioning is not compromised due to the challenges. Additionally, this study clearly highlights that drug quality regulation in a hybrid socio-technical process and not limited to laboratories and guidelines and there is a need for forming a hybrid forum that brings social, political, economic, and technical perspectives in order to envision the future of drug and devise regulation in the best interest of public health in Kerala.

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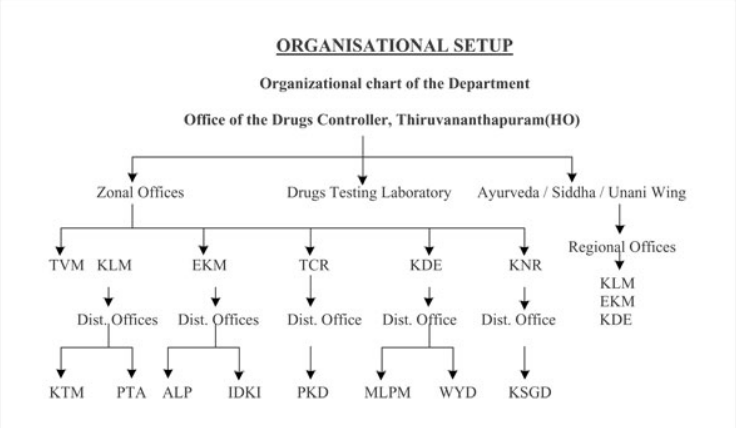
ANNEXURES –

I- ORGANIZATIONAL STRUCTURE AND FUNCTIONS OF THE DRUGS CONTROL DEPARTMENT, KERALA

Source: Official website of the Drugs Control Department



Hierarchical chart of Technical Staff

DRUGS CONTROLLER

(Modern drugs & Homoeo)	**(Drugs Testing Laboratory)**	**(Ayurveda)**
Deputy Drugs Controller(2)	Chief Government Analyst (1)	Deputy Drugs Controller(1)
Assistant Drugs Controller (7)	Analyst Grade I (3)	----
Regional Drugs Inspector (6)	Analyst Grade II (9)	Senior Drugs Inspector (1)
Drugs Inspector (47)	Analyst Grade III (20)	Drugs Inspector (3)
	Scientific Assistant (1)	
	Media Maker (1)	
	Technical Assistant (8)	
	L. D. Technician (8)	
	Laboratory Attender (9)	

Hierarchical chart of Ministerial Staff

DRUGS CONTROLLER

Law officer	Administrative Assistant (1)	
	Senior Superintendent (4)	
	Junior Superintendent (9)	Fair Copy Superintendent (1)
	Head Clerks (3)	
	Statistical Assistant (1)	
	U. D./L. D. Clerks (83)	Typists (27)
	Record Attender (1)	
	Drivers (7)	
	Class IV Officers (31)	
	Part Time Employees (16)	

II - DRUGS CONTROL DEPARTMENT STAFF STRENGTH

Sl.No.	Category	No.of Sanctioned Posts
1	Drugs Controller	1
2	Deputy Drugs Controller (Ay.)	1
3	Deputy Drugs Controller	2
4	Assistant Drugs Controller	7
5	Regional Drugs Inspector	3
6	Senior Drugs Inspector	2
7	Senior Drugs Inspector (Ayu.)	1
8	Drugs Inspector	47
9	Chief Inspector (Drugs Intelligence Squad	1
10	Drugs Inspector (Ay)	8
11	Administrative Assistant	1
12	Senior Superintendent	4
13	Law Officer	1
14	Legal Assistant	1
15	Junior Superintendent	13
16	Head Clerk (including Store Suptd)	2
17	L.D Clerk/ U.D Clerk	85
18	Fair Copy Superintendent	1
19	L.D Typist/ U.D Typist	27
20	Confidential Assistant	1
21	U.D. Compiler	1
22	Librarian	1
23	Record Attender	1
24	Driver	8
25	Office Assistant	29
26	Chief Government Analyst	1
27	Analyst Gr.I	4
28	Analyst Gr.II	14
29	Analyst Gr.III	25
30	Scientific Assistant	2
31	Technical Assistant	11
32	Media Maker	1
33	L.D. Technician (including Technical Store Keeper)	13
34	Laboratory Attender	14
35	Scavancher	1
36	Watcher	1
37	Part Time Sweeper	16
	TOTAL	352

