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Administrative Structure and Functions of Drug Regulatory Authorities in India

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ADC	Assistant Drug Controllers
ADR	Adverse Drug Reactions
CCEA	Cabinet Committee on Economic Affairs
CDSCO	Central Drugs Standard Control Organisation
CDL	Central Drugs Laboratory
C-DAC	Centre for Development of Advanced Computing
CFDA	China Food and Drug Administration
CHMP	Committee for Medicinal Products for Human Use
COPP	Certificate of Pharmaceutical Product
DCA	Drugs and Cosmetics Act, 1940
DCGI	Drugs Controller General of India
DGHS	Director-General of Health Services
DI	Drug Inspector
DTAB	Drugs Technical Advisory Board
DCC	Drugs Consultative Committee
EMA	European Medicines Agency
EUDRA	European Union Drug Regulatory Authorities
FSSAI	Food Safety and Standards Authority of India
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonisation
ICMRA	International Coalition of Medicines Regulatory Authorities
PIC/S	Pharmaceutical Inspection Co-operation Scheme
IPC	Indian Pharmacopoeia Commission
KMSCL	Kerala Medical Services Corporation Ltd.

MHRA	Medicines and Healthcare Products Regulatory Agency
MOHFW	Ministry of Health and Family Welfare
NABL	National Accreditation Board for Testing and Calibration Laboratories
NA-DFC	National Agency of Drug and Food Control, Indonesia
NIB	National Institute of Biologicals
NSQ	Not of Standard Quality
RRCC	Professor Ranjit Roy Choudhary expert committee
RTI	Right to Information
SDC	State Drug Controller
SDRA	State Drug Regulatory Authority
UPSC	Union Public Service Commission
USFDA	United States Food and Drug Administration
WHO	World Health Organization
XLN	Xtended Licensing, Laboratory and Legal Node

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Abstract

Drug Regulation has been the focus of several recent policy reform efforts in India, starting with the Mashelkar Committee Report in 2003 to the most recent report of the Ranjit Roy Chaudhary Committee in 2013. Nevertheless, the regulatory structure continues to be plagued with several structural challenges, including issues related to regulatory harmonisation between the centre and the states, access to regulatory resources, transparency, which have undermined the general effectiveness of the regulatory system. At the juncture when the Drugs and Cosmetics (Amendment) Bill, 2015 to amend the Drugs and Cosmetic Act, 1940, is expected to overhaul the drug regulation, this study, the first of its kind, evaluates the administrative structure and functions of drug regulatory authorities at both the federal and state level along with comparative perspectives on similar challenges from other international jurisdictions. Through legal and policy analysis, supported by stakeholder interactions, this study not only provides a systematic analysis of the current challenges, along with actionable policy recommendations and suggests possible means for their operationalisation.[α]

Keywords: *Government Policy, Regulation, Public Health; Environmental, Health, Safety Law, Illegal Behaviour and the Enforcement of Law*

JEL classification: *I18, K32, K42*

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[α] **Disclaimer**: This paper is part of ICRIER's Research Program on Drug Regulatory Reforms in India under the Health Policy Initiative, and reflects the views of its authors, and not that of any other individual or institution, including ICRIER.

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1. Introduction

Drugs or pharmaceutical[1] products have several attributes, which are unique and differentiate them from other consumer products. In most cases, the patients are not equipped with the specialised knowledge needed to make an independent assessment of the safety, quality and efficacy of the medicines. Given the asymmetry of information between the manufacturers, the doctors who prescribe drugs and patients who ultimately consume them, the need for regulatory supervision is widely acknowledged amongst all stakeholders in the realm of public health. The quality and efficacy of the medicines also contribute to strengthening the faith in health systems, health professionals, pharmaceutical manufacturers and distributors in the country.[2] Hence, the objective of all drug regulatory regimes is to ensure that safe, good quality and efficacious drugs reach the patients. However, mechanisms designed to meet these objectives vary, and rightly so, given that the nature and scale of the regulatory space[3] that frame the operation of these regimes differ across countries. This poses significant challenges to the principles of design and functioning of the regulatory structure.

Drug regulation is a public policy response to the demands of public health and the changing needs of pharmaceutical industry (Ratanawijitrasin and Wondemagegnehu, 2002). Thus, the objective of regulatory control is a question of achieving a 'balance' between protecting and promoting public health and facilitating the industry vis-à-vis compliance with regulatory standards. Consequently, although the regulatory objectives seem clear, the actual quantum of regulatory oversight, the mechanism for achieving regulatory compliance and the actions needed to deal with non-compliance have to be designed in a manner that is sensitive to the characteristics of the regulatory space,[4] and specifically, the actors operating in that space. This is the basic premise in the conceptual approach proposed by 'Smart or Responsive Regulation'. The rationale behind this is to design a regulatory system where the choice of regulatory instruments not only match the imperatives/objectives of regulation, but also take into consideration the range and the intrinsic characteristics of each of the regulatory stakeholders (Ayers and Braithwaite, 1992).

In the Indian context, the architecture of drug regulation is designed as a classic command-and- control system in which the regulator prescribes standards, distributes licences and then

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[1] Drugs, pharmaceuticals and medicines have been used inter-changeably throughout this paper.

[2] WHO Policy Perspectives on Medicines No. 7, 2003.

[3] 'Regulatory space' is the term first used in any methodological fashion by Hancher and Moran (1989). Here, we use the term in a limited sense to denote the nature of norms, the process of norm creation, enforcement and adjudication and the various public and private actors involved in these processes.

[4] For instance, India being a federal country, regulatory competence for drug regulation is shared between the centre and the states. For a detailed map of distribution of regulatory powers, see Table 1.

undertakes inspection to check for compliance. This has a number of positive attributes including clarity in regulatory standards, which makes it easier to apply and to spot instances of non-compliance. However, such a system also requires considerable investment of resources, in areas ranging from setting standards to maintenance of records, conducting inspections, collecting and testing samples, etc. With an aim of gaining a global position in new drug discovery, India currently can be characterized as a country that focuses on the manufacture and export of generic drugs. Therefore, this should be factored into the allocation of regulatory resources for specific functions. Lack of access to resources (both physical infrastructure and human resources) has continued to plague Indian drug regulators. This problem is more acute amongst the State Drug Regulatory Authorities (SDRAs). As an RTI application[5] revealed, the Orissa State Drug Controller has requested the implementation of the Mashelkar Committee ratio (scale of operations in terms of licences granted and the number of inspectors) in the Institutional Development Plan submitted to the Union Ministry of Health and Family Welfare (MOHFW) this year. Thus, the state of affairs has remained largely unchanged for more than a decade, since the Mashelkar Committee Report (2003) appeared (ideally the recommendations should have been implemented by now and indeed improved further). Since then, there have been many proposals for reform including the Department-Related Parliamentary Standing Committee on Health and Family Welfare 59th Report on the functioning of the Central Drugs Standard Control Organisation (CDSCO) (2012) (henceforth, the 59th Parliamentary Committee Report) and the Ranjit Roy Chaudhary Committee Report (2013) and most recently, the Drugs and Cosmetics (Amendment) Bill, 2015 (henceforth, the DCA Bill, 2015).

Given this context, this is a first of its kind study of the legal architecture, administrative structure and functioning of drug regulatory authorities (CDSCO and SDRAs) in India, focussing on,

(i) functioning of Central Drugs Standard Control Organization (CDSCO), the national level regulator, and State Drug Regulatory Authorities (SDRAs) in India, which are governed by the Drugs and Cosmetics Act, 1940 (DCA);

(ii) examining the nature and the scale of the regulatory challenges facing the administrative structure and functioning of drug regulatory authorities in India;

(iii) exploring the lessons that can be drawn from regulatory experience within the country and in other jurisdictions;

(iv) interviews with more than 100 stakeholders and targeted use of RTI applications; and

(v) evolving a set of actionable policy recommendations reflecting the views of a range of stakeholders.

Therefore, primary research questions framing this study include problems and challenges confronting the current drug regulatory system and potential mechanisms for addressing such problems and challenges. The findings and analysis of the study are based on legal and policy analysis, field research in terms of stakeholder interviews and information gathered through

[5] Orissa RTI No.6516/DC-RTI-18/2015.

filing of RTI applications. For the national round of stakeholders' interviews, National Capital Region (where CDSCO is located) and four states were selected, namely, Himachal Pradesh, Bihar, Kerala and Gujarat; internationally, the USA, the UK, China and Indonesia were identified for the purposes of targeted field research. Section 3 on research methodology discusses the justification for their selection.

The research findings of the study are presented in a thematic manner along with a set of actionable policy recommendations. One of the major challenges confronting the Indian drug regulatory system is that, there is no single entity which is ultimately responsible for ensuring the regulatory effectiveness of the system as a whole. This was highlighted in our interactions with the CDSCO officials. The officials, despite being well aware of the differing levels of competence among SDRAs and the resource challenges that have undermined regulatory functioning of a number of SDRAs, did not consider that it was the CDSCO's responsibility to address such problems. In this regard, we have suggested two possible policy interventions either of which could be alternatively explored as solutions to this issue. The first is to make the CDSCO the supervisory and reporting authority for SDRAs. The second would be to strengthen the institutional mechanism already in place i.e., the Drugs Consultative Committee, which was established to facilitate uniform implementation of the DCA across country. This could be operationalised by expanding the legislative mandate of the DCC.

Further, the CDSCO and the SDRAs are umbilically tied to their parent ministries and departments of health respectively. This impedes flexibility in decision-making and autonomy in a host of areas including financial autonomy, recruitment and other areas of institutional policy. Thus, another important requirement is the autonomy of regulatory agency for greater flexibility and increase the operational effectiveness of both these regulatory agencies.

Given the paucity of human resource, capacity building in form of periodic training programmes for regulatory officials is the need of the hour. In this regard, we found that there has been a lack of planning and execution of training programmes for drug inspectors. A significant number of SDRAs do not have a planned schedule for training programs thus rendering this very important part of human resource development as an *ad hoc* affair, the gains from which are necessarily limited.

It is important to underline specific aspects that were kept out of the purview of this study. Substantive policy areas such as clinical trials, pricing and post-marketing surveillance are not covered in this study. Some of these policy areas are expected to be covered in the subsequent years of the Research Program on Drug Regulatory Reforms in India under the Health Policy Initiative of ICRIER.

This working paper is divided into five sections. Section 2 provides an overview of the regulatory structure in India and the selected international jurisdictions, and serves to contextualise this study. Section 3 discusses the research methodology. Section 4 presents a

thematic analysis of research findings along with a set of actionable policy recommendations. Finally, Section 5 concludes with a discussion of the main findings.

2. Overview of the regulatory structure

2.1 Indian Regulatory Structure

2.1.1 Historical Background of the Drugs and Cosmetics Act 1940

During the first three decades after the turn of the century, India was largely dependent on imported drugs. Lack of regulations meant that there was a high quantity of adulterated, spurious and substandard drugs in the market. The Drugs and Cosmetics Act in 1940 (henceforth, DCA or "the Act") was enacted to address this problem. The DCA provides for the regulation of import, manufacture and sale and distribution of drugs. The emphasis in the DCA is on the regulation of imported products. This may also explain the reason behind the lack of regulation of exports. Further, this also provides a key to the reason behind the distribution of regulatory powers between the centre and the state/provincial governments. Licensing of drug imports was considered urgent and more important and, therefore, is the remit of the central government, whereas the manufacture, sale and distribution of drugs are the responsibilities of the state government. The nature and scale of the regulatory sector in 1940 determined this division of responsibility. Since then, there has been a dramatic change in the sector, without a corresponding modification in the distribution of the regulatory responsibilities. India has emerged as a manufacturing hub for generic medicine, and this requires greater regulatory focus and resources to be invested on manufacturing licensing and enforcement. However, both these functions are largely outside the purview of the central government and fall squarely within the competence of state governments. Another important aspect of the DCA is the large body of rules, the Drugs and Cosmetics Rules, 1945, that are appended to the Act. The Act itself only provides the bare structure and the rules that have been amended and updated regularly, provide the necessary details. There has been an overwhelming concentration on subordinate legislation leading to increasingly complicated system of rules that are difficult to track and understand. This sector, therefore, is characterised by lack of legal certainty experienced by both regulatees and regulators alike.

2.1.2 "Health" in the Constitutional Scheme

The Seventh Schedule to the Constitution of India (henceforth, the Constitution) lists the distribution of legislative subject matters across three lists – List 1 (Union list); List 2 (State list) and List 3 (Concurrent list). Entry 6 in the State List refers to "Public health and sanitation; and hospitals and dispensaries." This subject matter forms the legal basis for the regulation of pharmaceuticals in India. The Constitution does allow for certain exceptional conditions under which the Union Parliament may legislate on a subject matter on the State List. Article 252 of the Constitution empowers the Union Parliament to legislate on a subject matter which is on the State List. Thus, the constitutional position is such that although Article 252 may lead to a central legislation, it does not diminish the powers of state governments to exercise control over that area of governance. This position is reflected in the

DCA. The legal basis for the enactment of the DCA was Section 103 of the Government of India Act 1935 (equivalent to Article 252 of the Constitution in terms of legal effect).

Thus although the DCA is a central legislation, given that 'health' is a subject matter on List 2, states exercise enormous control over the manner in which it is implemented in the state, starting from the financial allocation to the SDRA to the interpretation of specific provisions of the DCA. The Constitutional scheme has also inhibited the central government from proactively taking measures to ensure uniformity and harmonisation in the implementation of the DCA.[6]

2.1.3 Mapping the Administrative Structure

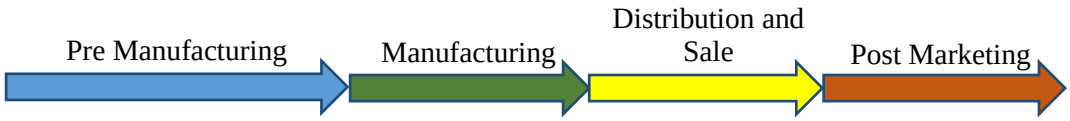
The central and the state governments are both identified as regulators under the DCA. Regulatory functions are clearly separated between these two primary regulators. The table below provides a detailed mapping of regulatory responsibilities distributed between the national government (CDSCO) and the state government (SDRAs). (See Table 1 for details on distribution of regulatory functions between CDSCO and SDRAs along with the product life cycle).

The main functions of the central government include approval of new drugs; registration and control of imported drugs; approvals for clinical trials; laying down standards for drugs, cosmetics, diagnostics and devices; approval of licences for high risk products (large volume parenterals, vaccines and biotechnology products and operation of blood banks); co-ordinating activities of the states and advising them on matters of uniformity in regulatory administration in the implementation of the DCA. The state governments are responsible for licensing of manufacturing establishments and sale premises, undertaking inspections of such premises to ensure compliance with licence conditions, drawing samples for testing and monitoring of quality of drugs, taking actions like suspension/cancellation of licences, surveillance over sale of spurious and adulterated drugs, instituting legal prosecution when required and monitoring of objectionable advertisements for drugs.

The MOHFW represents the central government in this regard. The Director-General of Health Services (DGHS) oversees the regulatory functions of the MOHFW. Under the DGHS, the CDSCO holds the final delegation of regulatory responsibility. The CDSCO is not a statutory body and, therefore, is not independent of the MOHFW. The regulatory functions specified above are distributed among the CDSCO head office (New Delhi) and its six zonal offices. The CDSCO is headed by the Drugs Controller General of India (DCGI). A similar structure operates at the state level where the State Drug Controller (SDC) heads the SDRA and reports to a joint secretary in the health department of state governments.

[6] The Fifty-Ninth Report on the Functioning of CDSCO; also making the same point, states, "*The Committee understands that these provisions are meant to be used sparingly. However, there have been several situations which warrant intervention through Rule 33 P. Therefore, the committee hopes that in future the Ministry would not be found wanting in considering the option of using Section 33P to ensure that provisions of central drug acts are implemented uniformly in all States".* (Para. 4.7).

Table 1: Distribution of Regulatory Functions along the Drug Product Life Cycle



STAGE	CLINICAL TRIALS	NEW DRUG APPROVALS	MANUFACTURING	DISTRIBUTION AND SALE	POST MARKETING SURVEILLANCE
Regulatory Functions	• Applications online in the Clinical Trials Registry - India (CTRI) • Approval of applications • Good Clinical Practices • Inspections • Registration of Ethics Committee • Serious Adverse Events (SAE)	• 12 Subject Expert Committees (SECs) for deliberation on new drug applications for grant of marketing licence • Import of new drugs (Registration of foreign manufacturers and grant of licence to import)	• Application for Licence to manufacture (Generics and those with marketing licence) • Inspection of Good Manufacturing Practices (WHO-GMP/Schedule M) • Grant of Licence to Manufacture • Collection of Samples, testing and prosecution for Non-Compliance	• Application for Licence to distribute and sell • Inspection of Good Distribution Practices (GDP) and sale premises • Grant of Licence to distribute and sell • Prosecution for Non-Compliance	• Periodic Safety Update Reports (PSURs) required to be submitted (Schedule Y of the Drugs and Cosmetics Rules) for new drugs granted marketing licence • Banning of Drugs considered harmful or sub-therapeutic under Sec. 26A of the DCA • Pharmacovigilance Programme of India (PvPI) is the national co-ordinating centre for collecting Adverse Drug Reaction Reports from Adverse Drug Monitoring Centre(AMCs)
Authority Responsible	CDSCO (appointed by the MOHFW, Central Government.) has the sole responsibility – relies on expert committees.	CDSCO has the sole responsibility	SDRA (appointed by the Department of Health, State Government) has primary responsibility Exceptions (CDSCO competence) - CDSCO acts as SDRA in Union Territories (e.g. Delhi) - WHO-GMP Inspections - High Risk Products (IV Fluids, Large volume parenterals, Vaccine and Sera, Blood and Blood Products, r-DNA products (CDSCO may include new products in this list via notification)	SDRA has the sole responsibility	CDSCO has sole responsibility for PSURs and Indian Pharmacopoeia Commission (IPC) is in charge of co-ordinating Adverse Drug Reports (ADRs)

Source: Authors' own compilation.

