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Policy Brief # 1

Administrative Structure & Functions of Drug Regulatory Authorities in India

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TABLE OF CONTENTS

Executive Summary	1
Need for Effective Regulation	2
Theme 1: Uniformity	4
Theme 2: Regulatory Agency Autonomy	6
Theme 3: Inspections	8
Theme 4: Physical Infrastructure	10
Theme 5: Human Resources and Training	13
Theme 6: Financing	16
Theme 7: Transparency	19
Theme 8: Public Outreach and International Cooperation	22
Concluding Remarks	24
References	26
Snapshot of Policy Recommendations	28

EXECUTIVE SUMMARY

In an increasingly globalised world, the impact of public policy is far reaching. In this context, effective drug¹ regulation is an important concern for promoting and protecting public health, both domestically and across the world. The extent of quality and efficacy of the medicines also contributes to strengthening of faith in health systems, health professionals, pharmaceutical manufacturers and distributors of the country (WHO 2003). Given the asymmetry of information between the manufacturers, the doctors who prescribe medicines and the patients who eventually consume them, the need for regulatory supervision is widely acknowledged amongst all stakeholders in the realm of public health.

In light of the foregoing, this document forms a part of the study on 'Administrative Structure and Functions of Drug Regulatory Authorities in India', which is the first of its kind on the legal architecture, administrative structure and functioning of drug regulatory authorities in India, focusing 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 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.

At present, there is no single entity that is ultimately responsible for ensuring effectiveness of the Indian drug regulatory system as a whole. This is also reflected in the lack of uniformity in legal interpretations of DCA among states and highlights the urgent need for unity of command for effective coordination between the regulatory agencies. We have suggested two policy alternatives to facilitate effective coordination between the regulatory agencies. First is to make the CDSCO the supervisory and reporting authority for SDRAs. Second could be to strengthen the institutional mechanisms already in place i.e., the Drugs Consultative Committee (DCC), which was established to facilitate uniform implementation of the DCA across the country. This could be done by amending the DCA to provide for an expanded and an unambiguous mandate to the DCC.

The research findings presented in this study are based on legal and policy analysis, field research in terms of stakeholder interviews conducted nationally (Delhi, Gujarat, Himachal Pradesh, Bihar, and Kerala) and internationally (USA, Europe, China and Indonesia), and information gathered through RTI applications.

Admittedly, drug regulation encompasses substantive policy areas such as pharmaceutical pricing, clinical trials, medical devices, post marketing surveillance, objectionable advertisement and marketing, which are beyond the scope of the present 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.

¹ 'Drugs', 'pharmaceuticals' and 'medicines' have been used interchangeably in this document.

NEED FOR EFFECTIVE DRUG REGULATION

The need for effective drug regulation becomes imperative as drugs form an integral part of medical care. Drug regulation is essentially a public policy response to the demands of public health and the changing needs of pharmaceutical industry. Hence, the objective of all drug regulatory regimes is to ensure that safe, good quality and efficacious drugs reach the patients. And this 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. However, mechanisms designed to meet these objectives vary, and rightly so, given that the nature and scale of the regulatory space² that frame the operation of these regimes differ across countries.

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 undertakes inspections to check for compliance. This has a number of positive attributes including clarity in regulatory standards, which makes it easier to apply and also spot instances of non-compliance. However, such a system also requires coherence of regulatory objectives between the centre and states, and considerable investment in resources for efficient delivery of regulatory functions (setting standards for maintenance of records, conducting inspections, collection and testing of samples, etc.). Therefore, effective drug regulation requires a host of factors to work together, including strong political will, sound management for streamlining the procedures and uniform implementation of law, coordination among law enforcement agencies and all the other stakeholders, and transparent and speedy decision making that garner strong public support.

The federal system of government in India makes it essential to streamline the regulatory functions in a way that ensures that division of regulatory responsibility does not compromise the overall effectiveness of drug regulation. In the process of strengthening drug regulation, there have been an array of regulatory challenges. These challenges have led to a number of developments including identifying the nature and scale of these challenges and subsequent proposals for reforms. The reform efforts include the Mashelkar Committee Report (2003), the 59th Parliamentary Committee Report on the Functioning of the Central Drugs Standard Control Organization (CDSCO) (2012), the Ranjit Roy Chaudhury Committee Report (2013) and most recently the Drugs and Cosmetics Amendment Bill (2015).³ The present study is expected to contribute to this reform exercise

² '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, norm enforcement and norm adjudication and the various public and private actors involved in these processes.