III - Activities-Services Rendered and Procedures

Main Functions of the Department are as follows:

1 To ensure availability of quality medicines in the state.

2 To regulate the manufacture, distribution and sale of drugs & cosmetics including homoeopathic drugs.

3 To detect spurious, adulterated and Sub-Standard drugs and Cosmetics and to prevent their sale.

4 To detect and prohibit manufacture & sale of banned drugs.

5 To prevent sales of drugs at excess price than permitted retail price.

6 To detect and prohibit false and misleading advertisements of drugs for certain diseases and disorders.

7 To check the pilferage of drugs from Government hospitals & stores.

8 To ensure availability of essential drugs.

9 To control possession and sale of certain poisons.

10 To regulate the manufacture of Ayurvedic drugs.

11 To ensure the availability of narcotic drugs in the management of Pain & Palliative Cases.

12 To test and analyze quality of drugs in the Drugs Testing Laboratory.

Services Provided by Various Offices of the Department:

Head office: Office of the Drugs Controller, Red Cross Road, Thiruvananthapuram 695035	Grant of licences and loan Licences for manufacture of Allopathic drugs, Homeopathic Drugs, Ayurvedic Drugs, Cosmetics. Grant of licences for Blood Banks. Recognition of Pain and Palliative Care Centres for stocking Oral Morphine Preparations. Grant of Essentiality Certificates for Narcotic Drugs to Hospitals. Approval of Laboratories for carrying out tests of drugs/Cosmetics. Issue of Certificates like GMP, Market Standing, COP Non-Conviction, Free Sale, Performance, Validity Approval of Technical Staff in Manufacturing and Testing Units.
Zonal Offices at Thiruvananthapuram, Kollam, Ernakulam, Trissur, Kozhikode and Kannur	Grant of Licences for wholesale and retail sale of Allopathic, Homeopathic Medicines. Grant of Poison Licences, Poison Permits. Allotment of Narcotic Drugs to hospitals. Approval of Competent person for whole sale licenses.
District Offices of Drugs Inspectors	Endorsement of the name of Registered Pharmacist in Drug Licences.

Drugs Testing: The Drugs Testing Laboratory is the testing wing of the Department. This Laboratory tests the samples of Allopathic, Homeopathic & Ayurvedic Drugs and cosmetics sent for analysis. Samples are drawn by the Drugs Inspectors and Regional Drugs Inspectors from the market and manufacturing premises at random, and sent to the Drugs Testing Laboratory. Besides these, samples from consumers are also analysed on payment of requisite fees. This is done by

(i) Allocating the samples received in the concerned section depending on the tests to be performed in the Labortaory

(ii) Reporting the tests and results, in the prescribed form and forwarding it to the concerned drugs inspector & Regional Drugs Inspector

(iii) Sending the Sample Reports to the Private Parties in case of Private Samples

Sales Licences

1. Different Forms of Licences are specified in the drugs and cosmetics Rules for sales of drugs:
2. Documents required for grant/renewal of sales licences.

Manufacturing Licences: Certificate of

- Renewal of licence for the operation of blood bank and/or processing of whole human blood for component and/or manufacture of blood products
- Large Volume Parenterals/Sera and vaccines specified in Schedules C a and C1 excluding those specified in Schedule X
- Renewal of licence to manufacture cosmetics for sale
- Loan licence
- The approval for carrying out tests on drugs, cosmetics and raw materials
- The Report of test or analysis by the approved institution
- Poison Licence - The Licencing Authority may issue licences to enable the distributors to procure and supply poisons to other dealers and consumers.

Certificates: Good Manufacturing Practices Certificate (GMP); Non-Conviction Certificate; Market Standing Certificate; Validity Certificate; Certificate of Performance; Certificate of Capacity; Approval of Plan

Permits: The following permits are issued by the department

(a) Permits for Pethidine and Morphine Injections to Registered Medical Practitioners.

(b) Permits to hospitals possessing under NDPS Rules for possession of Pethidine, Morphine and Fentanyl Citrate Injections.