Thus, both the CDSCO and the SDRAs exercise regulatory control exclusively on the basis of executive fiat and delegation. In effect, both have limited

operational freedom and, therefore flexibility, to develop and operationalise their regulatory powers.

Along with the central and the state governments, the other statutory bodies include the Drugs Technical Advisory Board (DTAB), Drugs Consultative Committee (DCC) and the Central Drugs Laboratory (CDL, Kolkata). The Act specifies that the DTAB is the body that guides and advises the central government on technical issues arising out of implementation of the regulation. In effect, this means that the DTAB acts as a primary forum for rulemaking under the DCA, but it is an advisory body and, therefore, can only make recommendations to the CDSCO. Earlier, DTAB used to also review applications for new drugs. Reacting to the criticisms in their functioning by the 59th Parliamentary Committee Report, this function has been recently handed over to the newly established twelve subject-level expert committees (SECs). Now, it is the SECs that review new applications and recommend actions to the CDSCO. CDSCO has recently revealed to a parliamentary committee that it has set up a deadline of 45 days for the first response to an applicant. However, there is no time limit for the final disposal of applications.

It was recognised during the framing of the DCA that uniformity would be a particular challenge given the distribution of regulatory responsibilities between the CDSCO and the SDRAs. To address this particular challenge, the DCC was established. As per the DCA, the DCC is an advisory committee to advise the central government, the state governments and the DTAB on any matter tending to secure uniformity throughout the country in the administration of the DCA. The DCC includes representatives from both the CDSCO and SDRAs. The DCC meets periodically to deliberate upon and provide recommendations on various issues including (but not limited to) the issue of manufacturing licences, amendments to the Drugs and Cosmetic Rules, and state specific issues. The minutes of these meetings can be accessed from CDSCO website. The deliberations of these meetings are aimed at facilitating dialogue between the CDSCO and SDRAs, and uniformity in interpretation of the DCA, the rules and their implementation. For instance, to harmonise the regulatory performance, it was resolved in the special DCC meeting held on October 27, 2014, that the SDRAs will also adopt the same mission and vision statement, as that of the CDSCO, i.e., "*To [sic] safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.*"

Nevertheless, the functioning of the DCC and uniformity in interpretation and enforcement of DCA has been a challenge.[7] This, in many ways underlines the failure of the DCC to evolve as a credible institutional mechanism to address this challenge.

2.1.4 Overview of Reform Efforts

[7] The instance of several SDRAs providing manufacturing licence to Fixed Dose Combinations (FDCs) without their prior approval as new drugs by CDSCO is a specific instance of this problem. (McGettigan P. et al, 2015)

This section provides an overview of the major reform efforts in this sector and an analysis of these efforts. (See Table 2 below for a comparative summary of such reform efforts).

The Mashelkar Committee Report was published in 2003, and it remains one of the most quoted reform proposals in the context of drug regulation in India. The immediate imperative driving the establishment of the committee was a news report on the growing circulation of spurious and adulterous drugs in India. The Committee made specific recommendations for offences related to spurious drugs, including making them cognisable and non-bailable offence, penalties to be made more stringent (fines and imprisonment for life depending on the gravity of the crime) and establish special courts for fast-tracking such cases. More importantly, it highlighted the challenges that the drug regulatory system faces. These included the inadequacy of trained and skilled personnel at the centre and state levels, lack of uniformity in the implementation of regulatory requirements and variations in regulatory enforcement, the lack of database on drug products licensed and inadequacy and lack of co-ordination among drug testing laboratories drug testing laboratories.

The Mashelkar Committee Report made numerous recommendations for overhauling the system. For the purpose of this study, we will highlight only a few pertinent ones. First, to revamp the CDSCO so as to make it "*strong, well-equipped, empowered, independent and professionally managed, it could be given the status of Central Drug Administration (CDA) reporting directly to Ministry of Health."*[8]Second, it categorised the states in terms of scale of industry (manufacturing and sale) and regulatory operations and advocated a differential approach in terms of public investment in regulatory resources. Thirdly, it suggested the revision and imposition of higher fees for drug applications, clinical trials and registration of imported drugs and foreign manufacturers. Lastly, it worked out a formula for adjudging the required personnel. It advocated that there should be one drug inspector per 50 manufacturing units and per 200 sales/distribution outlets for effective implementation.

Interestingly, all the recommendations with reference to spurious drugs were eventually adopted and implemented by the central government and to a certain extent, by the state governments. However, the other recommendations, including those culled out in the preceding paragraph, have been largely ignored. Coming a decade after the Mashelkar Committee Report, the 59th Parliamentary Committee Report was published in 2013. It made a damning indictment of the functioning of CDSCO[9] and highlighted the regulatory failures brought on by the non-adoption of the Mashelkar Committee recommendations. The main recommendations of the 59th Parliamentary Committee Report include,

(i) reformulating the mission statement of CDSCO (which has been implemented),

(ii) hiring short-term consultants (with clear conflict of interest guidelines) to address recurrent staff shortages due to staggered recruitment through the UPSC,

[8] Mashelkar Committee Report (2003), Executive Summary, p2, para 9, http://cdsco.nic.in/html/html/Final%20Report%20mashelkar.pdf accessed on 7 May 2014 at 1445hrs.

[9] Sonal Matharu, 'Parliament committee indicts drugs regulatory authority', May 10, 2012, Down to Earth, http://www.downtoearth.org.in/content/parliament-committee-indicts-drug-regulatory-authority.

(iii) prioritising clinical trials over new drug licences in terms of investment of regulatory resources (given that the scale of the former is much larger than the latter),

(iv) review the qualification, procedure of selection, appointment, tenure, emoluments, allowances and powers, both administrative and financial, of the DCGI,

(v) following the Mashelkar Committee formula for appointment of adequate regulatory personnel,

(vi) deciding the financial package for State Drug Authorities to upgrade infrastructure facilities (specifically drug laboratories) and co-ordinating between SDRAs through a centralized database,

(vii) conducting Phase IV trials of approved drugs for locating side effects instead of relying on spontaneous reporting, and

(viii) widely publicising the news of substandard drugs through press releases and paid newspaper advertisements.

In response to this, the MOHFW constituted an expert committee under Professor Ranjit Roy Chaudhary (RRCC) to formulate policy and guidelines for the approval of drugs, clinical trials and banning of drugs. The RRCC has made recommendations for the development of standard operating procedures (SOPs) and establishment of technical expert committees for new drug approvals, registration of institutional ethics committees, firm timelines for processing of applications and clarification on the public interest waiver for clinical trials and weeding out of hazardous and irrational drugs. It also supported the expansion of the list of products for which manufacturing licence shall be granted by the CDSCO. Most of the recommendations with reference to institutional reforms in clinical trials and new drug approvals have been adopted and implemented by the CDSCO.

The CDSCO drafted the Drugs and Cosmetics Amendment Bill 2013 (henceforth, the DCA Bill, 2013) to incorporate some of these recommendations. This was reviewed by the Parliamentary Standing Committee in its 79th Report. The DCA Bill 2013 proposed a revised approach for centralised licensing (manufacturing) for seventeen categories of critical drugs (to be included in the Third Schedule to the Act), a separate chapter for medical devices and a complete overhaul of the provisions on clinical trials and exports. Most importantly, it proposed the creation of a Central Drugs Authority, consisting of secretaries from seven different ministries and departments of the central government, four state drugs controllers and four experts. The DCGI would be its member secretary. It also proposed the dissolution of the DCC but retention of the DTAB.

The 79th Report of the Parliamentary Committee reviewed the DCA Bill, 2013 and suggested a slew of changes. It rejected the idea of a Central Drugs Authority, with a view that it would be overly bureaucratic and instead proposed a strong and professionally managed Central Drug Administration (CDA), to be headed by the DCGI, who would be given the status of a Secretary (the highest administrative officer in a ministry/department) and reporting directly to the MOHFW (instead of the DGHS to which it is reporting at present). Further, it stated

that the CDA should have adequate autonomy and that its functioning should be reviewed by an independent panel of experts. Another important suggestion of the committee was that the appellate authority for actions taken by the state licensing authority should be the state government and not the central government. It is abundantly clear from these suggestions that the Committee did not fully endorse the idea of greater centralization through the establishment of an administratively independent drug regulator at the Centre.

Thereafter, the MOHFW drafted the DCA Bill, 2015. Apart from the comprehensive provisions on clinical trials and medical device regulation, it proposes the reconstitution of the DCC into a Drugs, Cosmetics and Medical Devices Consultative Committee. Reiterating that the committee will be in charge of ensuring uniformity, all SDRAs are required to send one representative each to become a member of this committee. However, the bill proposes that the meetings of this committee will be scheduled as and when required by the central government and the DCGI will chair this committee. Although mandating the participation of each SDRA is an important step, this does not go far enough to strengthen this body in terms of a clear mandate, resources and functional autonomy to advise and review the functioning of CDSCO.

The Third Schedule specifying centralized manufacturing license for 17 categories of critical drugs has been retained. Interestingly, the entire proposal for an independent authority in the form of a CDA has been dropped in the DCA Bill, 2015. However, recently there have been media reports suggesting that the proposal for establishing a CDA has been forwarded for consideration to the Cabinet.[10]

It is evident from the above discussion that several efforts have been made to reform the regulatory system. Clinical trials, a separate regulatory structure for ayurvedic drugs (AYUSH) and medical devices have been the three most important aspects of this revision. Although there have been some incremental changes in the functioning of the CDSCO as well, the institutional structure continues to be dogged by several problems. These include regulatory challenges emanating from the division of regulatory responsibilities between the centre and the states (lack of uniformity in legal interpretation and harmonisation of the enforcement function), resource deficits owing to the absence of substantial investments in public infrastructure (specifically laboratories) and personnel, and low levels of transparency owing to lack of digitisation, and processing time-lines.

In the following section, we adopt a comparative analysis to perspective to discuss these issues portray how similar regulatory issues and challenges have been addressed across international jurisdictions (USA, EU, China and Indonesia).

[10] Himani Chanda, 'Quality check: Pharmaceuticals regulator set for revamp'', Hindustan Times, New Delhi, June 29, 2015. http://www.hindustantimes.com/business-news/quality-check-pharmaceuticals-regulator-set-for-revamp/article1-1363892.aspx

Table 2: Overview of major reform efforts

	Mashelkar Committee Report	59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha	Professor Ranjit Roy Chaudhary Committee report	DCA Bill 2015
Manpower	(1) CDA will require creation of new posts (senior and supporting levels) (2) Augment no. of drug inspectors especially in category 1 states (3) Capabilities and skills of enforcement staff needs to be upgraded by training in specific areas. (4) Structured mechanisms set up to enable inter-state exchange of officials.	(1) Employing medically qualified persons as Consultants/Advisers (on the pattern of Planning Commission) at suitable rank. (2) Engagement of professionally qualified persons on short-term contract or on deputation basis until the vacancies are filled up with appropriate confidentiality and conflict of interest agreements (3) Optimal utilisation of current staff by prioritising as per the nature of the work (4) Skill development of the regulatory officials, implementation of an effective result-oriented pharmacovigilance programme drawing on global experience.	(1) Attract better-qualified candidates by offering emoluments matching the knowledge and experience required for high-level posts (2) Identification and creation of positions in different disciplines which have become more important in drug regulation (3) Minimum additional requirement sanctioned and implemented immediately; also periodic reviews to assess the needs of expansion (4) Employing subject specialists on a contractual basis, till the in-house expertise is developed (appropriate confidentiality and conflict of interest agreements) (5) Suitable in-service training programmes within and outside the country in the CDSCO and state DCAs	NA
Infrastructure	(1) Expansion of zonal and sub-zonal offices, creation of additional infrastructure for new offices in states for the CDA. (2) The state government must provide adequate infrastructure for the office of DRA, including vehicles and purchase of samples.	(1) Capacity building of CDSCO including upgradation of existing offices and setting up of new offices. (2)Laboratories: -Strengthening of both central and state drug testing laboratories -Creation of new central and state drugs testing laboratories and equipping them with the state-of-the-art technology to enable them to carry	(1) Strengthening and capacity building of zonal and sub-zonal offices and state DCAs (2) Expansion of current pharmacovigilance programme to cover the whole country – reviewed and reorganised to detect unsafe drugs.	NA

	Mashelkar Committee Report	59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha	Professor Ranjit Roy Chaudhary Committee report	DCA Bill 2015
	(3) Designated courts for speedy disposal of cases (4) Laboratories: - Set up adequate testing laboratories that are NABL accredited and follow GLP norms -Central government should have a programme to have coded samples of same product tested at different central/state labs from time to time and have results assessed by experts. - Technical audit of state labs frequently. - Separate division within CDA to oversee the overall working of drug labs in the country. -Continue central assistance to states where it is not technically viable.	out sophisticated analysis of drugs -Upgradation of the existing six Central Drugs Testing Laboratories		
Inspections	(1) The CDA grants the manufacturing licences (in light of the recommendations of the Hathi report), done separately in phases for Category 1 and Category 2 states. (2) Set up intelligence cum legal cell under supervision of senior nodal officers. (3) State should put in efficient mechanism for timely police help to these officers. (4) Establish proper surveillance system for keeping a watch over suspected persons. Watchers should be employed	NA	NA	NA

	Mashelkar Committee Report	59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha	Professor Ranjit Roy Chaudhary Committee report	DCA Bill 2015
	and secret funds may be made available for intelligence activities.			
Financing	Require additional funds for setting up the world class CDA.	MOHFW should work out a fully centrally sponsored scheme for the purpose so that the state drug regulatory authorities do not continue to suffer from lack of infrastructure and manpower anymore		NA
Inter-Agency Interactions	(1) Guidelines and directions to the state/UT drug regulatory authorities must be complied with, failing which action should be taken against regulatory authorities. (2) Section 33P must be amended to issue directives to state licensing authorities to review the orders passed by them and, if necessary, revoke the product permission granted by them.	(1) The Committee recommends that the MOHFW work out a fully centrally sponsored scheme for providing central assistance to the states (2) The Committee hopes that the Ministry can use the Section 33P to ensure that provisions of Central Drug act are implemented uniformly in all states (3) Ministry should play a more pro-active role in encouraging states to employ modern information technology to establish a system of harmonised and inter-connected databanks.	Regular dialogue between the Central and state regulatory agencies regarding reporting of adverse events (AEs) and SAEs for better co-ordination and early intervention for weeding out unsafe, ineffective drugs.	(1)The central government should constitute a consultative committee called the Drugs, Cosmetics and Medical Devices Committee to advise the central government, the state governments, the DTAB and the MTAB. Consist of two representatives of the central government, one representative each of the state governments. It will meet as and when required to do so by the central government and shall have power to regulate its own procedure. The DCGI would be the Chairperson. (2)There will be separate technical advisory boards for Medical Devices : MTAB

	Mashelkar Committee Report	59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha	Professor Ranjit Roy Chaudhary Committee report	DCA Bill 2015
Centralization	Creating an NDA will not solve the problem of an inefficient state and central regulatory system. A strong well equipped, empowered, independent CDSCO can be given the status of CDA reporting directly to the Ministry of Health.	A centralised databank (e.g. licences issued, cancelled, list of sub-standard drugs, prosecutions etc.) may be created to which all the state drug authorities should be linked.	While all drug approvals, new or existing or generic, should lie only with the CDSCO, some of the functions related to inspections, monitoring clinical trials and pharmacovigilance can be shared with the state authorities.	(1) Under the 3rd Schedule there are 17 categories of drugs for which the Central Licensing Authority (CLA) is empowered to issue licence and permission. (2) The central government may suspend/cancel any permission, licence or certificate issued by the CLA or SLA in public interest and the reasons should be recorded in writing.
Independent Regulator	Independent CDA reporting directly to MOH.		(1) Urgent need to reorganise the CDSCO with enhanced facilities to have a strong, efficient and effective drug control authority (DCA) in the country (2)CDSCO should be upgraded to a separate organisation/authority with functional and financial autonomy with DCGI on par with heads of similar organisations of the Government of India (GOl). The qualification and experience of the DCGI should be similar to that of a secretary or director general of other councils as this will overcome the current discrepancy that a Deputy Drugs Controller is expected to be more qualified and experienced than the DCGI	

	Mashelkar Committee Report	59th Report on the Functioning of CDSCO, Department Related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha	Professor Ranjit Roy Chaudhary Committee report	DCA Bill 2015
Transparency and Third Party Oversight	(1) Provide toll free number to receive public complaints/information (2) Proactive role needs to be played by Pharma Trade Association to identify persons directly/indirectly involved in abetting distribution of spurious drugs. (3) Pharma industry needs to use well developed marketing and distribution channels to detect spurious drugs and the people involved; needs to formulate its own spurious drugs policy and surveillance strategy and establish close interaction with regulatory authorities, streamline supply chain and ensure proper storage of products in transit. (4)Awareness campaign by consumer and other professional associations.	(1) The Committee was of the opinion that there is no justification in withholding opinions of experts on matters that affect the safety of patients from the public. Consideration should be given to upload all opinions on CDSCO website. (2) Given widespread internet connectivity, it is advisable to devise a system where patients can get unbiased information on drugs at the click of the mouse in any language. (3) Once a batch of a drug is found to be sub-standard and reported to CDSCO, it should issue a press release forthwith and even insert paid advertisements in the newspapers apart from uploading the information on the CDSCO website. Retail chemists should be advised to stop selling unsold stocks and return the same to local drugs inspectors as per rules. Maharashtra and Kerala, have taken the initiative to upload information on spurious and sub-standard drugs on their websites on a monthly basis	(1) A transparent website containing up-to-date information with relevant regulatory laws, guidelines and their amendments. (2) Application forms, standard operating procedures (SOPs), model agreements for confidentiality and conflict of interest, samples of informed consent forms, checklist for participant information sheet, serious adverse effect (SAE) reporting form, FAQs and answers, etc., should be made available on the website. (3) Regular updating of information (4) Clear-cut timelines for different activities (5) A system of pre-submission dialogue with the applicants to clear all doubts and reduce the delays due to failure of communication channels (6) Display of the lists of members of all committees and subject experts	

Source: Authors' compilation from various reports.