³ As per telephonic discussion with the officials of Ministry of Health & Family Welfare (MOHFW) on 8 September 2015, the Drugs and Cosmetics (Amendment) Bill, 2015 is pending with MOHFW.

by presenting a thematic analysis of regulatory challenges (national and international) and proposing a set of actionable policy recommendations based on them.

In the following pages, the research findings and the corresponding recommendations are presented in terms of thematic areas. The working paper⁴ can be referred to, for a detailed analysis of these themes.

⁴ For a detailed analysis of the research findings, please refer to the relevant working paper enclosed herewith and also accessible at <http://icrier.org/publications/working-papers/>.

THEME 1: UNIFORMITY

Current Scenario

Division of responsibilities

CDSCO is responsible for granting approvals for clinical trials, new drugs and specialised medicinal products (vaccines, parenterals, and other high risk products) and authorizations for import and export. SDRAs are responsible for granting manufacturing, distribution and sale licences, inspections, sampling and testing and overall quality control of medicinal products (including investigating violations and launching prosecutions).

This division of responsibilities may create risk of fragmentation as there is no unity of command. This risk is exacerbated by the lack of hierarchy between the 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 states.

Lack of uniformity in legal interpretations of Drugs and Cosmetics Act 1940 (DCA)

The lack of uniformity in legal interpretations of the DCA, and regulatory decision-making between the national regulatory authority (CDSCO) and the state regulatory agencies (SDRAs) is a continuous challenge in ensuring harmonized application of drug regulatory standards throughout the country. This lack of uniformity extends to the competencies and resources of the regulatory agencies.

Section 33P,⁵ which empowers the CDSCO to issue directions to the SDRAs, to ensure that provisions of DCA are implemented uniformly in all states, is rarely used and even if it is used, there is no penalty for non-compliance by the states.

Inter-agency interactions

The institutional channels of interaction between the CDSCO and SDRAs are limited. 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 State Drug Controllers (SDCs)) and joint inspections. A similar state of affairs exists among other SDRAs. The interaction has been confined to association activity among the staff and training programs, viz. Gujarat FDCA trained Drugs Inspectors (DIs) from Chhattisgarh and Haryana.

⁵ 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."

Recommendations

We propose two recommendations, either of which may be considered for implementation.

Make CDSCO controlling and reporting authority for SDRAs

This would lead to a clear hierarchy and reduce the risk of fragmentation in functioning of the drug regulatory agencies in India. Functions may continue to be distributed between the national and state agencies, but CDSCO would be the managing authority, and therefore responsible for ensuring uniformity. This can be done if the Union Parliament enacts a new legislation to replace the DCA. To achieve this, the Union Parliament will have to establish its competence to enact such a legislation.

There are three ways in which this can be operationalized: first, by moving 'health' subject matter from State List (List II) to Concurrent List (List III) of the Constitution. For this a constitutional amendment is required. Thereafter, the Union Parliament can enact a new legislation to replace the DCA. A second way is, to enact a new legislation under the 'Drugs and Poisons' Entry 19 in the Concurrent List. Third, a new legislation may be enacted to replace the DCA, 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).

Empowering and strengthening 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 formalize standard operating procedures (SOPs) and interpretations of key legal provisions. Regular meetings, mandatory representations from all SDRAs and dedicated funding for such participation and a secretariat are absolutely critical. A similar model exists in European Union in form of Committee for Medicinal Products for Human use (CHMP), which is an empowered body with representation from all member states. This can be operationalized by amending the DCA. The currently pending DCA Amendment Bill 2015, envisages representation from all SDRAs, but lacks sufficient details in terms of the functional scope, financial support and regularity of meetings.

THEME 2: REGULATORY AGENCY AUTONOMY

Current Scenario

CDSCO and the SDRAs are umbilically tied to their parent ministries and departments of health

This impedes flexibility in decision-making and autonomy in a host of areas including finance, recruitment and other areas of institutional policy.