(c) Permits for Oral Morphine Preparation to recognised Pain and Palliative Care Centres for use of cancer patients

(d) Permits for possession and use of the for the poison Methyl Alcohol

Poison permit

Approvals: The licencing authority may issue approval for Laboratories for conducting tests to be done in the case of drugs, cosmetics & raw materials sent by the manufacturers on behalf of manufacture for sale of drugs.

IV – Study participant information sheet – In depth interview

Interview serial no: _____

Good morning. I am _____, working as _____ on the project titled "Effectiveness of drugs control and regulating mechanism of the Drugs Control Department in Kerala State" at the Achutha Menon Centre for Health Science Studies, SCTIMST. The Government of Kerala through the Drug Control Department is working to ensure the quality of drugs patients receive and to make them available to the public at controlled prices by regulating and controlling the manufacture and sale.

As part of this study, I am undertaking some interviews of eminent persons who will be able to offer guidance on this. Given your experience in your area of work, I would like your opinions on the structure and functions of your department and it's linkages with other departments in achieving safety and efficacy of medicines received by patients in our state.

This interview would take about 30 minutes of your time. All the questions are aimed at understanding the existing administrative framework and functioning of drug control mechanisms in the State. In all we will be interviewing about 20-25 persons who are in positions like you in order to understand what more may need to be done by the State in this regard.

You will not benefit from this interview in any way. All the details of your interview, including your identity will be kept confidential and only used for analytical purposes. Only myself and a another researcher would have access to actual transcripts of your interview. You will not be identified individually in any of the reports or publications that are developed from the research.

Should you not choose to answer any specific question or any questions related to a specific topic, you can let me know and I will not ask any further questions in that context.

If you need any further clarifications regarding the purpose of this study in general or my role in it you can contact the Principal Investigator of the study, Dr. Ravi Prasad Varma P, Associate Professor, AMCHSS, SCTIMST. Our contact details are provided below:

Principal Investigator	Interviewer name and contact details
Dr. Ravi Prasad Varma P, Associate Professor, AMCHSS, SCTIMST, Thiruvananthapuram 695011 Phone: 9400570835 E mail: rpvarma@sctimst.ac.in	

This study has been reviewed by the SCTIMST-IEC and should you have any questions regarding the ethical issues involved you can contact the Member-Secretary of the IEC, Dr. Mala Ramanathan. Contact details for the Member Secretary of the SCTIMST-IEC are given below:

Dr. Mala Ramanathan, Member Secretary, SCTIMST-IEC, SCTIMST
Medical College PO, Thiruvananthapuram 695011
Email: iec.mem.sec@sctimst.ac.in Ph: 0471 2524234

Would you be willing to be part of this study and be interviewed for about 30 minutes?	Yes/No
If yes, would you permit me to record this interview so that I can make more accurate transcripts of what is being said during the interview? The interview will not be heard by anyone other than the researchers.	Yes/No

Signature with date:

Name of the Interviewer:

Informed consent form – In depth interview

Interview serial no: _____ Interviewer name: _____

- ☐ I confirm that I have read and understood the information provided in the participant information sheet dated..... for the study titled "Effectiveness of drugs control and regulating mechanism of the Drugs Control Department in Kerala State" being undertaken by Dr Ravi Prasad Varma, AMCHSS, SCTIMST.
- ☐ I have been given an opportunity to seek clarifications regarding my participation in this study.
- ☐ I understand that my participation is voluntary and that I am free to withdraw my participation at any moment during the study.
- ☐ I have been informed that there are no benefits, financial or otherwise that accrue to me due to my participation in this study. I also understand that my identity or details of the information that I provide will be used only for research purposes and that my individual details will not be revealed in any research reports or publications.

I agree to participate in this study.	Yes/No
I consent to the recording of the interview using appropriate recording devices.	Yes/No

Signature:

Name

Date: Time:

Signature of the Witness (in case of oral consent)

Signature:

Name:

Date: Time:

V –

Va – Study Interview guidelines

The Government of Kerala has been working through the Drug Control Department and related line departments to ensure quality of drugs available to the public and their affordability by various strategies.

Researchers at the Achutha Menon Centre for Health Science Studies, SCTIMST, are undertaking a research study on the structure and functioning of the state Drug Control Department. As part of this study, I am undertaking some interviews of eminent persons who will be able to offer guidance in this area. Given your experience in this area, I would like your professional experiences and opinions related to drug control mechanisms in the State.