2.2 Regulatory Overview of Other Jurisdictions

As a part of our research, we reviewed the drug regulatory system in four jurisdictions, namely, USA, EU, Indonesia and China. The jurisdictions were chosen based on their similarity to India and regulatory leadership so that we can learn from their experiences.

The Food, Drug and Cosmetics (FDC) Act, 1938, forms the basis for drug regulation in the USA. The corresponding law in the EU is Article 55 of Regulation (EC) No 726/2004; in Indonesia, it is the Decree of the Head of the National Agency of Drug and Food Control, 2011, and for China, it is the Drug Administration Law of the People's Republic of China. With the exception of the EU, all the other three jurisdictions have a singularly centralised system of drug regulation where the central drug regulatory system is empowered to provide licences for marketing and manufacturing. This body takes the form of an agency in the USA and Indonesia (the Food and Drug Administration (USFDA) in the case of the USA and Badan POM or the National Agency of Drug and Food Control (NA-DFC) for Indonesia). In China, the China Food and Drug Administration (CFDA) is a ministry-level agency responsible for drug regulation and provide policy guidance at the provincial level FDA.

In contrast to this, the EU has a federal system of regulation where the European Medicines Agency (EMA) forms the central authority (Committee for Medicinal Products for Human Use (CHMP), which is responsible for human medicine) and each of the member states has a national drug regulatory authority like the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. While granting licences for manufacturing is the jurisdiction of the regulatory authority of the member states, the EU has a unique structure for marketing authorisation. There are three pathways to apply for marketing authorisation for drugs in the EU. In the centralised procedure, the applicant can apply to the EMA for a marketing licence in multiple member states. The decentralised procedure allows the applicant to apply directly to the regulatory agency in a particular member state. Further, the mutual recognition procedure (MRP) pathway exists through which the manufacturer applies to other member states to recognise the marketing authorisation granted under the national procedure by the 'reference member state'.

In contrast to India, both the USA and the EU follow a risk-based approach to inspections. The USFDA has devised quality metrics (based on history of inspection, risk associated with the product and record of past inspections) to identify the facilities that need to be inspected. Risk-based inspections have resulted in efficient allocation of resources and incentivised better quality products. The same procedure is followed in the EU. The inspection system in Indonesia is a combination of a risk-based and random sampling approach. The system in China reflects a similar ad hoc approach. The inspections are random but they use the information from a well-developed network of the ADR monitoring system and the system of drug recalls.

The financing model for the EMA and FDA is a combination of government budgetary allocation and user fee system. The proceeds of the user fee as a proportion of the drug

regulatory budget are higher for the FDA than for the EU. In the case of both China and Indonesia, the government's budgetary allocation is the major source of revenue, supplemented by registration fee. The registration fee is much higher in China than in Indonesia.

Both China and Indonesia face challenges similar to those in India and hence, there are many lessons to be learnt from their experience in handling growing manufacturing bases and the challenges of regulating the quality of medicine on tight budgets. The EU and USA have shown remarkable regulatory leadership and their sophisticated models of financing and inspections are worth exploring.

3. Research methodology

There are two components to the methodology adopted in the study, desk research and field research. The desk research component of the paper involves three dimensions. First, we analysed the primary statute, the DCA and the Drugs and Cosmetics Rules, 1945 along with the review of parliamentary committee reports, reports of government established expert committees and annual reports of regulating agencies. Second, we mapped the regulatory structure in the USA, Europe, China and Indonesia. Third, we documented the regulatory challenges that have emerged in the Indian context, based on a review of both policy reports and academic literature.

The field research involved semi-structured qualitative interviews to gather insights on the regulatory challenges and the best practices adopted nationally as well as internationally. The key respondents included regulators,[11] industry, academia and association representatives such as consumer groups, industry associations and pharmacy associations. One of the principal investigators conducted these interviews with a representative sample of the groups identified above.

With regard to the assessment criteria, we have drawn on the theoretical framework of smart or responsive regulation. The rationale behind this is to design a regulatory system where the choice of regulatory instruments not only match the imperatives/objectives of regulation, but also take into consideration the range of regulatory stakeholders and the intrinsic characteristics of each.[12] The most interesting contribution of this framework is to critically evaluate different kinds of regulatory frameworks in different contexts and to explain why one works and another fails.

In the context of this study, the Indian regulatory system is an archetypical command and control regulation – wherein standards are formulated, licences are distributed and inspections are undertaken to check compliance. Given the current challenges confronting the drug regulatory system in India, it was interesting to explore whether the regulatory architecture of command control is suitable to the structural characteristics of the Indian drug regulatory space. Therefore, the aim of the paper is three-fold, first, to suggest the criteria for assessment of the pharmaceutical regulatory regime in India; second, to examine the suitability or appropriateness of the present regime in terms of these criteria; and third, to suggest a possible basket of measures that could be explored to strengthen the present regulatory regime.

There were three steps involved in the selection of states. First, the top fifteen states were selected based on their pharmaceutical manufacturing capacity. Second, these fifteen states were ranked in terms of their population. Population to some extent reflects the demand for drugs and, along with the scale of manufacturing, gives us a good idea of the scale of

[11] Amongst the regulators, we have interviewed officials from the CDSCO, Ministry of Health and Family Welfare (MOHFW), SDRAs, Assistant Drug Controllers (ADC), Deputy Drug Controllers, Drug Inspectors (DI) and retired SDC and other retired staff.

[12] See, Gunningham and Grabosky (2004), and Ayers and Brathwaite (1992)

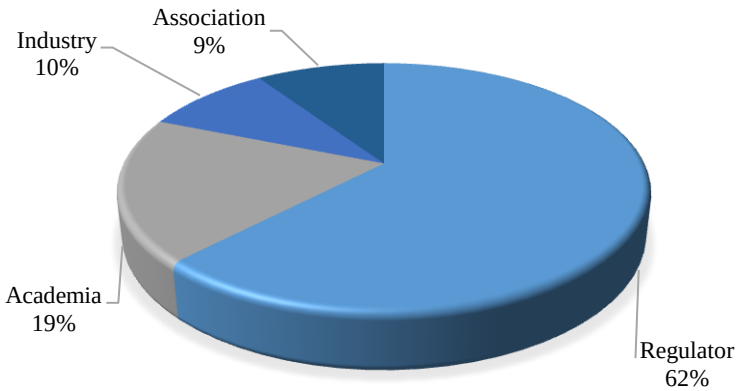
activities being regulated by the SDRA. Third, rankings have been given to these states on the basis of regulatory enforcement **(See Annexure 1)**. The number of drug samples tested and the prosecutions for violations pursued by SDRAs over the last five years (2009-2014) have been taken together as indicators of their performance on regulatory enforcement. While data is the primary basis for our selection, we have also considered anecdotal evidence that may not be reflected in the figures.

Table 3: Selection criteria for states of the study[13]

	Enforcement		
Manufacturing	**Criteria**	**Good**	**Weak**
	High Level of Manufacturing Activity/Facilities	Gujarat	Himachal Pradesh
	Low level of Manufacturing Activity/Facilities'	Kerala	Bihar

One of the concerns maybe that a state with a larger number of manufacturing units will have larger number of samples tested and hence, the number of samples tested may not accurately reveal regulatory performance. However, we have in the first instance segregated states based on their population size. Following from this we then selected only those states which, on the basis of population, have been ranked in the top 20. Population has been used a proxy for the scale of manufacturing and sales. Consequently using the number of samples tested as one of the metrics for performance on regulatory enforcement, does not bias our choice of states. (Detailed methodology adopted for selection of states is discussed in Annexure 1)

Figure 1: Stakeholders' selection in the national sample



[13] We have selected four states for in-depth analysis based on the following criteria (See Table 3)
(i) a state with high level of manufacturing activity/facilities and good performance,
(ii) a state with high level of manufacturing activity/facilities and weak performance,
(iii) a state with low level of manufacturing activity/facilities and good performance,
(iv) a state with low level of manufacturing activity/facilities and weak performance.

Hence, in order to understand the inter-state variations in the enforcement of drug regulations, we have selected four states, namely, Himachal Pradesh, Bihar, Kerala and Gujarat. Along with this, we have also conducted semi-structured interviews in the National Capital Region (where the CDSCO is located), in order to get in-depth insight into the functioning of both the national and state level regulators, various challenges faced by them, and more importantly the issues in their interface. Thereby, identifying the regulatory gaps and suggest possible reform measures.

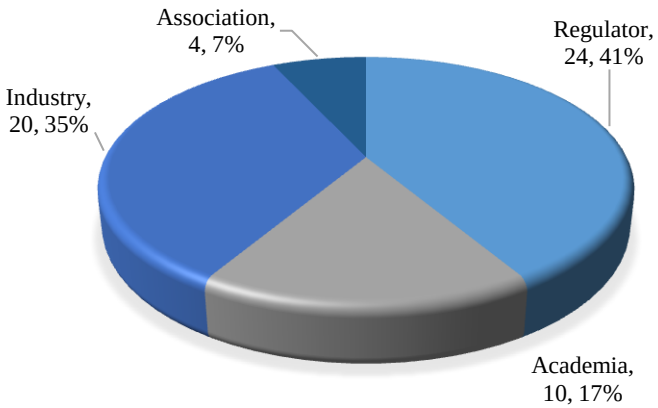
This was followed by interviews in international jurisdictions (USA, Europe, China and Indonesia) to compare the Indian regulatory structure with that in other countries.

Table 4: Selected International Jurisdictions

	Jurisdiction 1	Jurisdiction 2
Developed	USA	European Union
Developing	China	Indonesia

Pharmaceutical sales and employment were used as the basis for short-listing countries. USA has emerged as a leader in drug regulation. Europe is an interesting case because the administrative structure is akin to a federal union. China and Indonesia are both developing countries with large pharmaceutical markets. Indonesia has devolved the powers of enforcement to provincial governments and, therefore, is of additional comparative interest. Thus, four countries selected are USA and Europe in terms of regulatory leadership and China and Indonesia in terms of comparability with India. The limited aim here was to explore how common challenges could be addressed. The international jurisdictions have been selected based on regulatory leadership and comparability with India in terms of economic status and general administrative structure **(for details see Annexure 2)**.

Figure 2: Stakeholders' selection in the international sample



The sample selection for field research was undertaken through a three-stage process. We identified approximately 300 respondents, who were invited to participate in this study; we

received responses from approximately 120 experts. This initial sample expanded through strategically targeted interviews with other key stakeholders identified through 'snowball' sampling. Finally, a total of 111 interviews were conducted, of which more than 95 per cent were undertaken through field visit and direct interviews and the rest were done through telephone and video conferencing. The detailed composition of the stakeholders across types and states/countries has been represented in Table 3.

Table 5: Composition of various types of stakeholders in the field research

State/Country	Values in Number					Values in Percentage					Total No. Contacted	Response (%)
	Regulator	Academia	Industry	Association	Total	Regulator	Academia	Industry	Association	Total		
Kerala	10	5		1	16	63	31	0	6	100	42	38
Gujarat	2	3	1	1	7	29	43	14	14	100	12	58
Himachal Pradesh	8				8	100				100	27	30
Bihar	8				8	100				100	16	50
National[14]	5	2	4	3	14	35.71	14.28	28.57	21.41	100	57	23
Sub-total	***33***	***10***	***5***	***5***	***53***	***62***	***19***	***10***	***9***	***100***	***154***	***37***
USA	2	2	15		19	11	11	79	0	100	32	59
UK	10	4	2		16	63	25	13	0	100	38	42
Indonesia	8		1	4	13	62	0	8	31	100	40	33
China	4	4	2		10	40	40	20		100	*	**
Sub-total	***24***	***10***	***20***	***4***	***58***	***41.24***	***17.10***	***35.20***	***7.46***	***100***	***110***	***52***
Grand Total	**57**	**20**	**25**	**9**	***111***	**51**	**18**	**23**	**8**	**100**	**260**	**42**

*Note: *, **: Stakeholders in China were contacted in an international conference on the DAL revision and the improvement of China drug regulatory system co-organised by the Tsinghua University School of Law's Pharmaceutical Law Institute, China Pharmaceutical Enterprises Association and China Pharmaceutical Industry Research and Development Association. This conference was held on May 29 and May 30, 2015, at Beijing. Thereafter, the sample expanded through strategically targeted interviews with other key stakeholders identified through 'snowball' sampling.*

Additionally, we filed RTI applications (we developed a generic application that was used for all the RTIs – see Annexure 3) in 10 states, viz. West Bengal, Uttar Pradesh, Orissa, Maharashtra, Andhra Pradesh, Kerala, Bihar, Gujarat, Himachal Pradesh, and Tamil Nadu (a copy of the RTI application is enclosed as an annexure). We selected both high-performance

[14] In the states of Bihar and Himachal Pradesh, most of the respondents were regulators. In Himachal Pradesh and Bihar, we interviewed regulators at various levels including Health Secretary, current and former SDCs, ADCs, and Drug Inspectors. We also interviewed Government Analysts in Drug Laboratories in Himachal Pradesh, Bihar and Kerala. The respondents in Gujarat also included academicians at pharmacy colleges and Industry Associations. Further, interviews conducted in Kerala also included members of the pharmacy association.

states low-performance states, based on the drug samples tested across states in 2013-2014 (see Annexure 1).

We received partial responses only from Kerala, West Bengal, Tamil Nadu, Gujarat and Orissa. The other states remained non-responsive, despite appeals being filed. The RTI responses have been tabulated to illustrate responses received on many issues. Given that they refer to multiple thematic areas, responses have been summarised in Box 2 presented at the end of section 4.

4. Research Findings, Analysis and Recommendations

4.1 Uniformity

4.1.1 Current Scenario

Currently, regulatory responsibilities are divided between CDSCO and SDRAs. CDSCO is responsible for granting approvals for clinical trials, new drugs and specialised medicinal products (vaccines, parenterals, and other high risk products) and authorisations for import and export. SDRAs are responsible for granting manufacturing, distribution and sale licences and for inspections, sampling and testing and overall quality control of medicinal products (including investigating violations and launching prosecutions). This division of responsibilities may create the risk of fragmentation.

This risk is exacerbated by the lack of hierarchy between CDSCO and the SDRAs. Both are legally entitled to function autonomously, since 'health' is a subject matter under the State List and therefore, the legislative mandate rests with the state. The lack of uniformity in legal interpretations of the DCA, and in regulatory decision making between CDSCO and SDRA, is a continuous challenge in ensuring harmonised application of drug regulatory standards throughout the country. The DCC has not been able to address this challenge of uniformity adequately. Further, Section 33P[15] which empowers the CDSCO to issue directions to SDRAs, to ensure that provisions of DCA are implemented uniformly in all states, has been rarely used and, even if it is used, the CDSCO has no power to enforce compliance by states. The DCA Bill, 2015 has sought to address this issue by expanding the functional mandate of the CDSCO to include 17 new categories of products for which manufacturing and sales licences will be granted by it. This is only a partial solution, as this only covers around 10 per cent of the products.[16]

Our field research results suggest that institutional channels of interaction between the CDSCO and the SDRAs are lacking. Almost all the regulatory officials from Kerala said that there is limited interaction with the CDSCO except for the DCC meetings (attended only by the SDC) and joint inspections.