Lack of a central coordinating body which bears the holistic responsibility for the effective working of the regulatory system

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. This also emphasizes lack of uniformity in legal interpretations of DCA and highlights the urgent need for unity of command for effective coordination between the regulatory agencies.

Centralization

The proposal for extending the powers of the CDSCO allowing for greater centralization⁶ (by extending 17 categories of drugs, mentioned in the third schedule, for which the central licensing authority is empowered to issue licence and permission) has been suggested in the Drugs and Cosmetics Amendment Bill 2015. However, SDRAs across the country are not in favour of centralisation for different reasons, which also reflects the concerns of SDRAs in altering existing power relations with the CDSCO officials.

Need for regulatory autonomy: a wide consensus

Autonomy of the drug regulator, both at the centre and at the state level, was stressed upon by several respondents as crucial in facing the operational challenges and also in gaining flexibility and credibility as an administrator. The officers from the SDRAs supported the idea of an independent regulator for drugs, considering administrative distance between the SDRAs and the State Department of Health, as an important step for greater operational freedom.

⁶ Also, previously Drugs and Cosmetics Amendment Bill 2013 (introduced in the Rajya Sabha on 29 August 2013) proposed establishment of Central Drug Administration to subsume CDSCO.

Food Safety and Standards Authority of India (FSSAI) - a model for emulation

FSSAI can be taken as a good reference point of an independent and technically autonomous regulator. The FSSAI is a statutory independent body with all the powers of financial planning and administrative flexibility.

Recommendations

There is a need to streamline regulatory decision-making, in the context of federal division of competencies between the centre and the states.

Establishment of a financially independent and technically autonomous (politically accountable to the Parliament) statutory regulatory agency

Establishment of an autonomous regulatory agency (on the lines of FSSAI), will facilitate greater flexibility and increase 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 MOHFW/ State Department of Health.

Amendment in DCA

To operationalize the above recommendations, an amendment in the DCA can be brought about. However, given that 'health' is a subject matter in the State list, the States have to be taken into confidence before making such an amendment.

THEME 3: INSPECTIONS

Current Scenario

Great disparity in the system of inspections amongst SDRAs

At present, there is a random system of inspections. SDRAs rely on a combination of factors to determine the inspection protocol including which facilities are to be inspected, at what point in time and who will undertake the inspection. Unlike in other countries, the inspection targets in India are based on a host of factors which are not necessarily risk based.

Most states lack a proper database on manufacture and distribution of drugs

There is no common database between states with a record of inspections. The introduction of a common database eases investigation procedures. The use of the European Union Drug Regulatory Authorities (Eudra) GMP database (that documents the compliance history of firms in various countries shared between the regulatory authorities in the member states of EU) was cited as a good practice which could be explored in India.

Table 1: Inspections methods across countries

USA	EU	China	Indonesia
Risk-based inspections	Risk-based inspections	Hybrid of the risk based and random sampling approach	Hybrid of the risk based and random sampling approach

Source : Authors' own compilation from the field research.

Recommendations

Given the limited resources, there is a need to efficiently utilize them for the purpose of inspections. For this to be operationalized, the following steps can be adopted.

Workforce rationalization

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 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).

Shifting to risk-based inspections

Risk-based inspections should be adopted as a statutory principle for organizing 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 the highest (the risk should be a standardized function of the compliance history of the unit, risk of product and other such variables). The effective risk based inspection and resource deployment for the same, requires continuous evaluation of risk levels through monitoring of the manufacturing environment, industry advancement and other factors.

Intelligence cells need to be set up in all SDRAs

Intelligence cells could establish a surveillance system and provide information to the inspectorate in conducting raids. Hence, having an investigation cell compliments the inspectorate particularly in a resource constraint situation.

SOPs to streamline the procedures

SOPs are needed to be adopted with reference to maintaining a database of manufacturing and sales units and introduction of a tracking mechanism archiving their compliance history. For this an amendment to the DCA may be made. Further the DCC could be tasked with the responsibility of developing such SOPs and ensuring an ongoing space for dialogue on this issue.