- Please describe the role of your department in ensuring quality of drugs available to patients in Kerala.
- How is the department organized to deliver these functions?
- Does the structure function well to achieve the said roles?
- Are the documents available for reviewing these functions? What are the monitoring mechanisms in place in your department to review these functions? Do you think they are adequate to monitor these functions? Can you explain your response further?
- How relevant is your department's role in ensuring quality of drugs available to patients in Kerala? Should it be more than what it is today? If yes, can you elaborate on it.
- Are you familiar other departments are relevant for this purpose? What is the relationship between your department and these other departments for the purpose of drug control? Is something more needed for collaborating for effective drug control in Kerala? Please explain further if yes.
- Are there other persons/ departments/ sources of information that can help me understand the state of drug control in Kerala? Can you share your knowledge of these with me?
- Are there any external factors outside of your department or other line departments that may influence the quality monitoring of drug control in Kerala? (Probe into political commitment, community participation, professional groups etc)
- How visible are the activities of your department to the general public or other line departments? Is it sufficient to convince doctors and patients about quality and safety of drugs they prescribe/ receive? Please explain your answer.

Thank you very much for sharing your knowledge and insights with us. Should we need some further clarifications, would you permit us to visit you again? [Document response]

Vb – Study Data extraction template

Use extra sheets as needed

1. Name of office:
2. District:
3. Staff pattern:

Designation	Sanctioned	In position

4. Training status of each staff in position

Designation	Pre-service	In-service

5. Details of enforcement activities: samples collected, tested in the last financial year (2018-19):
6. Details of testing (state level):
7. Details of licensing (if relevant) (state level):
8. Any other relevant information from periodic reports:

Themes used for exploration as probes in interviews

Regulation of distribution of pharmacological products

Regulation of storage

Regulation of transport

Documentation

Traceability

Routine checking

Complaints

Recall procedures

Returned products

Sale via the internet

Import/ Export/ Customs

Rational/irrational status of fixed dose combinations – any issues in this regard

Chain drug stores

People's awareness – democratic processes

Counterfeiting technologies – level of advancement and challenges thereof

Radiopharmaceuticals/ other categories that have different mechanisms, if any; adequacy of these mechanisms

General details of laboratory

Routine management

Scientific capacity

Processes: Incoming samples, testing process, documentation

Records – registry, traceability of sample based on data

Quality control

Safety

Any other important information

Vc - Reference list for lab equipment based on WHO recommendations

First-stage laboratory

Equipment and major instruments	***Quantity***
Top-loading balance	1
Analytical balance (5 digits)	1 or 2
Melting-point apparatus	1
pH meter (with assorted electrodes)	1
Microscope	1
Polarimeter	1
High-performance liquid chromatograph with ultraviolet detector	2
Ultraviolet/visible spectrophotometer	1
Infrared spectrophotometer with pellet press	1
Karl Fischer titrator (semi-micro determination of water)	1
Agate mortar with pestle	1
Equipment for thin-layer chromatography	1
Thin-layer chromatography spotter	1
Developing chambers	6 + 1[a]
Atomizers	6
Ultraviolet viewing lamp	1
Disintegration test equipment (1 basket for 6 tablets)	1
Dissolution apparatus	1

Soxhlet extraction apparatus (60 ml)	3 + 1[a]
Micrometer callipers	1
Pycnometers	2
Burettes/pipettes (10 ml and 25 ml/1, 2, 5, 10, 20, 25, 50 ml)	3 of each
Desiccator	1 + 1[a]
Centrifuge (table-top model, 4-place swing rotor)	1
Water-bath (20 litres)	1
Hot plates with magnetic stirrers	3
Vacuum pump (rotary, oil)	1
Drying oven (60 litres)	1
Vacuum oven (17 litres)	1
Muffle furnace	1
Refrigerator (explosion-proof)	1
Water distilling apparatus (8 litres/hour)	1
Water deionizer (10 litres/hour)	1
Dehumidifier (where needed)	1
Fume hood	1
Analytical microbalance	1
Flame photometer (including air compressor)	1
Refractometer	1
Viscometer	1
Vortex mixer	1
Shaker (wrist-action)	1
Pipette rinser	1
Constant temperature water-bath	1
Ultrasonic cleaner (5 litres)	1