There is divergence among the SDRAs too. One such concern was in grant of manufacturing licences for Fixed Dose Combinations (FDCs) by SDRAs. The 59th Parliamentary standing committee reported that due to some ambiguity on the powers of the SDRAs, some SDRAs have issued manufacturing licences for a very large number of FDCs without prior clearance from CDSCO in violation of rules. As per the law, a product is deemed to be a new drug when two or more drugs, already approved individually, are combined for the first time in an FDC. In order to ensure that the FDCs conform to safety and efficacy requirements, it has to

[15] As per Section 33P under DCA, "*Power to give directions. – The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.*"

[16] As stated by Shri Arun Kumar Panda, Joint Secretary, Department of Health and Family Welfare, in the 79th Parliamentary Committee Report.

undergo the procedure applicable to other new drugs. It is only when FDCs receive approval from CDSCO that manufacturers can approach SDRAs to obtain manufacturing licences.

The divergence also became apparent in our field interactions; we observed that most regulators are of the view that the inter-state interaction of SDRAs will enhance the sharing of knowledge and effective implementation of the policy and can reduce the differences in penalties from state to state. A few officials have personal contacts with other SDRA officials through the activities of staff associations. For instance, there have been training programmes where the Gujarat FDCA trained DIs from Chhattisgarh and Haryana amongst other states. The need for increased interaction with Himachal Pradesh was highlighted from the interviews conducted in Kerala since Baddi (Himachal Pradesh) is a major drug supplier to the country.

For the purpose of uniform implementation of rules and policies, Dr GN Singh (Drugs Controller General of India) in the inaugural deliberations of the 46th meeting of DCC[17] suggested that zonal level meetings of the SDRAs could be convened to deliberate on common regulatory issues.

Approvals in China work on a system of "vertical management". Every application has to be first approved by the Provincial Drug Regulatory Authority and then finally by the CFDA. As the CFDA is the final authority for approval, there is uniformity in decisions. The Chinese drug regulatory regime has been subjected to varying degrees of centralisation. The recent spate of reforms is aimed at replicating a centralized bureaucracy in the mould of the USFDA to facilitate greater coordination and uniformity between the centre and the provinces. Currently, the CFDA is an autonomous body with a central office and nodal offices in every province.

Experiences of reform efforts in other jurisdictions seem to suggest that centralization is the key to ensuring greater uniformity. Of course, this may be much easily pursued in the context of the Chinese political system, than in a federal polity like India. Especially since, it is the State which holds the direct legislative competence on the subject matter of public health. Thus it may be more politically feasible to explore alternate models of cooperation between the CDSCO and SDRAs.

4.1.2 Issue

The lack of uniformity in the legal interpretation of the DCA, and regulatory decision-making, between the CDSCO and SDRAs as well as divergence among SDRAs is a challenge to the harmonised application of drug regulatory standards throughout the country.

4.1.3 Recommendations and Measures for Operationalisation

We propose two recommendations either of which may be considered.

[17]Report Of The 46th Meeting Of The Drugs Consultative Committee Held On 12th And 13th November, 2013 Source: http://www.cdsco.nic.in/writereaddata/Report%20of%2046th%20DCC%20Meeting.pdf

i. Make CDSCO the controlling and reporting authority for SDRAs

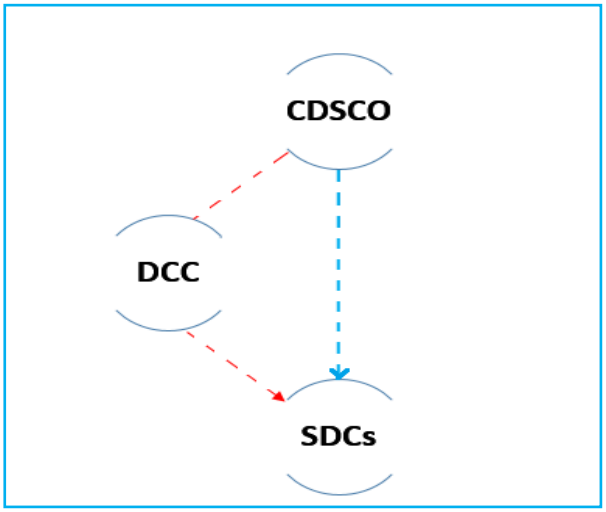
This would lead to a clear hierarchical structure and reduce the risk of fragmentation in functioning. Functions may continue to be distributed between the national and state levels but CDSCO would be the managing authority and, therefore, responsible for ensuring uniformity. This can be done if Parliament enacts a new legislation to replace the DCA. To achieve this, Parliament will have to clarify its competence to enact it.

There are three ways that this can be operationalised: first, by moving 'health' subject matter from the State List (List II) to the Concurrent List (List III) of the Constitution. For this, a constitutional amendment is required. Thereafter, Parliament can enact a new legislation to replace the DCA. Second, is to enact new legislation under the 'Drugs and Poisons' Entry 19 in the Concurrent List. Third, a new legislation may be enacted using 'Industries the control of which by the Union is declared by Parliament by law to be expedient in the public interest' Entry 52 of the Union List (List I), to replace the DCA.

ii. Empower and strengthen SDRAs to become regulatory partners of CDSCO

This can be done by expanding and strengthening the role of the DCC in key regulatory areas such as developing guidance documents to formalise SOPs and interpretations of key legal provisions. A similar model exists in the EU in the form of CHMP, which is an empowered body with representation from all member states. Thus, regular meetings, mandatory representations from all SDRAs and dedicated funding for such participation and a secretariat are absolutely critical. This can be operationalised by amending the DCA. The current DCA Bill 2015, pending with the MOHFW, envisages representation from all SDRAs, but lacks sufficient details in terms of functional scope, financial support and regularity of meetings.

Box 1: Addressing the challenge of uniformity: Vertical versus horizontal approaches



Vertical versus horizontal approach:

Lack of uniformity can be tackled in either of two ways:

(i) CDSCO should be hierarchically superior to SDRAs
- CDSCO should be the managing authority and hierarchically superior to the SDRAs and hence, responsible for ensuring uniformity or

(ii) SDRAs should be made regulatory partners of the CDSCO through the DCC
- A model similar to CHMP, which is an empowered body with representation from all member state in EU.

4.2 Regulatory Agency Autonomy

4.2.1 Current Scenario

At present, both the CDSCO and the SDRAs are umbilically tied to their parent ministries and departments of health respectively. This impedes flexibility in decision-making and autonomy in a host of areas beginning with finance, recruitment and other areas of institutional policy. This is particularly acute in some states where critical appointments are made on a contractual basis (as against permanent posts that give security of tenure and, therefore, functional independence) and where even minimum operational support facilities are missing. Some parts of the system have been made technically autonomous such as the review of new drug applications by subject expert committees in the CDSCO, but both sets of agencies remain effectively accountable to bureaucrats in their respective parent ministries. The DCA Bill, 2013 had envisaged the establishment of a Central Drug Administration that includes certain features such as the DCGI being given a post equivalent to that of a Secretary, Government of India. However, it still fell short of securing autonomy of the CDSCO, since it would still continue to be under the administrative authority of the MOHFW. The need to streamline regulatory decision-making is important both in the context of a federal division of responsibilities between the centre and the states and to provide them with the technical and financial autonomy to function effectively. In this context, it is pertinent to highlight as put forth by Ratanawijitrasin and Wondemagegnehu (2002),

> *"In some countries, Drug Regulatory functions are assigned to two or more agencies, at either the same or different level of Government. Fragmentation and uncoordinated delegation of powers can impede the regulatory effectiveness of a country. Ideally, drug regulatory systems should be designed in such a way that the central co-ordinating body has overall responsibility and is accountable for all aspects of drug regulation for the entire country".*

This captures the problem in India as well, where there is no single entity that is ultimately responsible for ensuring the effectiveness of the regulatory system as a whole. Our interaction with the CDSCO was revealing in this context. We were told that the CDSCO officials were aware of the differing levels of competence among SDRAs. They also agreed that lack of uniformity in functioning and enforcement among SDRAs is a problem and SDRAs in many cases lack the necessary staff and resource strength to undertake their functions. However, they did not consider that it was their responsibility to address this issue. This again highlights that there is no agency that bears holistic responsibility for the effective working of the regulatory system.

The proposal for extending the powers of CDSCO allowing for greater centralisation (establishment of Central Drug Administration) has been suggested as a key proposal in the DCA Bill, 2013 and in the follow up DCA Bill, 2015.

SDRAs across the country are not in favour of centralisation for different reasons. The SDRA in Bihar contended that centralisation would lead to delayed approvals. Renewal of licences of blood banks was given as an example of such delays. Blood banks deal with high risk products and, therefore, are under the regulatory control of the CDSCO. It was pointed out by several Drug inspectors in different states that renewal of blood bank licences gets inordinately delayed due to the capacity constraints in CDSCO's zonal offices. There have

been instances when blood banks have been allowed to function even without renewal of licences because of delay to ensure that no inconvenience was caused to the public. The proposal for extending the functional ambit of the CDSCO and a concomitant reduction in the powers of SDRAs was viewed as both impractical and something that would make compliance prohibitively costly for smaller manufacturers However, this also reflects the anxieties of SDRAs regarding the altered power relations with CDSCO officials that this would imply.

A majority of the respondents, especially officers from the SDRAs supported the idea of an independent regulator for drugs – in terms of administrative distance between the SDRA and the state department of health. Officials from the SDRA in Bihar specifically mentioned this as an important step towards greater operational freedom. Financial budgets were tightly controlled by the bureaucrats at the Department of Health with very little formal input or interaction between them.

The Food Safety and Standards Authority of India (FSSAI), was suggested as a good reference point for an independent and autonomous regulator. The FSSAI is a statutorily independent body with all the powers of financial planning and administrative flexibility. The need to ensure the autonomy of the drug control organisation, both at the centre and at the state level, was emphasised by several respondents as being critical to handle operational challenges and to gain flexibility and credibility as an administrator.

Part of the problem is also in the way that pharmacists are perceived. According to many regulators whom we interviewed in India, doctors in general perceive pharmacy graduates as persons who failed to be doctors, undermining the critical role played by pharmacists in regulating the quality and safety of drugs and thereby ensuring public health. The role of doctors in society is physically visible and, therefore, celebrated. Since pharmacists work behind the scenes, there is little public recognition of their role. This also influences intra-departmental dynamics – wherein doctors tend to hold prominent positions in the Health ministry/department bureaucracy routinely devalue the role and function of the CDSCO and SDRA respectively. Establishing an autonomous regulator would to a large extent would ensure administrative distance with the parent ministry and help circumvent such cultural limitations.

Interestingly, our field research provided insights into the perception of pharmacists.[18] This perception seems to physically manifest itself in the dynamics of MOHFW; as one regulator puts it, *"Ministry of Health tends to be dominated by personnel who are usually doctors by training."* On the other hand, SDRAs' regulatory personnel are mainly drawn from pharmacists. As a result, the functioning of the CDSCO and SDRAs are routinely sidelined within the MOHFW and the Departments of Health respectively. This is reflected in the relatively lack of interest, commitment and financial investment in creating permanent positions (specifically Drug Inspectors for undertaking enforcement), limited expansion in

[18]Pharmacists receive a formal degree in pharmacy sciences (B. Pharm/M.Pharm).

infrastructure support (definitely not in proportion to the scale of operations) and lack of general public visibility.

4.2.2 Issue

Many of the critical challenges faced by the regulatory agencies, both the CDSCO and the SDRAs, stem from their lack of independence and autonomy.

4.2.3 Recommendations and Measures for Operationalisation

There is need to establish a financially independent and technically autonomous (politically accountable to the Parliament) statutory regulatory agency to replace the CDSCO and SDRA on the lines of the FSSAI (Food Safety and Standards Authority of India).[19] This will allow greater flexibility and increase the operational effectiveness of both these regulatory agencies. The fees collected by the regulator can be assigned directly to itself instead of being routed through the Department of Health.

An amendment in the DCA can be brought in to achieve this. However, given that 'public health' is a subject matter in the state list, states have to be taken into confidence before making such an amendment.

4.3 Inspections

4.3.1 Current Scenario

Drug inspectors in India rely on a system of 'random' collection of samples from the market and government institutions. Drug inspectors are required to inspect all the licensed premises assigned by area. Inspectors collect samples randomly and send it to the laboratory for testing by the government analyst. In Kerala, the drug inspectors with administrative charge have a target of 25 inspections. Sometimes The Pharmacy Council in Kerala also conducts inspections at the distributor level. Drugs that are found "not of standard quality" are recalled with the cost being borne by the stockists.

A discussion with the drug inspectors in Bihar, highlighted several issues related to inspections, "*Regular inspections are required and the inspectors need to be more aware. Drug inspectors have no assurance of their safety and do not have the power of arrest."* Another senior drug inspector (Patna) in Bihar said, *"There have been instances when there were attempts on our lives by the local mafia. The absence of a vehicle and adequate safety measures make it extremely difficult for us to conduct inspections".* They suggested that the number of drug inspectors needs to be increased and adequate measures should be taken for their safety.

It also emerged from our discussions that most SDRAs do not maintain a firm level database that tracks inspections of manufacturers and distributors. The introduction and maintenance

[19] Refer to Annexure 5 for a case study of FSSAI.

of such a database eases investigation procedures. The use of the European Union Drug Regulatory Authorities (EUDRA) GMP[20] database, that documents the compliance history of firms in various countries shared between the regulatory authorities in the member states of the EU, was cited as a good practice that could be explored in India. Xtended Licensing and Laboratory Node (XLN)[21] software can be utilised to create such a database tracking compliance up to the distributor level.

In sharp contrast to the Indian regulatory system,[22] both EMA (and its national counterparts such as Medicine and Healthcare products Regulatory Agency – MHRA in the UK) and the USFDA have a 'risk-based' approach to inspections. The system of risk-based inspections is based on experience: the frequency of inspections depends on the nature of the products manufactured, size of the facility and history of the facility's compliance (based on recalls, defect reports, inspections and other objective information). The USFDA has devised a system of quality metrics to select the facilities that need to be inspected. The risk-based approach to inspection has resulted in an efficient allocation of resources and incentivised better quality. The user fee funds some inspections in the USA, unlike in India where they are entirely paid for by the state. This reflects the difference in the perception of inspection as a service by the regulator to the manufacturer as opposed to a burden. The USFDA has been fairly successful with enforcement through strict penalties in the form of warning letters, consent decrees and suspension of manufacturing activities. These enforcement activities are a companion to the clear regulatory guidelines and educational activity to support industry compliance with USFDA standards.

In Indonesia, there are two kinds of sample selection, namely, routine sampling which is a random selection of samples and surveillance sampling conducted only for those products which the regulator considers to be a significant risk. This is a hybrid of the risk-based and random sampling approach. What is particularly striking about the Indonesian system is that the police also have the authority to undertake enforcement actions including collection of samples. China also has an ad hoc system of inspections. However, as a senior academic in China told us, the sophisticated ADR monitoring system contributes to streamlining their inspection activity.

Having an investigation cell complements the inspectorate particularly when the regulator is faced with resource constraints. The Mashelkar Committee recognised this and had observed that '*right from the time of Hathi Committee Report (1975), the states had been repeatedly requested to set up an intelligence-cum-legal cell but so far only 10 states are reported to*

[20] EUDRA GMP database, maintained and operated by the EMA, is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates. (http://eudragmdp.ema.europa.eu/inspections/displayHome.do)

[21] XLN software is explained in the theme discussing physical infrastructure.

[22] Inspections conducted by the SDRAs are usually conducted on a rotational basis – wherein a schedule is drawn up to cover all manufacturing units over a period of time. The aim is to cover as many units as possible rather than focus on specific units where there is a higher risk of non-compliance. Raids or inspections of sales premises are also rotational but can be prioritised based on other information which may be received from medical reports.

have set up such cells. It was not clear how many of these are really functioning actively and effectively'.[23]

While attending the Indian Pharma Summit,[24] we had a chance to speak with o the regulatory officials from the Food and Drug Administration Maharashtra (FDA Maharashtra), who spoke of how establishment of an intelligence cell has allowed them to function as a watchdog. The cell has ably assisted Drug Inspectors by establishing a surveillance system for detection and investigation of suspicious persons.

The EU has worked on co-ordination between member states by establishing real time intranet sites accessible by all participating regulators; adopting procedures to issue alerts when significant problems arise that affect more than one member state and by enforcing common standards and procedures for conducting regular inspections. They have joint audit programmes and Good Manufacturing Practice (GMP) committees where inspectors from all member states discuss the implementation of the GMP guidelines. One drug inspector at MHRA told us, *"On joint inspections with other EU member states, we found that there wasn't much difference in the implementation among states"*.

In Indonesia, respondents are of the view that the scale and quality of inspection operations have been hobbled by physical and human resource constraints. The number of inspectors and the scale of operations are determined by extraneous factors rather than the nature and scale of regulatory operations. This is corroborated by one of the industry experts we interviewed who was of the view that even though training facilities for officers are good, their work is hampered by lack of proper infrastructure.[25] Lack of SOPs for undertaking inspections and collection of samples and testing further exacerbates this problem.

4.3.2 Issue

Currently there is great disparity in the practice of inspection amongst SDRAs. SDRAs rely on a combination of factors to determine the inspection protocol – who is inspected, at what point in time and who undertakes the inspection. Unlike in other countries, inspection targets are not necessarily risk-based (thus for instance Drug Inspectors in Kerala have to complete a mandatory target of inspections). Risk-based regulatory systems use a host of factors to determine risk and to refine the parameters used to assess risk continually.