THEME 4: PHYSICAL INFRASTRUCTURE

Current Scenario

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

Digitalization with an aim of end-to-end online system with no requirement of physical files - varied experience among states

To discharge the functions efficiently, there is a greater need for better infrastructure in regulatory agencies. Towards this end, digitalization has begun, and it is expected that movement to complete electronic platform, that is shared between the CDSCO and the SDRAs, will become operational in around three years. However, it has emerged from the field research that most states lack a proper database on manufacturing and distribution of drugs. At present, Xtended Licensing, Laboratory and Legal Node (XLN) system has been adopted by Gujarat, followed by several other states such as Himachal Pradesh and Bihar. However, in Bihar, the implementation of XLN is mainly on paper, and there is minimal computerization. In Himachal Pradesh, the sales licensing is now entirely online. Further, the state is in the process of extending it to the manufacturing licences as well. In Kerala, the software is operational since August 2012 and is available for sales licences. Gujarat also has the Drug Manufacturing License-Allopathic (DMLA) system, which has enabled the regulator paper less services, resulting in reduction of the challenges faced by the stakeholders.

Alarming state of drug laboratories

The state of physical infrastructure in drug laboratories is quite alarming. While the Central laboratories are of good quality but lack in capacity; the state level laboratories vary greatly in terms of both quality and capacity. On visiting Bihar Drug Control Laboratory (BDCL) in Agamkuan, Bihar, we found that it receives minimal support from the Central Drug Testing Laboratory (CDL) and other national laboratories due to non-payment of arrears by the Bihar Government. Moreover, there are limited testing facilities, for instance, HVAC and micro-biologicals are unavailable. A similar situation exists in Himachal Pradesh, where at present all the drug testing is carried out in the Kandaghat Laboratory, which is not only overburdened but is also without any facility for disintegration test and biological test.

Inadequacy of qualified laboratory personnel in the State laboratories

This has adversely affected the testing of samples, and was largely observed at Bihar, Kerala and Himachal Pradesh. The shortage of laboratory personnel has, in turn, lead to backlogs in testing of samples, particularly in Bihar.

Inadequacy of support infrastructure

The availability of supporting infrastructure like transport facility in departments for inspections, appeared inadequate in the states of Bihar, Kerala and Himachal Pradesh. All the respondents in Himachal Pradesh are of the opinion that the department lacks adequate transport facility, which is very essential for efficient functioning of the department. The evidence from Kerala supports the same where the major infrastructural hurdle faced by the DIs is the extremely old vehicles. In the absence of proper transport facilities, inspections become a burdensome task particularly in hilly terrain of Himachal Pradesh, and Idukki and Wayanad in Kerala.

Recommendations

There is a need to strengthen the capacity of physical infrastructure to match it with the volume of regulatory functions of the agencies. To this effect, the following measures should be implemented.

Survey of laboratories to identify critical gaps

A survey of all state government laboratories needs to be conducted to identify critical gaps, followed by adoption of a de minimus rule (should be statutorily recognized) specifying the minimum laboratory facilities (instrumentation and manpower) required for each states.

Provision of grant from Union Budget

Financial support should be provided to the states from the Union Budget, in form of one time grant on the agreement that the state governments will provide similar grants to maintain the facilities (five year commitment).

Movement towards National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation of all central and state laboratories

Rapid universalization of XLN with a focus on building a complete and coherent database

For universalization of XLN software across the SDRAs, the states can make use of Rapid Replication Roll Out Initiative of Department of Electronics and Information Technology, which leverages sharing of infrastructure and facilitates for rapid customization and replication of successful applications across the states. Also, having adequately trained personnel in each SDRA to operate the database is necessary. 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 uniform centrally integrated data bank. A well-knit database would also tackle the problem of lack of common database between states and can inter alia facilitate a record of inspections.

Immediate measures, small yet sure steps

Drug laboratories in pharmacy colleges could be recognised for drug sampling purposes. Measures like accreditation of private laboratories and those in pharmaceutical colleges may be included as part of the program, wherein certain sampling may be shifted to such facilities. The utilization of the existing capacity would tackle the issues of manpower and infrastructure without any additional fiscal burden on the states.