4.3.3 Recommendations and Measures for Operationalisation

Given the limited resources there is a need for efficient utilization of resources for the purpose of inspections. For this to be operationalised, the following steps need to be adopted. First, states need to rationalise the workforce in terms of the number of inspectors in proportion to the scale of the industry in that state. Thus, Himachal Pradesh should have

[23] Mashelkar Committee Report (2003) -Executive Summary (Page 3).
[24] 'India Pharma Summit 2014–15' was organized by FICCI–WHO on 23rd March, 2015 in Mumbai, under the aegis of Department of Pharmaceuticals (Government of India).
[25] For instance the police personnel are allowed 10 litres of petrol per day! This leads to backlogs that may stretch to over a year.

greater number of inspectors in comparison to say Madhya Pradesh (since Himachal Pradesh is ranked higher both in terms of population (sales units) and manufacturing). Second, risk-based inspections should be adopted as a statutory principle for establishing inspection protocols, i.e., initiate risk based inspections for all regulatory agencies, which would concentrate regulatory resources at the point where the risk of non-compliance is highest (the risk should be a standardised function of the compliance history of the unit, risk associated with the product and other such variables).

Effective risk-based inspection and associated resource deployment requires continuous revaluation of risk by monitoring the manufacturing environment, industry advancement and other factors. Third intelligence cells need to be set up in SDRAs to provide information to the inspectorate to conduct raids. Fourth, SOPs are needed to be adopted for establishing a database of manufacturing and sales units and to introduce a tracking mechanism to track their compliance history. The DCA should be amended to allow for this. The DCC could provide a forum at the national level through which state inspectorates can meet to discuss issues of common concern, develop standard procedures for inspections and templates for inspection reports, and share information on results of inspections across the country.

4.4 Physical Infrastructure

4.4.1 Current Scenario

Our field research provided evidence that pointed towards the need for better infrastructure in regulatory agencies. The process of digitisation has already begun with the Government of India awarding a contract to Centre for Development of Advanced Computing (C-DAC) to introduce the XLN software in more states and it is expected that, over the next three years, the process of moving to a complete electronic platform that is shared between the CDSCO and the SDRAs will become operational.

The XLN system has been implemented since 2007 to result in an end-to-end online system with no physical file requirements. It also has an auto-reminder for renewal of licences, a centralised approval system for licences, one database accessed by states, a single sign-in for multiple states, details of samples drawn and results of samples tested by drug inspectors. Among the states we studied, we observed that Gujarat has a sophisticated IT system, being the first state to introduce the XLN system. The XLN system has now been adopted by several other states such as Himachal Pradesh and Bihar. Gujarat also has the Drug Manufacturing License-Allopathic (DMLA) system, which has allowed the regulator to migrate to a platform for providing paper less services to stakeholders applying for manufacturing licences for allopathic drugs.

In Kerala, the software has been operational since August 2012 and is available for sales licences. The respondents are of the view that it has been very effective although there are some technical issues in its functioning. With regard to the efficiency of the software, a member of a prominent All India Industry Association said, *"We find the application system in Gujarat to be very smooth. However, it still requires manual payment of application fee,*

which results in double the amount of work". In Himachal Pradesh, sales licensing is now entirely online. Further, the state is in the process of extending it to manufacturing licences as well. Although in the initial stages, there have been reports of problems faced due to poor network connectivity. Despite these limitations, the software installation led to speedy disposal of the applications, especially since the SDRA (on an average) reviews around 200 applications each day.

In Bihar, the implementation of XLN is mainly on paper, and there is minimal computerisation. All licence applications (sales and manufacturing) are paper based. District based drug inspectors rarely have a dedicated and permanent office space or access to computers. Regulatory officials told us, *"Apart from the SDRA's dedicated office in the Health Ministry secretariat at Vikas Bhawan in Patna – most drug inspectors do not have dedicated offices in districts and divisions. They operate out of hospitals or the civil surgeons' offices and this has not changed in the last 30 years*."

The supporting infrastructure for the department appeared inadequate in the states of Bihar, Kerala and Himachal Pradesh. All respondents in Himachal Pradesh are of the opinion that the department lacks adequate transport facility, which is very essential for the efficient working of the department. The officials cannot wait for the public bus service when they have to conduct a raid. This view was also echoed in Kerala. The major infrastructure hurdle faced by the drug inspectors in Kerala is that they have to rely on old vehicles. As per the SDRA, there are 5 vehicles available in the state and they are all 15-20 years old. In the absence of proper vehicle facilities, inspections become a burdensome task, particularly in hilly districts like Idukki and Wayanad. Infrastructural inadequacies have serious implications when we cross-examine the words of a former state drug controller, *"Most drug inspectors are going for inspections in the manufacturer's vehicle!"*

The state of physical infrastructure of drug laboratories is quite alarming. The CDSCO operates eight laboratories (six for drugs, one for vaccines and one for DNA and diagnostic kits), with a combined capacity to process 8000 samples per annum. All the central laboratories are NABL accredited. As per a senior CDSCO official, "*All central laboratories are of good quality but lack capacity*".

By contrast, state-level laboratories vary greatly in terms of both quality and capacity. On visiting the Bihar Drug Control Laboratory (BDCL) in Agamkuan, Bihar, we found that it receives minimal support from the CDL and national laboratories due to non-payment of arrears by the Bihar government. Testing facilities are limited (HVAC and micro-biologicals were unavailable). A similar situation exists in Himachal Pradesh, where currently all the drug testing is carried out in the Kandaghat Laboratory, which is not only overburdened but also lacks facilities for disintegration and biological tests. Being the major supplier of drugs to the entire country, the quality of drug testing in Himachal Pradesh in turn affects drug quality across all states in India. In this context, the regulatory officials put forth a question, *"What is the use of taking samples without having adequate testing facilities?"* A representative of an industry association in Delhi said, "*There are too few public drug testing laboratories – there is a lot of pressure on CDL Kolkata".*

The inadequacy of qualified laboratory personnel in state drug laboratories has adversely affected the testing of samples. A shortage of manpower in drug laboratories is a common complaint across states, such as Bihar, Kerala and Himachal Pradesh, the shortage being more acute in states like Bihar. We have noticed from the Himachal Pradesh SDRA website that 23 out of the 54 sanctioned posts in the state laboratory are lying vacant.[26]

Further, an official at a Bihar Drug Laboratory elaborated on the implications of this shortage, saying, *"The backlogs in samples are huge, so the samples often expire before they can be tested. All purchases require approvals which create further delays. There needs to be enhancement of financial powers of purchase. The state drug laboratories need to be independent entities like CDL Kolkata".* An academic in Gujarat suggested that drug laboratories in pharmacy colleges could be recognised for drug sampling purposes. Better utilisation of existing capacity will enable state to tackle issues of manpower and infrastructure without imposing any additional fiscal burden on them.

The states of affairs in SDRAs are in sharp contrast to the physical infrastructure in countries such as the EU and the USA. We find that the EMA and the USFDA respectively have excellent physical infrastructure. This may be due to larger budgets realised by implementing the user fee system along with efficient utilisation. They also have excellent IT systems in place so that all applications are processed online.

There is consensus among various stakeholders that the shortage of physical infrastructure is an impediment to the efficient working regulatory system. However, a senior member of an industry association in Gujarat cautioned, *"Yes, there are infrastructure problems including lack of staff and resources. No doubt, infrastructure update is needed, but merely providing more of it will not solve the problem. It needs to be backed by strong political commitment."*

4.4.2 Issue

Lack of infrastructure, specifically laboratories, digital databases, e-licensing and transport, are the key areas where investment and expansion of facilities are necessary, especially at the level of SDRAs.

4.4.3 Recommendations and Measures for Operationalisation

A survey of all state government laboratories needs to be conducted to identify critical gaps. This has to be followed up by adopting a *de minimus* rule (should be statutorily recognised), which specifies the minimum laboratory facilities (instrumentation and manpower) that should be adopted in all states. Thereafter, financial support can be made available by way of a one-time grant from the union budget, on the agreement that state governments will give matching grants to maintain the facilities (at least five year commitment). In addition to this, there should be a movement towards NABL accreditation for all central and state laboratories. Measures like accreditation of private laboratories and those in pharmaceutical

[26] Available at, http://www.hp.gov.in/dhsrhp/CTL%20KANDAGHAT.html, Accessed on 26th February, 2015.

colleges may be included as part of the programme, with some of the sampling being shifted to such facilities.

The success of the digitisation process depends on the success of adaptation and universalisation of the XLN software, which should be initiated by all SDRAs at the earliest. A complete real time common database (including manufacturing/sales activity, inspection records, applications and their status) for all SDRAs created using the XLN software should have robust security protocols and allow public access to specifically designated information.

In this regard, "rapid replication roll out" initiative[27] of the Department of Electronics and Information Technology, Government of India, can facilitate digitalisation by creation of a common database and the development of security protocols. This initiative leverages sharing of infrastructure and facilitates rapid customisation and replication of successful applications across states. These applications are envisaged to be hosted on cloud at a later stage for the purpose of efficient service delivery. It was also an important agenda item discussed in the 47thMeeting of the DCC, which also highlighted that online licensing system software is available for adoption by the states. An important example of this initiative is XLN developed by National Informatics Centre (NIC), Gujarat –an application that has been replicated in Chhattisgarh, Karnataka, Himachal Pradesh[28] and Kerala. It is also necessary to have adequately trained personnel in each SDRA to operate the database. All licensing activities should be through the database. Public interface must also be built into the database, including real time tracking of applications and responses to Right to Information applications. This will result in a coherent and centrally integrated data bank.

With the aim to facilitate speedy and regular inspections, dedicated transport for SDRAs should be made available reflecting current and projected scale of operations. All these are policy measures that can be easily discussed in the DCC and monitored by it as well.

4.5 Human Resource and Training

4.5.1 Current Scenario

The CDSCO had a sanctioned strength of 111 posts in 2008, which was increased to 474 posts by 2014. At present, the actual strength is 220 regular officers. The remaining 254 posts have been advertised through Union Public Service Commission (UPSC). The UPSC process of recruitment is often staggered and delayed.[29] To cope with this, 250 contractual staff have been recruited to assist in processing applications for new drugs and clinical trials.[30] Both the Mashelkar Committee and the Parliamentary Committee (59th Report) had suggested the lateral entry of consultants on contracts as a measure to address the shortfall. However, it is pertinent to underline that only clerical and routine administrative and expert positions can be filled by hiring contractual employees, under clear conflict of interest rules. Nevertheless, we

[27] http://indianict.com/nict14/about_nict/endorsement.php.
[28] http://informatics.nic.in/news/newsdetail/newsID/446.
[29] Annual Report of the Ministry of Health and Family Welfare (MOHFW) 2014-2015.
[30] Annual Report of the Ministry of Health and Family Welfare (MOHFW) 2014-2015.

see that in some SDRAs, such as that in Himachal Pradesh (an important state given that it has one of the largest number of manufacturing units), in the most recent round of recruitments, drug inspectors have been given contractual positions.

In the words of a regulatory official, *"The industry has grown at a higher rate with inadequate growth in the regulatory system/staff. In 2012, 6 new drug inspectors (DIs) were appointed. However, they were appointed on a contractual basis. Contractual employment in gazetted position is against the law…."* These newly appointed DIs have to wait for 6 years to become regular employees. One such DI said that their salary is INR 15388 per month without any of the perks of permanent government service. The vacant posts, therefore, could be attributed to the fact despite their work being of a critical nature, job satisfaction in terms of remuneration and job security for the Drug inspectors are lacking. The DI stated,*"We are dealing with highly sensitive information including drafting of plaints and prosecution. What if we were to quit today? The department will have no institutional memory! There is very little financial incentive for me in this job!"*

Drug inspectors in Kerala, Himachal Pradesh and Bihar also face another common problem. Drug inspectors have to perform multiple tasks including being the prosecuting authority in courts. This demands time away from their primary function – that of inspections. In Bihar, this problem is magnified because DIs are often deputed for other administrative functions (e.g. electioneering, flood control and crowd management) by the district magistrate (DM). The DM is the drawing and disbursing officer (DDO) for DIs in Bihar. This means that the DM is the person authorising salaries for DIs and, therefore, exercises inordinate control in terms of deputing them for non-drug related administrative functions. The SDC in such case is rendered powerless in terms of affecting functional control over its DIs. Thus, relieving DIs from non-technical functions is urgently required.

Staffing is also a concern in drug laboratories. On visiting the Bihar Drug Control Laboratory (BDCL) in Agamkuan, Bihar, we found only 3 persons running the laboratory, whereas at full capacity the laboratory requires around 40 technicians. The number of sanctioned posts is around 15, but recruitment has not kept pace with retirement of staff. There is also a basic problem with recruitment through the Bihar Staff Selection Commission, where advertisement of vacancies is staggered and recruitment and joining takes an average of 5 years. The current laboratory in-charge is an acting government analyst and has been in this position for two years, since the retirement of the previous government analyst. Given the paucity of technicians, sparing them for training is not an option.

Training has been identified by multiple stakeholders as one of the most critical areas that require urgent attention. None of the SDRAs whom we interviewed have an annual training programme, reflecting the ad hoc nature of scheduling training programmes. Almost all SDCs and ADCs have had the opportunity of attending training programmes organised by CDSCO; however, most DIs have had no such opportunities. It was observed from the information received through RTIs that specific funds are not allocated for training in the budget of SDRAs. In Kerala, training programmes are being conducted by the Institute of Management in Government (IMG) whose focus is on administrative rather than technical skills.

The National Institute of Pharmaceutical Education and Research (NIPER) was earlier involved in imparting technical training but that has been discontinued for seven years now. Drug Inspectors in all the states felt that CDSCO officers were given regular training, which should also be extended to them. A Drug Inspector from CDSCO confirmed that there are regular trainings for CDSCO officers and representations from states are nominated by SDRAs. He also pointed that they are not trained to specialise in a particular area. A senior member of an industry association for exports suggests, "*Setting up of an institute for training is required with participation from the academia and regulators, including the Health Ministry etc."* Further, to enhance the capacity building exercise, the background of the officials is also crucial. For example, in Gujarat, the commissioners and drug inspectorate officials usually have had industry experience and this is considered enriching for a regulator.

The almost total lack of clerical support for Drug Inspectors in SDRAs was identified as a significant problem across all states.

A senior regulatory official in the CDSCO also underlined the need to match regulatory functions with personnel requirement. According to him, "*Currently, India is not one of the drug discovery countries. The market here is dominated by generic manufacturers. Therefore, there is a need to prioritise and dedicate more regulatory resources for manufacturing licences and enforcement rather than on new drug approvals…. There is need to hire more pharmacists rather than doctors*".[31]

A representative of an industry association also echoed the same sentiment, *"The DCGI – should be somebody with a background in pharmacy studies....it is not appropriate to have an IAS officer without technical knowledge of the sector, formulations, etc."*

The general impression from the field research is that the lack of dedicated support staff (both laboratory technicians and administrative clerks), inadequate training of DIs, and discharge of non-work related duties are the major challenges faced by the SDRAs. The overall view is that although, at the entry level, both the SDRA and CDSCO staff are similarly qualified, the latter, through better training programmes and exposure, become much more capable compared to the former within a short span of time after entering service.

4.5.2 Issue

There are two issues that require urgent attention. The first is the quantitative aspect of matching the number of regulatory personnel to the scale of activities. The Mashelkar Committee had advanced a formula of one drug inspector per 50 manufacturing units and per 200 sales/distribution outlets for effective implementation. This is yet to be achieved. Next, from a qualitative perspective, the nature and thrust of regulatory functions should determine

[31] This is also borne out of evidence – India received 8 new drug applications in 2014-2015 (tabulated until October 2014) as compared with 41 in the EU and 41 applications received in the USA. http://www.readcube.com/articles/10.1038/nrd4548?utm_campaign=readcube_access&utm_source=nature.com&utm_medium=purchase_option&utm_content=thumb_version&show_checkout=1&tracking_action=preview_click ; http://www.nature.com/nrd/journal/v14/n2/full/nrd4545.html;

the qualifications of the regulatory personnel and adequate training should be imparted to further enhance the capacity of existing personnel. Given that currently India is largely a generic manufacturing country (rather than a drug discovery country), there is need for regulatory prioritisation, i.e., we would require many more pharmacists to review samples than doctors who can review applications for new drugs. Additionally, there is a great disparity in pay, work conditions and training facilities for employees among SDRAs. This has an adverse impact on the functioning of the SDRAs.

4.5.3 Recommendations and Measures for Operationalisation

The recommendation can be operationalised in two ways –by addressing the requirement of additional human resources and more importantly, by enhancing the capabilities of the already existing officials through periodic training programmes. Training should be a priority area and annual training plans should be developed based on current and projected requirements.