Dedicated transport for SDRAs

Provision of adequate transportation should be made to SDRAs considering the current and projected scale of operation and the geographical disadvantages in states such as hilly terrains of Himachal Pradesh and parts of Kerala.

THEME 5: HUMAN RESOURCES AND TRAINING

Current Scenario

At present, the issues with respect to human resources and training in drug regulation are twofold. First, the quantitative aspect of matching the number of regulatory personnel to the scale of activities; second, from a qualitative perspective, the nature and thrust of regulatory functions should determine the qualifications of the regulatory personnel and adequate training should be imparted to further enhance the capacity of existing personnel.

Major Challenges

High number of vacant positions for DIs, lack of dedicated support staff (both laboratory technicians and administrative clerks), inadequate training of DIs, and discharge of non-work related duties to DIs are the major challenges faced by the SDRAs.

- The Mashelkar Committee had advanced a formula of one DI per 50 manufacturing units and per 200 sales/distribution outlets for effective implementation of regulatory objectives. This is yet to be achieved in many states.
- In the case of Himachal Pradesh, which has one of the largest number of manufacturing units in India, the drug inspectors have been given contractual positions in the most recent round of recruitments. These newly appointed DIs have to wait for six years to become regular employees.
- Another issue faced by DIs in Kerala, Himachal Pradesh and Bihar is that they often have to perform multiple tasks that are unrelated and demand time away from their primary function of inspection.
- The slow and staggered recruitment process is a major cause of concern in drug laboratories. In case of Bihar, the advertisement of vacancies is staggered as recruitment and joining takes an average of five years. As a result, the recruitment has not kept pace with retirement of the staff. Also, with regard to training, due to the paucity of technicians, sparing them for training is not a feasible option.

Capacity building initiatives: Training Programs

Training has been identified as one of the most critical areas which requires urgent attention. None of the SDRAs whom we interviewed have an annual training program, reflecting the ad hoc nature of scheduling training programs. The overall view is that though at the entry level both the SDRA and CDSCO staff are similarly qualified, the latter,

through better training programs and exposure, become much more capable compared to the former within short span of time after entering service. As per the responses received under RTI, separate funds have not been allocated in the budget for training in West Bengal, Tamil Nadu, and Kerala and no training program such refresher as course and orientation camp were held in West Bengal and Tamil Nadu.

Specialised training - lessons to be learnt

Training at UK's regulatory agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), is an interesting model to learn from wherein each new Good Manufacturing Practices (GMP) inspector is trained in a limited area of GMP at a given point in time, and once they are assessed as competent in that field, only then do they begin training in the next area.

Recommendations

The issue of human resources can be tackled in two ways, by addressing the requirement of additional human resources and more importantly by enhancing the capabilities of the already existing officials by way of periodic training programs.

Discontinuation of contractual appointments for undertaking core regulatory functions

The nature of duties that encompasses drug regulation is sensitive and technical in nature. The discharge of duties requires precision and experience. The personnel in regulatory bodies are tasked with very sensitive functions including conducting inspections and launching legal prosecutions. The contractual positions create a high risk of dissatisfaction and may lead to corruption. Also, permanent positions provide security of tenure and therefore independence. For this purpose, we recommend, the contractual positions for core regulatory work such as Drug Inspectors (DIs) should be discontinued.

Increase in human resource strength (both technical and administrative staff) and filling up of vacant positions

The staff strength should reflect current and projected scales of operations. To address the issue of delayed recruitment, independent recruitment (direct recruitment) instead through Public Service Commissions should take place to ensure speedy recruitment, as is the case of other regulatory agencies like Telecom Regulatory Authority of India (TRAI).

Establishment of a national institute for training and uniform modules for training

For efficient functioning of the state and the central regulatory agencies, there is a need for capacity building. To make it effective and uniform across the states, the CDSCO should form a national institute of training and formulate specific modules facilitating specialised training to the all the officials. This would help in streamlining the work across the Centre and the States. Training at UK's regulatory agency, the MHRA, can be taken as an example of imparting specialised training.

Creating incentive structures for human resource (For example, promotions linked to trainings)

Linking the training programmes to promotion could bring about willful participation and enhancement of individual performance in the long term. The training system could be evolved in manner similar to the one that exists within the University Grants Commission (UGC), to provide a continuous knowledge building exercise 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 a year.