To make training effective and uniform across states, the CDSCO should formulate specific modules facilitating specialised training to all officials. Training programmes, if linked to promotion, could incentivise participation and go a long way in enhancing individual performance. The training system could be evolved in manner similar to the one that exists in the University Grants Commission (UGC) to provide continuous knowledge building to the university faculty through refresher courses. To take a cue from this, inspectors should be required to attend a training course once in six months to once a year, and this could be linked to their promotions. Such training may not necessarily be onsite and may be imparted through IT enabled channels. Training at UK's regulatory agency, the MHRA, is an interesting model to learn from, wherein, each new GMP inspector is trained in a limited area of GMP at a given point in time, and once they have been assessed as competent in that field, only then do they begin training in the next area. Similarly, an accreditation system for inspectors should be set up in India, which certifies their competence and assesses further training needs, linking this to their promotions.

Most respondents were of the opinion that for the efficient functioning of state and central regulatory agencies, there is need for capacity building. In the last few years, there have been attempts at improving this by increasing the number of inspectors at CDCSO from 40 to 350. As indicated above, these inspectors should be given due training, which can be off site and provided through the web, but for the purpose of course designing and having a common training agenda, private colleges can brought in. Private pharmacy colleges and training institutes can be helpful in drafting the curriculum for IT-enabled training in specific courses in specialised areas.

Since drug regulation is sensitive and technical in nature, it is important to address concerns associated with contractual positions for core regulatory work. The nature of duties that encompasses drug regulation is sensitive and technical in nature (including inspections and prosecutions) and discharge of these duties requires precision and experience. In such scenario, contractual positions create a high risk of dissatisfaction and may lead to corruption.

Therefore, contractual positions for core regulatory personnel such as DIs should be discontinued. For the work that is of critical in nature, permanent positions would provide job satisfaction in terms of remuneration, security of tenure and also retaining the institutional memory. However, contractual employees may be hired for administrative and expert positions with adherence to clear conflict of interest rules.

Staff strength should reflect the current and projected scale of operations. Vacant positions must be filled with urgency. Recruitment can be independent as in the case of other regulatory agencies like the Telecom Regulatory Authority of India (TRAI) instead of through public service commissions to ensure speedy recruitment. Further, the DCGI should be headed by somebody with a pharmacy background.

In field research, we found that the DDO is the local district magistrate exercising inordinate control in terms of deputing DIs for non-drug related administrative functions. To address this, the SDC should be appointed the DDO for all personnel in the SDRA. This will tackle the problem of regulatory personnel being answerable to other officers. All these can be instituted through policy measures at the central and state government level. (See section 4.2.).

4.6 Financing

4.6.1 Current Scenario

The financial outlay for SDRAs has not increased as per their regulatory functions. Although the CDSCO outlay has increased significantly, the disbursement of funds is a problem because it is done through a centralised public procurement process. There has not been any regular revision of regulatory fees and the fee structure does not have any rational linkage with the cost of service provided. Fund mobilisation has been negatively affected by the lack of public visibility of the functions of the department and under-appreciation of the agency's activities by the parent ministry.

The financing of the regulatory authority is an important aspect from our research. In the states that we studied, the SDRA falls under the state department of health. The budget for the SDRA is decided by the Department of Health, which in turn is decided by the budget allocation by the state government.

In Himachal Pradesh, it was seen that despite the department generating a surplus, there is a general feeling that the user fees may be increased at regular intervals for various applications and the surplus can be utilised for infrastructure development. An experienced regulatory official in Himachal Pradesh said, *"Earlier, the application fee under Form 20 and 21 was only INR 80, which was revised to INR 3000 in 2001. Now the manufacturing licensing fee is INR 15000 for five years. With this amount itself, the government is generating crores in revenue. If it is used in the department's own development, it would be good"*. Another regulator was of the opinion that currently, the licensing application fee per formulation is only INR 300; manufacturers are willing to pay INR 1000 for the service if the system were

faster. However, the proposal to raise fees was rejected by an association member in Kerala who contended, "*Many shops are run by self-employed people and it is their livelihood. If it (fee) is increased, it will affect them*". In Bihar, the regulators say, "*We need to have an independent system of financing the drug regulatory authority. The Drug Regulatory Authority is neglected in the Department of Health."*

The international round of interviews gave us an idea of systems of financing that are very different from those in India. The USFDA has implemented a user fee system for USA. In FY2015, a total of 2.7 billion US dollars were allocated to program level funds of medical product safety regulation, of which the US Federal Government funded 1.3 billion US dollars (49 per cent of the total funding allocation of USFDA per cent) and user fees provided 1.4 billion US dollars (51 per cent).[32] The FDA first introduced user fees for only prescription drugs following the implementation of the Prescription Drugs User Fee Act (PDUFA) in 1992 that allowed for a higher fee to be charged for new drug applications (NDA) in exchange for an agreed percentage of applications being reviewed within designated timelines. This has recently been extended to generic drug applications as well through the Generic Drugs User Fee Amendments (GDUFA) implemented in 2012. The PDUFA resulted in USFDA employing additional reviewers for reviewing prescription drug applications. Initially, it only resulted in clearing the backlog of applications but was gradually used to hire additional reviewers, introducing IT in the system and improving timelines. The PDUFA has also attracted criticism on the ground that increasing reliance on user fees has created "rich and poor" departments within the agency, thereby undermining the overall growth of the agency.[33]

A similar user fee system exists in the EU. However, a greater proportion of the budget is allocated by the European Commission. The EU has had a long history of registration fees and this tradition has continued. A senior official at the European Medicines Agency said, "*The budgetary allocation has been rising over the years from 14 per cent in 2014, to 15 per cent in 2015. Any balance or profits at the end of the year are routed to the EMA through the European Commission.*"

While analysing the systems in the USA and the EU, we must keep in mind that the user fee system of raising revenue is complemented by a broad range of systems to ensure that regulatory functions are carried out efficiently and effectively. These are not simply a matter of money, but depend on the adoption of good business practices, such as process management, training programmes, and building effective IT infrastructure.

The financing of the Indonesian Regulatory Authority is somewhere between the USA and Indian systems. It has two sources of revenue. The first is the national budget and the second is the registration fee. At present, the contribution from the national budget is the major source of revenue. A similar system exists for China but with a considerably higher contribution from registration fee. The budget constraint has been repeatedly mentioned by

[32] Source: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432650.pdf.
[33] Srinivasan and Jesani (2012).

all types of stakeholders. One of the respondents mentioned that police are unable to carry out the inspection against counterfeits since they do not have enough money and resources; sometimes, companies help to undertake raids, if counterfeit drugs using that company's brand name are found.

The 12th Five-year Plan outlay for drug regulatory mechanism (both physical and human resources) proposed INR 1800 crore and INR 1200 crore for strengthening the CDSCO and SDRAs respectively. The outlay was modified INR 1058.68 crore. Further, a new centrally sponsored scheme under the National Health Mission with a 75:25 sharing pattern between the centre and the states has been proposed. As per the said proposed scheme, an allocation of INR 850 crore would be the centre's share and INR 229 crore the state's share. The approved expense heads include creation of new labs and upgradation of state labs and expansion of existing offices and manpower. This scheme is yet to be approved by the Cabinet Committee on Economic Affairs (CCEA) and hence, no financial assistance has been provided till date under the scheme. The same has been criticised by the Parliamentary Committee in its 82nd Report.

Underutilisation of funds has also attracted criticism from the Parliamentary Committee. The actual utilisation has been persistently and significantly less than the allotted funds. This has been attributed to inadequate budgetary planning (this has also negatively affected future fund deployment) (see Table 2 for details). However, our interaction with CDSCO officials gave us the other side of the picture. They stated that the process for procurement is extremely complicated and lengthy with innumerable technical queries being made by the Department of Expenditure for clearance purposes. It was pointed out that, unlike the CDSCO, the Indian Pharmacopoeia Commission (IPC) has financial autonomy; therefore, payments to external experts (who come for the various technical committee meetings for new drugs approvals and clinical trials) are made through the IPC rather than the CDSCO. The DCGI, being also the administrative head of the IPC, allowed the CDSCO to adopt this route. Nevertheless, this underlines the fundamental problems within the current system of procurement and fund disbursal and the need to explore alternative mechanisms to smoothen the process. This also calls for improvement in the financial performance of the drug regulator(s).

Table 6: Trend of funds allotted and expenditure incurred (in INR Crores)

Year	Budgetary Estimate	Revised Estimate	Actual Expenditure
2012-13	72.60	62.38	27.82
2013-14	251	110.36	58.61
2014-2015	100.00	67.00	39.33(up to 5/3/15)

Source: 82nd Report of the Department Related Parliamentary Committee on Health and Family Welfare.

4.6.2 Issue

At present, the SDRAs and CDSCO are financially reliant on government funding. Although budgets have increased, financial disbursement remains a problem, since regulatory agencies have to go through a complicated system of approvals for financial disbursement to acquire services and machinery. There is wide disparity of funding amongst SDRAs and it is usually staggered so that by the time of its disbursement, requirements have also increased.

4.6.3 Recommendations and Measures for Operationalisation

Financial autonomy in revenue generation and disbursement is critical in guaranteeing flexibility in planning and operationalisation of institutional plans. This will address delays arising due to complicated and lengthy approval systems for financial disbursement. The regulatory agencies should also focus on prioritizing the deployment of funds in critical areas, and aim for maintaining periodic expenditure targets in order to improve the financial performance.

Financial models that are partly funded by budgetary allocation and partly by a user fee (that sufficiently reflects the cost of providing a service) should be explored. However, user fee models need to be complemented with specific performance goals and measures of success (these measures can be subject to review and revision by some entity independent of authorities that receive the funds). Budgetary allocations rather than user fee should take care of the financial requirements of core regulatory functions. Revenue mobilisation through this process will also ensure the financial sustainability of the agency. Further, user fees can be specified in separate schedules to the DCA, which can be regularly updated through administrative orders (office memoranda).

Moreover, the regulators are of the view that the registration fee can be hiked at regular intervals. There should be some mechanism to use the surplus revenue mobilised for the development of the department. In general, the respondents from industry are ready to pay higher fees if regulators are able to provide better service faster. However, any increase in the fee should be on a sliding scale to ensure that their effect on small and medium enterprises is not excessive.

Misra R. et al (2003) have recommended a public finance model of a small cess on the manufacture and import of pharmaceuticals, the revenue generated through which can support the operational requirements of the agency and reduce the dependence on varying budgetary allocations. However, a potential concern with this could be that the additional taxes (on medicines) may have a negative implication for the patients. Therefore, a mix of sustainable financing alternatives could be explored for smooth functioning of drug regulatory agencies, with an overarching focus on public health in form of patients' wellbeing and strengthening health systems.

4.7 Transparency

4.7.1 Current Scenario

Transparent regulatory decision-making can improve industry compliance as well as ensure consistency in decision-making and help in establishing precedent. Predictability in decision making also increases the trust of the industry and other stakeholders in the regulatory system. However, transparency should be increased while still protecting sensitive information and the competitive interests of regulated firms. In some areas, like clinical trials, there has been marked improvement in public accessibility to information, decision-making and public accountability. The imperative for this was driven by adverse orders of the Supreme Court[34]and by critical Parliamentary reports.[35] However, in most other areas, the agencies have been slow to initiate and adopt reform. One of the primary reasons for this slow reaction is that regulatory authorities are not legally bound to do so. There have been some measures such as developing SOPs for all regulatory decisions and functions taken in the CDSCO to improve transparency. However, the SDRAs are not legally mandated to adopt these SOPs. Additionally, the processes of setting up of subject expert committees is not very transparent nor are efforts made to publicise the proceedings of these meetings.

The following observations were made from the field about the prevalence of corruption. In Himachal Pradesh, an experienced regulator mentioned that the decisions on approvals are often overturned by politicians. One unique aspect of Kerala is that unlike in other states, there is strong involvement of professional associations in the state. Even the regulators said the associations are strong and hence, subletting of licenses is not possible in the state. In the words of the president of an association, "*spurious drugs are fewer in the state due to the active involvement of the SDRA as well as the strong association activity in the state. People are also active and aware. Traders associations are involved in each of these issues. All drugs are sold and handled by licensed dealers only. Unlike other states, some understanding exists between the companies and the stockist. No sub-stockists exist in the market. It will not be allowed by the association. Members strictly follow the discipline and subletting of licences is impossible".*

FDCA in Gujarat has used IT to improve transparency resulting in enhanced public access to information. The FDCA has introduced a toll free number to lodge complaints along with an online complaints lodging system .The positive response we received from the industry may also result from a collusion of interest. This was brought out by the points made by officers from Kerala and Himachal Pradesh about Gujarat. An official from Kerala said, *"Even if we ask for action against a company registered in Gujarat, they will not take appropriate action. Sometimes, they suspend the company for one day to three days, which destroys the purpose of regulation. All other states suspend for at least one month…"*

Transparency should be increased in the organisational structure, procedure and personnel within the agency. Gujarat has improved transparency within the agency by using the XLN

[34] Supreme Court has been hearing a public interest litigation case (Swasthya Adhikar Manch and Another vs. UOI and Ors, Writ Petition Civil No. 33/2012) on regulation of clinical trials.

[35] The 59th report of the Parliamentary Standing Committee on Health and Family Welfare on the functioning of the CDSCO.

software so that it is possible to see which FDCA employees are logged in and what they are working on, including the commissioner. They also have a rating system within FDCA to rate inspectors based on the number of inspections.

All regulators agreed that special courts would help considerably in hastening prosecution. Kerala, Himachal Pradesh and Bihar did not have designated special courts for prosecution under the DCA.

The EMA is known for transparency in its processes. The EMA and the European Commission as well as member states maintain useful websites[36] with full details of applicable legislation, guidelines, forms, etc. Procedures for meetings with regulated entities differ, depending on the nature of the issues to be discussed and the authority with which the meetings are sought. Thus, companies seeking advice on clinical development issues may consult informally with national officials in one or more member states and seek formal scientific advice under a procedure established by the EMA. However, an industry person we interviewed told us, "*There are pipeline meetings with the industry once a year to discuss the drugs they are planning to introduce in the next year. There are also annual conferences that the EMA organises where industry is also invited. Thus, there is limited but useful interaction*." When national authorities carry out inspections (for compliance with requirements for GMP, GCP, pharmacovigilance, etc.), they routinely hold closed meetings with the affected company and share the draft inspection report for comment. EMA and national authorities also maintain procedures for disclosure of documents in response to requests under public information procedures. These ordinarily include provisions to protect against release of trade secrets and confidential commercial information and to comply with requirements under international agreements (e.g., TRIPS). Access to documents provided to all states is further evidence of transparency within the system.

Transparency in the USA and the EU has been strengthened through a series of initiatives taken over the years. For example, the 'Transparency Initiative'[37] which is overseen by a task force representing key leaders of the USFDA has released various proposals for *r*eporting of public comment and dissemination of information. These include draft proposals about expanding the disclosure of information by USFDA while maintaining the confidentiality for trade secrets and individually identifiable patient information. The US- FDA also released various draft proposals to improve transparency including availability of compliance and enforcement data and issued a report focused on improving the transparency and efficiency of the agency's guidance development processes. However, one industry member told us that the generics approval process is a "guessing game" where the agency does not clearly discuss the requirements for getting approval with the industry.

[36] These websites are in English as well as the national language of the member states.

[37] FDA Transparency Initiative: Improving Transparency to Regulated Industry, Source: http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/UCM239088.pdf.

In Indonesia, the existence of a Pramuka market[38] itself is an indication of the prevailing corruption in the country. One industry expert pointed out in this connection, *"In Pramuka wholesale market, there are no bills, no prescription, even doctors buy medicines from there, though they are not allowed; counter tracking will become difficult in the absence of bills…"* In order to prevent the smuggling of APIs, there is a counterfeit cell, (which includes NA-DFC and police. It is also known that the delay in processing applications can be avoided if companies bribe officials. Out of court settlements are common in the country for all types of cases, which again points to the depth of corruption. According to an industry expert, there is no transparency in the system. There is no consultation with the industry while making rules and regulations.

4.7.2 Issue

Regulatory decision-making in India has long functioned within closed doors. The information available on the agencies' websites are voluntary and, in most cases, incomplete and ad hoc.

4.7.3 Recommendations and Measures for Operationalisation

It is important to adopt the principle of transparency in decision-making and functioning at all levels as a clear statutory duty under the DCA. There is an urgent need to standardise operational protocols and provide key access points for public information, in addition to the Right to Information route, which is an ex-post avenue available. The digitisation project is expected to contribute to this process. The XLN software can also be used to increase transparency within the organisation, as in the case of Gujarat. Transparency can improve industry compliance and ensure consistency in decision-making by establishing precedent. Therefore, timelines for all regulatory decisions should be clearly specified. Further, all regulatory decisions should be adequately publicised including the rationale for decisions taken on grant of approvals for clinical trials, new drugs and manufacturing licenses. The regulator should encourage professional associations so that they can partner in checking corruption such as subletting of licences.

4.8 Public Outreach and International Co-operation

4.8.1 Current Scenario

Currently, there is limited interaction between the general public and regulatory agencies. Of course, regulatees themselves interact with departmental officers. However, publicity of the aims and functions of the agencies is not undertaken. There is no dedicated website for the SDRAs of Himachal Pradesh and Bihar, reflecting the poor access to information for the general public. Such websites, however, do exist in Kerala and Gujarat. The absence of standardised protocols to ensure transparency has led to varied levels of transparency across

[38] Pramuka is a large retail market in east Jakarta. It has over 300 drug stores (both registered and unregistered), selling prescription and over the counter drugs, at about 30% less than the market price. These stores are usually not manned by pharmacists and there have been several reports of counterfeit drugs being sold here.

states. Information on the websites of the agencies is made partially accessible on an ad hoc basis, further reducing the space for public interaction. While the CDSCO does invite comments from the public with regard to their draft policy recommendations and legal reform proposals, most SDRAs do not conduct a similar exercise. The public is largely unaware of the critical role played by these agencies in ensuring public health and safety. Creating a positive public image of the regulatory agency is important in garnering public support.