Involving technology in imparting training

The trainings may be imparted through IT enabled channels (off site) and inducted through the web. This would be helpful in engaging more participants, thereby overcoming the problem in attending the onsite and in-person training programs. Private sector pharmacy colleges and training institutes, can be helpful in drafting the curriculum for IT-enabled training in specific courses in specialised areas.

Designation of SDC as Drawing and Disbursing Officer (DDO) across all the states

At present, the DDO for DIs is District Magistrate (DM) who exercises inordinate control in terms of deputing DIs for non-drug related administrative functions, rendering the SDC powerless in terms of effecting functional control over its DIs. The SDC should be appointed as the DDO for all personnel in the SDRA office. This will tackle the problem of regulatory personnel being answerable to other officers.

THEME 6: FINANCING

Current Scenario

Reliance on government funding and complicated centralised public procurement process

The financing of the regulatory authority is an important aspect of our field 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 of the state government.

The SDRAs and CDSCO are reliant on the government funding. Although budgets and CDSCO outlay have increased, financial disbursement remains a problem. This is particularly because regulatory agencies have to go through a centralised public procurement process which entails complicated system of approvals for financial disbursement towards acquiring services and machinery. In this regard, our interaction with CDSCO officials also revealed that the process for procurement is extremely complicated and lengthy, with innumerable technical queries being made by the Department of Expenditure for clearance purposes.

No increment in the financial outlay for SDRAs as per their regulatory functions and footprint

There is wide disparity of funding amongst SDRAs and it is usually staggered so that by the time of its disbursement, the requirements have also increased. 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 the general under appreciation of the agency's activities by the parent ministry.

Underutilization of funds

The actual utilization of funds by CDSCO has been persistently and significantly lesser than the allotted funds (see the following table). The 82nd Report of the Department-Related Parliamentary Standing Committee on Health and Family Welfare (henceforth, the 82nd Committee Report) attributed this as inadequate budgetary planning and suboptimal deployment of funds. On the other hand, our interaction with CDSCO officials also highlighted that this is partly due to the extremely complicated procurement process. This underlines the fundamental problems within the current system of procurement, fund disbursal, and the need to explore alternative mechanisms to smoothen the process. Also, there is a need to focus on improvement in the financial performance of the drug regulator(s).

Table 2: Trend of Budgetary Estimates 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
2014-15	100.00	67.00	39.33 (up to 5 March 2015)

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

Recent efforts

The 12th five year plan outlay for drug regulatory mechanism (both physical and human resources) proposed sums of Rs. 1800 crores and 1200 crores for strengthening the CDSCO and SDRAs respectively. Also, for strengthening SDRAs, a new centrally sponsored scheme has been proposed under the National Health Mission with a 75:25 sharing pattern between the centre and the states. For this an allocation of Rs. 850 crores would be the Centre's share and Rs. 229 crores the state's share. However, the scheme is yet to be approved by the Cabinet Committee on Economic Affairs.

Table 3: Practices in Other Countries

USA	EU	China	Indonesia
There is a combination of government funding and user fee (both prescription and generic drugs) in USA. The user fee is approximately 51% of the funding and government funding is 49%. The funds from the User Fees are paid directly to the FDA.	A combination of government funding and user fee. The User Fee as a proportion of the budget is lower than in the USA. All funds are directed to the European Commission (EC) and then the EC allocates the budget to the European Medicines Agency (EMA).	Financed largely by the budgetary allocation complimented with a high registration fee.	There are two sources of revenue. First is the national budget and the second is registration fee. Presently, the contribution from national budget is the major source of revenue.

Source : Authors' own compilation from the field research.

Recommendations

Financial autonomy in revenue generation and disbursement is critical in guaranteeing flexibility in planning and operationalization of institutional plans. This would address the delays arising due to complicated and lengthy approval systems for financial disbursement.

Financial models that are partly funded by budgetary allocation and partly by a user fee model (that sufficiently reflects cost of provision of service) should be explored

Budgetary allocations should take care of the financial requirements of core regulatory functions, rather than reliance on user fee for these purposes. Revenue mobilization, through this process, will also ensure financial sustainability of the agency. The alternative financing mechanism in form of the user fee based model can be explored through an amendment in the DCA. Further, the user fees can be specified in separate schedules to the DCA which can be regularly updated through administrative orders (office memorandums).