Another critical aspect is to push for the participation of the Indian regulatory agencies in international regulatory networks. Participation in these networks is important for identifying synergies between national regulators and this will help leverage it for more effective regulatory decision-making through adoption of best practices at the national level. The 59th Committee Report has also underlined how participation in international regulatory networks could enhance information gathering and sharing amongst regulators contributing to better regulatory decision-making nationally.

4.8.2 Issue

The functioning of regulatory agencies has been below the public radar. This has been a major factor in undermining their functioning.

4.8.3 Recommendations and Measures for Operationalisation

Both the CDSCO and SDRAs should proactively develop a plan for public engagement. This can be done at the level of the agency. Publicity should be given to regulatory decisions including the scale of inspections conducted, manufacturing operations sealed for non-compliance and penalties imposed and licences granted and rejected. There should be standardised protocols to ensure transparency and interface with the public needs to be worked on in the form of working websites for each SDRA where information is made available to the public. The CDSCO website could provide web links to the SDRAs. It is an important function of the central and state government authorities to foster educational programmes in the form advocacy campaigns for industry and to introduce measures that will encourage voluntary compliance within industry. Periodic advocacy publications can also facilitate a connection with the public and a formal forum can be introduced for public comments. Public information should be placed in context and issued in a manner so that it does not provoke irrational reactions by the media or the public.

India should take steps to actively participate in the International Coalition of Medicines Regulatory Authorities (ICMRA), and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Developing countries like Brazil, China, Mexico, Nigeria and South Africa have joined as members in the ICMRA. India, being one of the largest manufacturer and exporter of generic medicines, should participate in these networks. India should continue to explore future opportunities to participate as an observer or member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), a forum which brings together regulatory authorities and pharmaceutical industry to discuss scientific and

technical aspects of drug registration. International co-operation will help regulatory agencies (both the CDSCO and SDRAs) to adopt international best practices and find ways to further streamline procedures in the Indian drug regulatory system. This issue was also discussed by the Parliamentary Committee in its 59th Report, which emphasised the need to participate in international networks so as to benefit from information on regulatory actions undertaken internationally and by national authorities.

Box 2: Key observations from the RTI applications

As per the RTI (partial) responses received from the Drugs Control offices of West Bengal (No. DCWB/2015/RTI/195), Tamil Nadu (Ref. No. 12504/E5/2015), Kerala (No.P – 6502/2015/DC), Gujarat (No.RTI/ID-67/2015/517) and Orissa (No. 6516/DC-RTI-18/2015):

- No separate funds have been allocated in the budget for training in West Bengal, Tamil Nadu, and Kerala and no training programme, such as refresher courses and orientation camps, were held in West Bengal and Tamil Nadu. In Kerala, training sessions are conducted by the Institute of Management in Government.
- Tamil Nadu and West Bengal reported no contractual arrangements for regulatory functions.
- Only Orissa and Tamil Nadu have submitted an Institutional Development Plan (IDP) for disbursement of budgetary allocation as per the 12th Five-year Plan. Interestingly, Orissa has submitted a proposal indicating a requirement of 90 drug inspectors (as per Mashelkar Committee Report formula) whereas the current sanctioned strength is only 44.
- In West Bengal, out of 50 sanctioned positions of senior drug inspectors' positions, 56 per cent are vacant. And of the 90 sanctioned positions of drug inspectors, 66 per cent are vacant. A similar state of affairs was observed in Tamil Nadu with more 50 per cent vacant positions for drug inspectors.
- XLN Software system for processing of sales licences is fully functional in Gujarat (with effect from January 1, 2007) and Kerala (with effect from October 12, 2012). However, in West Bengal and Tamil Nadu, it is yet to be introduced.
- West Bengal reported that they did not have district-wise allotment of vehicles for inspections.
- West Bengal's Directorate of Drugs control reported that no database is maintained for the number of inspections conducted and application received and reviewed (for manufacturing and sales licences); and no annual report is maintained.

5. Conclusions

The Indian regulatory system for drugs can be described as a classic command and control regime, wherein technical standards are set which the regulatee is expected to follow and the regulator then undertakes inspections to supervise compliance. Most other drug regulatory systems also follow the same pattern. There are certain aspects of a command and control system which aligns itself with the objectives of drug regulation. Established standards ensure clarity of what is expected from regulates and also make it relatively easier to identify breach of such standards. However, there are certain prerequisites to ensure success of such a regulatory structure. First, standard setting is expertise driven and requires considerable investment in accessing technical knowledge. Second, adequacy of staff and infrastructure is important to ensure quality and regularity of inspections. Third, as put forth by Kagan (1994), command and control norms are easier to enforce in the case of big and easily identifiable regulatees rather than smaller firms.

The Indian regulatory system has been suffering from critical shortfalls in regulatory resources (personnel and other infrastructure like drug laboratories), thus undermining its capacity to ensure effective enforcement. The division of regulatory responsibilities between the centre and states, without any single agency being made responsible for the holistic enforcement of law has led to fragmentation and undermined effectiveness. Given the nature of the regulatory space (characterised by high information asymmetries), consumers and patients are not in a position to ensure civil society supervision of the regulatory system.

While India has recently signalled its intentions[39] to become a global leader in drug discovery, India can currently be characterized as a country that focuses on the manufacture and export of generic drugs. Therefore, it makes sense to prioritise and invest regulatory resources on aspects such as granting manufacturing licences, inspections, sampling and testing (overall drug quality). Further, identification of priority areas should also guide the recruitment of regulatory personnel. Doctors required for reviewing new drug applications are relatively less important than pharmacists capable of drug quality testing.

Socio-culturally whereas the role of doctors are widely acknowledged and celebrated in public health, the role of pharmacists especially in regulatory roles lack public visibility. This in turn translates into lack of public awareness of functions of CDSCO and SDRAs. As mentioned earlier, transparency in decision-making and publicising the functions of drug regulators are necessary to foster greater public visibility, awareness and in imbibing a

[39]India has signalled its intention to become a more significant player in the innovative medicines sector, including by emphasizing life sciences as one of the critical sectors in the "Make in India" vision.

culture of vigilance. This is critical because regulatory resources, especially in developing countries like India, will be scarce and a classic command and control system will become effective only when it is supported by active public supervision of the regulator.

Finally, we strongly believe that many of the problems that ail the current regulatory system stems from the lack of technical and financial autonomy for the regulators (CDSCO and SDRAs). In this regard, the institutional structure of the FSSAI serves as a good example of a statutorily independent regulator. Lack of uniformity is expected to be addressed by pushing for greater centralisation of powers in the CDSCO. However, this is an inadequate solution; our findings suggest that an alternative and more suitable model would be that of the CHMP within the European Medicines Agency. An equivalent structure exists in the DCC, but this has faced institutional decay. The DCC should be completely overhauled and provided with a clear statutory mandate in four critical areas –manufacturing licences, inspection protocols, supervision of clinical trials and post-marketing surveillance. The DCC should have the mandatory participation of SDRAs and the DCGI. Additionally it should function as an appellate authority in case of disputes over interpretation of legal provisions and enforcement. This will allow the SDRAs to gain ownership of the regulatory system rather than functioning as disjointed parts of a single system. This also requires the state governments to make a *de minimus* commitment for financial support to upgrade the role of the SDRAs to that of regulatory partners of the CDSCO.

The DCA, 1940, as it currently stands, is a skeletal legislation supported by a complex and increasingly unwieldy body of subsidiary legislations (notifications). A statutory overhaul is also a necessary corollary to this. Many of the recommendations made in this paper can only be effective if there is a clear statutory commitment. The statute itself should include all the important aspects in terms of institutional structure, substantive responsibilities of licensees and penalties. Moreover, guidelines should be used as an instrument for ensuring harmonisation.

We would also like to underline the various aspects in which this study breaks new ground and contributes to the policy and academic literature available on this subject. First, this is the first in-depth qualitative study conducted on the functioning of SDRAs (in Himachal Pradesh, Gujarat, Bihar and Kerala) in India. Second, comparative perspectives both from regulatory leaders like USA and UK and other developing countries like China and Indonesia also enriched our understanding of common challenges and search for credible solutions. Third, in around 100 stakeholders (comprising both national and international stakeholders), including regulators, manufacturers, industry associations, civil society organizations and academicians were interviewed for this study, thus providing for a diversity of opinions. Fourth, targeted use of RTI applications have also contributed to collating a detailed set of responses from SDRAs, and which has helped us deepen our understanding of their functioning. This is also to underline that the analysis presented in this study is not only based on perception, but is based on hard facts. For all these reasons, we hope that this study is widely read by all stakeholders as it holds a clear mirror to the present challenges confronting the drug

regulatory system. We hope that this study will help contribute to the current discussions of regulatory reform of the Indian drug regulatory system.

THEME WISE LIST OF POLICY RECOMMENDATIONS

1. Uniformity: ensuring harmonised application of drug regulatory standards throughout the country

We propose two recommendations either of which may be considered for implementation. The first is to make the CDSCO the controlling and reporting authority for SDRAs. This will facilitate a clear hierarchical structure and reduce the risk of disjointed functioning. Functions may continue to be distributed between the national and state levels but the CDSCO would be the managing authority and therefore, responsible for ensuring uniformity. The second is to empower and strengthen the SDRAs to become regulatory partners of the CDSCO, by expanding and strengthening the role of the DCC in key regulatory areas such as developing guidance documents to formalise SOPs and legal interpretations of key legal provisions.

2. Regulatory Agency Autonomy: a financially independent and technically autonomous statutory regulatory agency(politically accountable to Parliament)

There is need to establish a financially independent and technically autonomous statutory regulatory agency (politically accountable to the Parliament) to replace the CDSCO and SDRA.[40]This will allow greater flexibility and increase the operational effectiveness of both these regulatory agencies. The fees collected by the regulator can be assigned directly to itself instead of being routed through the Department of Health. An amendment in the DCA can be brought in to achieve this. However, given that 'health' is a subject matter in the state list, the states have to be taken into confidence before moving such an amendment.

3. Inspections: need for efficient utilisation of resources for inspections

First, it is necessary to rationalise the workforce in terms of the number of inspectors in proportion to the scale of the industry in that State. Second, risk based inspections should be adopted as a statutory principle for organising inspection protocols, i.e., initiate risk-based inspections for all regulatory agencies to concentrate regulatory resources at the point where the risk of non-compliance is the highest (the risk should be a standardised function of the compliance history of the unit, the risk associated with the product and other such variables). Third, intelligence cells need to be set up in the SDRAs to provide information to the inspectorate for conducting raids. Lastly, SOPs need to be adopted with reference to maintaining a database of manufacturing and sales units and to introduce a tracking mechanism archiving their compliance history. To facilitate speedy and regular inspections, dedicated transport for SDRAs should be made available reflecting current and projected scale of operations.

[40] In this regard, the FSSAI can be taken as a reference point. See Annexure 5 for more details on FSSAI.

4. ***Physical Infrastructure: expansion of infrastructure for a more efficient regulatory process***

A survey of all state government laboratories needs to be conducted to identify critical gaps, and a *de minimus* rule should be adopted (and statutorily recognised), which specifies minimum laboratory facilities (instrumentation and manpower) for each state. Thereafter, financial support can be made available by way of a one-time grant from the Union Budget, on the condition that state governments will give matching grants to maintain facilities (a five-year commitment). Additionally, there must be movement towards NABL accreditation of all central and state laboratories. Measures like accreditation of private laboratories and those in pharmaceutical colleges may be included as part of the programme, with some sampling being shifted to be tested in such facilities. A step towards digitisation by replicating XLN could facilitate a complete real-time, common database (including manufacturing/sales activity, inspection records, applications and their status) for all SDRAs. This would facilitate a reduction in manual efforts to maintain records, and help improve accuracy. SDRAs should have adequately trained personnel to operate the database and all licensing activities should be through the database. Such a real-time database can also allow public access to specific information including real-time tracking of applications and responses to Right to Information applications.

5. ***Human Resource and Training: to facilitate time bound, effective and efficient regulatory duties***

There are two ways to address the requirement of human resources and skilled personnel. First, staff strength should be assessed based on current and projected scales of operations. Second, capacity building initiative should be undertaken by organising periodic training programmes. Recruitment can be independent as is the case of other regulatory agencies like the Telecom Regulatory Authority of India (TRAI) instead through public service commissions to ensure speedy recruitment. Since drug regulation is sensitive and technical in nature, it is important to address concerns associated with contractual positions for core regulatory work. For this reason, contractual positions for core regulatory personnel such as drug inspectors should be discontinued. Another critical area is enhancement of existing capacity through periodic training programmes for officials of the CDSCO and SDRAs. Training should be a priority area and annual training plans should be developed based on current and projected requirements. To make it effective and uniform across states, the CDSCO should formulate specific modules facilitating specialised training to all officials. Training programmes if linked to promotion could incentivise participation and go a long way in enhancing individual performance.

6. ***Financing: to facilitate greater flexibility in planning and operationalisation of institutional plans***

Financial autonomy in revenue generation and disbursement will address delays arising from complicated and lengthy approval systems for financial disbursement. Financial models that are partly funded by budgetary allocations and partly by user fees (that sufficiently reflects

the cost of providing service) should be explored. For efficient revenue mobilisation, it is important to deploy the funds strategically, i.e., budgetary allocations, rather than the proceeds of user fee, should be used for the financial requirements of core regulatory functions. Additionally, user fee models need to be complemented with adoption of good business practices, such as process management, training programmes, and building effective IT infrastructure. Therefore, as an additional financing system, user fee based model can be explored through an amendment of the DCA. Further, user fees can be specified in separate schedules to the DCA, which can be regularly updated through administrative orders (office memoranda). Moreover, regulators are of the view that the registration fee can be hiked at regular intervals. There should be some mechanism to use the surplus revenue mobilised for the development of the department. In general, respondents from industry were ready to pay higher fees if regulators were able to provide better service faster. However, any increases in fee should be on a sliding scale to ensure that fee hikes do not impose a prohibitive burden on small and medium enterprises. Therefore, a mix of sustainable financing alternatives could be explored for smooth functioning of drug regulatory agencies, with an overarching focus on public health in form of patients' wellbeing and strengthening health systems.

7. Transparency: for improving compliance and building trust among stakeholders

It is important to adopt the principle of transparency in decision-making and functioning at all levels as a clear statutory duty under the DCA. There is urgent need to standardise operational protocols and provide key access points for public information. This is apart from the Right to Information route, which is a post facto avenue available. The digitisation project is expected to contribute to this process. The XLN software can be used to increase transparency within the organisation, as in the case of Gujarat. Timelines for all regulatory decisions should be clearly specified. All regulatory decisions should be adequately publicised and the rationale behind the decision should be given clearly including the formation of Expert Committees and the minutes of their meetings (without revealing sensitive information about the product). The regulator should encourage professional associations so that they are partners in checking corruption such as subletting of licences.

8. Public Outreach and International Co-operation: a way to strengthen regulation

Both the CDSCO and SDRAs should proactively develop a plan for public engagement at the level of the agency. There should be standardised protocols for ensuring transparency and interface with the public needs to be worked on in the form of working websites for each SDRA where information is available to the public. Periodic notifications of regulatory decisions including the scale of inspections conducted, manufacturing operations sealed for non-compliance, penalties imposed and licences granted and rejected, should be made available in the websites. India should take steps to actively participate in internationals forums, viz., the International Coalition of Medicines Regulatory Authorities (ICMRA), the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Developing countries like Brazil, China, Mexico, Nigeria and South Africa have joined as members in the ICMRA. Also, India should continue to explore future opportunities to participate as an observer or member of the International Conference on

Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), a forum which brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. India, being one of the largest manufacturer and exporter of generic medicines, should participate in these networks. International co-operation will help regulatory agencies (both the CDSCO and SDRAs) to adopt international best practices and find ways to further streamline procedures in the Indian drug regulatory system. This issue was also discussed by the Parliamentary Committee in its 59th Report, which emphasised the need to participate in international networks so as to benefit from information on regulatory actions undertaken internationally and by national authorities.

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Annexure 1

SELECTION OF STATES

Table No. 1 Ranking of States based on Various Indicators

Sl. No	States	Manufacturing		Population	Samples Tested (Ranks)					Prosecutions (Ranks)				
		Units (No.)	Rank	Rank	2009-10	2010-11	2011-12	2012-13	2013-14	2009-10	2010-11	2011-12	2012-13	2013-14
1	Andhra Pradesh	1071	1	5	2	3	3	4	4	7	9		4	
2	Maharashtra	888	2	2	1	1	1	1	5	4	7	4		1
3	Gujarat	874	3	10	15	2	8	2	1		4	5	7	
4	Himachal Pradesh	537	4	15	13	14	12	12	15			10	9	
5	Uttar Pradesh	499	5	1	10	13	13	14	10	1	2	1	1	
6	Tamil Nadu	446	6	7	4	5	4	7	3	6	5	7	3	
7	Haryana	317	7	14	9	10	10	8	9	3	6	8	8	4
8	Rajasthan	299	8	8	11	11	11	11	11		6	3	2	
9	Madhya Pradesh	294	9	6	14	12	9	10	12					
10	Karnataka	231	10	9	5	4	2	3	2		7	8	5	3
11	Bihar	209	11	3	6	9	14	NA	13	2	1	2		2
12	Punjab	170	12	13	7	8	6	9	8			9		
13	West Bengal	165	13	4	12	15	15	13	14	4		6	6	5
14	Kerala	87	14	12	3	6	5	5	6		3			
15	Orissa	69	15	11	8	7	7	6	7		8			

Source: Authors' compilation from Rajya Sabha and Lok Sabha Question Answer Sections (Sessions 233 and 234).

As mentioned in the beginning, the aim of our analysis is to understand interstate variations in the enforcement of drug regulations and to draw lessons while forming the national policy. For this, we have selected four states for in-depth analysis based on the following criteria.

(i) a state with high level of manufacturing activity/facilities and good performance,

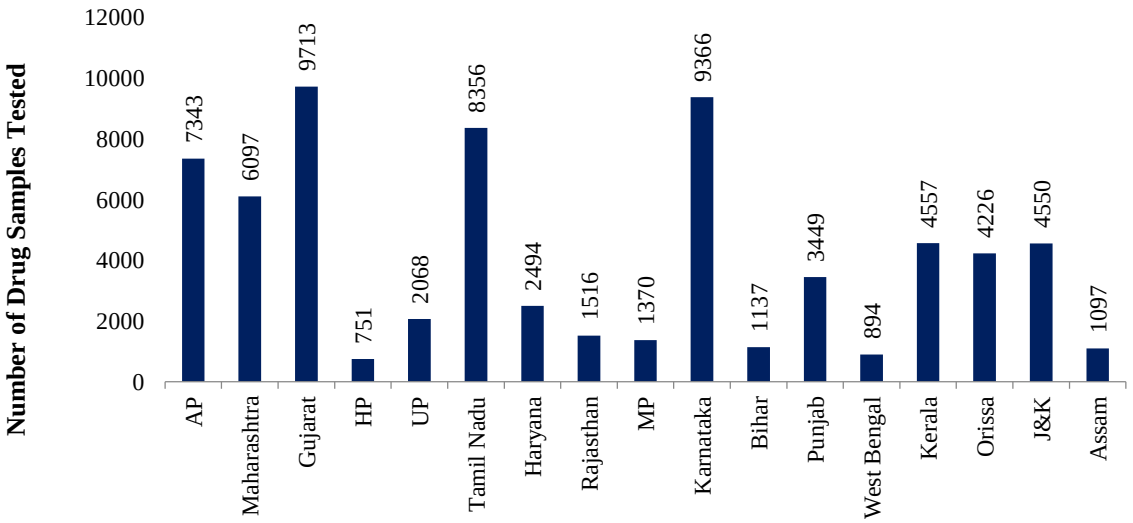
(ii) a state with high level of manufacturing activity/facilities and weak performance,

(iii) a state with low level of manufacturing activity/facilities and good performance,

(iv) a state with low level of manufacturing activity/facilities and weak performance.

While we make data the basis for our selection, we make sure that we consider anecdotal evidence that may not be reflected in the figures. Manufacturing facility is measured based on the number of manufacturing units, taken from the Directory of Pharmaceutical Manufacturing Units in India brought out by the Department of Pharmaceuticals.[41] The presence of a larger number of manufacturing units indirectly indicates the need for more regulatory activity in the respective state. A large manufacturing facility is defined as states with more than 500 manufacturing units and a small manufacturing facility is defined as one having less than 100 manufacturing units. Further, states are ranked based on the number of units. 'Performance' is restricted to regulatory enforcement. Regulatory enforcement has been captured through available indicators such as the number of drug samples tested (see figure below) and the prosecutions[42] undertaken during the last five years, i.e., 2009-10 to 2013-14.[43] These indicators are ranked accordingly.

Figure 3: Drug Samples Tested across States (2013-14)



While evaluating performance, we also look at anecdotal evidence on performance such as e-governance and the reputation of the regulator. Regarding drug samples tested, ranks from 1 to 5 are considered as having the best performance, 6 to 10 as average and the rest as weak performance. Similarly, for prosecutions, ranks 1 to 5 are taken as good performance and the rest are taken as weak performance.[44] These indicators are a preliminary indications about the extent to which rule are enforced in a state. The data has been compiled from responses given

[41] We have used CDSO (2011). The data is also available in the Annual Report of the Department of Pharmaceuticals (2010-11), available at http://pharmaceuticals.gov.in/AnnualReport1011/ch_9.pdf, accessed on 10th October, 2014. However, the number of units in these two reports differs substantially. We have used CDSCO figures since the figures in the Annual Report of the Department of Pharmaceuticals seem to be more inflated.

[42] The number of prosecutions may be lower due to the better performance of the firms. Hence, we have taken it along with the number of samples tested.

[43] Data for 2012-13 is available only for four months, i.e., up to July 2013. Hence, it is not taken for the analysis.

[44] Data is not available for all states for prosecution.

to questions posed by parliamentarians in the Rajya Sabha and Lok Sabha (Sessions 233 and 234).

We have restricted the analysis to the top 15 states in terms of population. Population size, which is captured from Census of India (2011) figures, indirectly indicates the demand for medicines. Further we have excluded newly formed states such as Jharkhand, Uttarakhand and Chhattisgarh.

It has been observed from the data that the large manufacturing states are Andhra Pradesh, Maharashtra, Gujarat, and Himachal Pradesh (see Table for details). Out of these, Gujarat is selected in the first category, i.e., the state with a large manufacturing facility as well as good performance. In addition to this, it ranks high in drug samples tested in most years. The state also has the second largest number of manufacturing units in India. In terms of prosecution, it shows good performance in three out of four years for which information is available. In this category, the performance of Andhra Pradesh, which accounts for the largest number of firms in India, is also commendable. In four out of five years, it is ranked in the top five in terms of the drug samples tested. The fact that no other state has incorporated e-governance to the extent that Gujarat has makes it an all the more interesting state to study. Hence, we have selected Gujarat over Andhra Pradesh, although the number of manufacturing units are less than that in Andhra Pradesh.

In the second category, we look for the state with a large manufacturing facility and weak performance. Himachal Pradesh, despite being the fourth largest state in terms of manufacturing size, ranked in weak performance in all the years for which the data is available for both the indicators. Himachal Pradesh is the fourth largest manufacturer in India and is ranked between 11 and 15 consistently across the years in terms of testing of drug samples. Prosecution based rank is available for two years only and the state ranked 10 for both years indicating poor performance. However, in terms of qualitative information available, the state is considered to be doing well. Hence, we have selected Himachal Pradesh in this category.

Regarding the states with a small manufacturing facility, two states, i.e., Bihar and Kerala had a lower number of manufacturing units compared to other states. Kerala performed well in four out of the five years in terms of the drugs samples tested. It also performed well in terms of prosecution for the one year for which data was available. Hence, we have selected Kerala in the third category, a state with a small manufacturing facility and good performance. Regarding the fourth state, i.e., the state with a small manufacturing facility and weak performance, we have selected Bihar, which ranked poorly in terms of the samples tested. Anecdotal evidence also suggests that Bihar performs poorly in terms of enforcement.

Annexure 2

SELECTION OF INTERNATIONAL JURISDICTIONS

This section elaborates on the choice of international jurisdictions for the purpose of international benchmarking. It is crucial to choose jurisdictions that have an active drug regulatory body and either exhibit regulatory leadership or are similar to India so we can learn from their experience. The primary criterion for selecting jurisdictions is pharmaceutical sales (US $ billion) in the jurisdictions. The pharmaceutical sales in a country reflect the size of the market in the industry. Large pharmaceutical sales in most cases represent an active drug regulatory authority that faces interesting challenges. That India has high pharmaceutical sales means that the challenges faced by the regulatory authorities are similar and their experience will be applicable to India. In addition to pharmaceutical sales, we would've liked to use pharmaceutical production in these countries. However, recent standardised data on production is extremely difficult to find for developing countries. The number of employees in the pharmaceutical sector is a good proxy for production activity (a larger number of employees implies higher production assuming the same technology for all countries). As a result, we use the number of employees hired in this sector as a secondary criterion for choosing countries. Table 1 and Table 2 provide figures for pharmaceutical sales and number of employees for the top 30 countries in the world.

On the basis of Table1, both USA and the EU (Germany, France, Italy and the UK are all in the top ten) are the top two jurisdictions that have the highest pharmaceutical sales and employees in this sector amongst developed countries. Both the USA and the EU have also shown regulatory leadership and have an interesting regulatory authority administrative structure. The fact that they have inspired regulatory bodies in China and other developing countries is testimony to their leadership amongst regulatory bodies.

Amongst developing countries, China and Indonesia both have a federal regulatory structure similar to that in India. China remains India's biggest competitor and it seems worthwhile to learn from China's experiences.

Thus, for the purpose of this study our choice of international jurisdictions is the USA, the EU, Indonesia and China.

Table 1: Pharmaceutical Sales for 2011[45]

Country	Pharmaceutical Sales, US$BN	Rank
USA	337.1	1
EU (Top 5 countries)	332.682	2
Japan	127.377	3
China	66.863	4
Germany	55.148	5
France	48.664	6
United Kingdom	38.334	7
Italy	34.63	8
Brazil	28.718	9
Spain	28.009	10
Canada	26.057	11
Russia	20.653	12
India	15.643	13
South Korea	14.796	14
Australia	13.268	15
Mexico	12.978	16
Poland	11.257	17
Turkey	10.242	18
Netherlands	9.38	19
Greece	9.347	20
Belgium	8.507	21
Venezuela	8.449	22
Switzerland	7.629	23
Argentina	7.582	24
Sweden	6.597	25
Austria	6.251	26
Portugal	6.211	27
Indonesia	6.044	28
Taiwan	4.594	29
Czech	4.563	30

[45]Source: Pharmaceutical Sales(2011): Business Monitor International

Table 2: No. of Employees in the Pharmaceutical Sector for the Top 30 Countries[46]

Country	Number of Employees	Rank	Year
China	1,604,800	1	2008
EU (Top5 countries)	903,775	2	2009
India	378,413	3	2008
USA	245,900	4	
Germany	115,141	5	2009
Japan	85,576	6	2007
France	78,745	7	2009
Russia	70,923	8	2009
Italy	65,117	9	2009
Indonesia	58,875	10	2009
UK	39,910	11	2009
Spain	38,983	12	2009
Egypt	37,494	13	2006
Pakistan	36,336	14	2006
Canada	28,338	15	2008
Thailand	27,080	16	2006
Korea	26035	17	2008
Poland	24,835	18	2009
Taiwan	21,363	19	2006
Iran	20,207	20	2008
Ukraine	19,295	21	2009
Belgium	18,614	22	2009
Denmark	16,949	23	2008
Sweden	16,883	24	2009
Ireland	16,570	25	2009
Netherlands	16,382	26	2008
Colombia	16,344	27	2005
Philippines	15,436	28	2006
Sri Lanka	11,654	29	2006
Austria	10,683	30	2009

[46] Source: United Nations Industrial Development Organization. ISIC Rev 3 – 2423, Pharmaceuticals, medicinal chemicals, etc.

Annexure 3

Questions included in RTI Application

- **Manufacturing and Sales Licences:**

1) What is the number of sales and manufacturing units for drugs in the state from 2008 - 2014?
2) What is the number of applications received, reviewed and granted annually for manufacturing and sales licences from 2008- 2014?
3) How many drug samples were annually collected and tested by the office of SDC and how many failed the quality test from 2008- 2014?
4) Has the XLN system (for processing of manufacturing and sales licences) been introduced and if so provide details thereof (date of introduction, whether fully integrated, etc.?
5) What is the number of inspections conducted (sales and manufacturing units) from 2008 -2014?
6) How many prosecutions have been launched under Drugs and Cosmetics Act (1940) and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, from 2008-2014?
7) What is the number of joint inspections with the CDSCO every year between 2008 and 2014?
8) Have you submitted an Institutional Developmental Plan (IDP) to the CDSCO (for disbursement of budgetary allocation as per the 12^{th} five-year plan) and if so, details thereof.
9) A copy of the annual report of the SDC for the year 2013- 2014.

- **Administrative Structure and Infrastructure of SDC:**

10) What is the organisational structure of the SDC and what is the number of posts (current number, number of sanctioned posts and number of vacant posts) for each element in the structure (e.g. drug inspectors, assistant drug controllers, administrative staff, etc)
11) What is the district wise allocation of vehicles to the SDC for conducting inspections from 2008- 2014?
12) What is the pay band for the above posts (monthly remuneration) for the years 2008 - 2013?
13) What is the breakdown of posts between permanent and contractual posts in the SDC every year from 2008 – 2014?

14) What is the plan and non-plan budget allocation and actual expenditure from 2008-2014 for the SDC? What is the breakdown of the above budget from 2008-2014 in terms of budget allocation to drug laboratories, salaries, etc.?

- **Drug Laboratories:**

15) How many drug laboratories have been functioning in the state (annually for2008 – 2014) and what was the number of drug laboratories planned to be built from 2008-2014?

16) How many laboratory analyst posts (current number, sanctioned and vacant posts) were there each year from 2008- 2014?

- **Training**

17) How many man days of training were provided by the SDC and what were the funds allocated for training from the total budget every year for the period 2008-2014?

18) Details of the training programmes (refresher courses, orientation, etc.) that were attended by SDC staff from the years between 2008 and 2014?

Annexure 4

FSSAI: A Case Study

The Food Safety and Standards Authority of India (FSSAI) – A case study

A successful example of an independent statutory authority is the central food safety regulator, FSSAI. FSSAI was established[47] under the Food Safety and Standards Act, 2006 ("the **FSS Act**") with a focus on laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The FSS Act has been implemented by all state/UT governments with effect from August 5, 2011, and clearly lays down the duties and functions of the FSSAI., The key features of the FSS Act are as under:

Uniformity and autonomy of regulatory body

- The FSS Act consolidates the various acts and orders that have handled food related issues in various ministries and departments to establish a *single reference point* for all matters relating to food safety and standards.
- The FSS Act mandates the central government to issue such directions to state governments to carry out all or any of the provisions of the Act and makes it mandatory for state government to comply with such directions.
- The FSSAI and the state food safety authorities have to monitor and verify that relevant legal requirements are fulfilled by food business operators at all stages of the food business.
- For effective implementation of the FSS Act, there is a mechanism of uniform licensing/registration[48] regime across the centre and states. The issue of licences by a central[49] licensing authority has started from four regional offices and three sub-regional offices.

Administration and composition

- The Ministry of Health & Family Welfare, Government of India is the administrative ministry for the implementation of FSSAI.
- The Chairperson, appointed by Government of India, is of the rank of Secretary to

[47] FSS Act consolidates various acts & orders that have previously handled food related issues in various Ministries and Departments.

[48] Clear guidelines for eligibility of state and central licence are available. Additionally, the food operators are required to take a Central License for their Head office, if they have operations in more than one state.

[49] As per FSSAI Office Order dated 16 February 2015 with regard to Central licensing, Haryana state has moved under Delhi Central Licensing Authority jurisdiction, and Jammu and Kashmir state has moved under Chandigarh Central Licensing Authority jurisdiction. Retrieved from: https://foodlicensing.fssai.gov.in/PDF/Notification_FSSAI_DOs.pdf.

Government of India.

- Ex officio members representing various ministries, departments, or organisations (total number is 22).
- The Chief Executive Officer is the legal representative of the FSSAI.
- State food authorities (Commissioner of Food Safety of the States) are responsible for enforcement of the FSS Act in states.
- Commissioner of Food Safety appoints the designated officer, food safety officer, and food analyst.
- The designated officer is in-charge of food safety administration of the area and for the grant of licence for commencement of food business. As per the FSS Act, there shall be a designated officer for each district. The food safety officer *inter-alia* is responsible for inspection of food business and drawing samples. The food analyst analyses samples received from a food safety officer or any other person.
- States/UTs have appointed food safety commissioners, notified designated officers, food analysts, adjudicating officers and food safety officers for respective areas within the state.

Central Advisory Committee

- As per Section 11 of the FSS Act, the FSSAI shall establish a committee to be known as the Central Advisory Committee for the purpose of ensuring close co-operation between the FSSAI and enforcement agencies and organisations operating in the field of food.
- Further, the key role of the Central Advisory Committee is to advise the FSSAI on various matters including drawing up of a proposal for the work programme, the prioritisation of work, identifying potential risks, pooling of knowledge, etc.

Scientific Panel and Scientific Committee

- FSSAI, under the provision of the FSS Act, has constituted a scientific committee and scientific panels consisting of independent scientific experts for providing scientific opinion on various issues.

Establishment of Food Safety Tribunal

- The central government or a state government may, by notification, establish one or more tribunals to be known as the Food Safety Appellate Tribunal to hear appeals relating to the decisions of the adjudicating officer.

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