With reference to increase in user fee, it is important to learn from US-FDA. Interestingly, some industry members say that for generic drugs, the Generic Drugs User Fee Amendments (GDUFA) has resulted in an increase in timelines for review. This may have been due to the increased volume of applications. The Prescription Drugs User Fee Act (PDUFA) has also attracted criticisms on the ground that increasing reliance on user fees has led to the creation of “rich and poor” departments within the agency thereby undermining the overall growth of the agency. ((Hutt Peter, 2008) (Srinivasan and Jesani, 2012)). Therefore any increase in fee should be on a sliding scale to ensure that its affect on small and medium scale 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 the smooth functioning of drug regulatory agencies, with an overarching focus on public health in the form of patients’ well-being and strengthening health systems.

Adoption of good business practices

The user fee system of raising revenue is also complemented by a broad range of systems to ensure that regulatory functions are carried out efficiently and effectively. The 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 the authorities that receive the funds). For effective functioning of regulatory agencies increased focus on adoption of good business practices is required, such as process management, training programs, and effective IT infrastructure.

THEME 7: TRANSPARENCY

Current Scenario

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

Lack of statutory duty for making important information accessible to the public

There are some areas, like clinical trials, in which there has been a marked improvement in public accessibility to information, decision-making and public accountability. The imperative for this was driven by adverse judgements of the apex court and by critical parliamentary reports (59th report of the Parliamentary Standing Committee on Health and Family Welfare on the functioning of the CDSCO). However, in most of the other areas, the agencies have not proactively initiated similar reforms. The lack of statutory duty to do so is also one of the primary reasons for this slow reaction.

Level of transparency across states

The transparency levels varies across the states. Gujarat is considered to have a well functioning SDRA, referred to as Food & Drugs Control Administration (FDCA), both by the industry and the academics. The FDCA has also introduced a toll free number and online system to lodge complaints and thus has used IT to a great extent in bringing more transparency. Further, Gujarat has improved transparency within the agency by using the XLN 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.

In Himachal Pradesh and Kerala, there is a perception among the stakeholders regarding prevalence of corrupt practices in decision making in the SDRAs. However, one unique aspect of Kerala is that unlike in other states, there is a strong involvement of professional associations within the state and this has allowed for third party supervision and helped combat corruption.

With regard to prosecution under DCA, Kerala, Himachal Pradesh and Bihar did not have designated special courts. In this regard, all regulators agreed that special courts would help considerably in hastening the prosecution.

Measures adopted to facilitate more transparency

Measures are taken by the CDSCO to improve transparency such as developing SOPs for all regulatory decisions and functions, but the efforts are still ongoing. However, the SDRAs, as of now, are not legally mandated to adopt these SOPs.

Table 4: Lessons from the World

US	EU	Indonesia
<p>The 'Transparency Initiative' which is overseen by a Task Force representing key leaders of the US-FDA, has re-released various proposals for reporting of public comments and dissemination of information.</p>	<p>The EMA and the EC as well as the member states maintain useful websites with full details of applicable legislation, guidelines, forms, etc. Under the procedures established by the EMA, informal consultation with national officials in one or more member states is facilitated for the companies seeking advice on clinical development issues and also formal scientific advice is provided. 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 comments.</p>	<p>In Indonesia, the existence of Pramuka market, a wholesale market of medicines which requires no prescription and bills, itself is an indication of the prevailing corruption and lack of regulatory oversight in the country. It is also known that the delay in processing applications can be avoided, if the companies bribe the officials. However, in order to prevent the smuggling of APIs, there is a counterfeit cell, (which includes National Agency for Drug and Food Control and police). Further, out of Court settlements are common in the country for all types of cases, which again points to the depth of corruption. From the point of view of an industry expert, the system is not very transparent.</p>

Source : Authors' own compilation from the field research.

Recommendations

The need for transparency is twofold, in the interactions with the stakeholders and the transparency within the agency.

Transparent regulatory decision-making can improve industry compliance, as well as, ensure consistency in decision-making and establishing precedent. This ensures the consistency of the regulator and strengthens the trust of the industry in the regulatory system. However, transparency should be increased, while still protecting sensitive information and the competitive interests of the regulated firms.

Transparency in decision making at all levels

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. A clear specification and strict adherence to the timelines for all regulatory decisions should be practiced.

All regulatory decisions should be adequately publicised and the rationale for decisions taken should be given clearly, including the formation of Expert Committees and the minutes of their meetings (without revealing sensitive information about the product).

There is an urgent need to standardize 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 digitalization is expected to contribute to this process, for instance, the XLN software can also be used to increase transparency within the organization, like in the case of Gujarat.

Further, the regulatory agencies should encourage professional association activity so that they are partners in checking corruption in areas such as subletting of licences.

THEME 8: PUBLIC OUTREACH AND INTERNATIONAL COOPERATION

Current Scenario

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

Limited public outreach

At present, there is limited interaction between general public and the regulatory agencies, with respect to the aims and functions of the agencies. Public is largely unaware of the critical role played by these agencies in ensuring public health and safety.

The information on the websites of the agencies is made partially accessible on an *ad hoc* basis, thus further reducing the space for public interaction. There is no dedicated website for the SDRAs of Himachal Pradesh and Bihar, pointing to the poor access to information for the general public. Such websites however do exist for Kerala and Gujarat. Thus the absence of standardised protocols for ensuring transparency has led to varied levels of transparency across the states.

Need for international cooperation

In the increasingly globalised and connected world, there is a growing need for active participation of the Indian regulatory agencies in international regulatory networks. Participation in these networks is particularly important for identifying synergies between various national regulators and this will help leveraging effective regulatory decision-making through adoption of best practices at the national level.

Recommendations

Creating a positive public image of a regulatory agency is also important in garnering public support for strengthening the agency.

CDSCO and SDRAs to proactively develop a plan for public engagement

Publicity should be given to regulatory decisions, including scale of inspections conducted, manufacturing operations sealed for non-compliance, penalties imposed, and licences granted and rejected. The interface with the public needs to be worked on, in the form of websites for each SDRA where information is available to the public. Cogent and

coherent standardised protocol can be devised at the agency level, as these will help in achieving uniformity in the transparency. CDSCO website could provide web links to the SDRAs.

Periodic advocacy initiatives

It is an important function of the central and state government authorities to foster educational programmes in the form of 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.

Active international cooperation with other regulatory bodies

India should take steps to actively participate in 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 generics 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 the regulatory agencies (both the CDSCO and SDRAs) to adopt best practices and ways to further streamline procedures in the Indian regulatory system. This issue was also discussed by the Parliamentary Committee in its 59th Report, which reiterated the need to participate in international networks so as to benefit from information regarding regulatory actions undertaken internationally and by other national authorities.

CONCLUDING REMARKS

The drug regulatory system in India can be characterised as a classic command and control system, wherein regulators establish technical standards, which are then enforced through a process of inspections and testing of samples collected. Nevertheless, shortages in physical infrastructure (drug laboratories for testing samples and vehicles for conducting inspections) and human resources (high percentage of vacancies for drug inspectors) have severely undermined the regulatory effectiveness. Absence of a clear statutory mandate to ensure effectiveness has also meant that there is no single entity that has the responsibility to ensure the effective functioning of the regulatory system that is federally structured. The Drugs and Cosmetics Amendment Bill 2015, has sought to address this issue by proposing greater centralization, including giving more powers of supervision and censure to the CDSCO. However, the present study reveals that there are limitations to this solution, especially given the scale of enforcement in a country the size of India and the reluctance of the SDRAs to relinquish regulatory control. As an alternative, we suggest strengthening of the DCC as a possible solution to this challenge of uniformity and effectiveness. This will allow the SDRAs to gain ownership of the regulatory system, rather than functioning as disjointed parts of a single system. The European experience of the functioning of the CHMP is a good example of effectuating collaboration amongst regulators.

An independent drug regulator is also the need of the hour. The CDSCO and the SDRAs are umbilically linked to their parent ministries/departments of health. Lack of technical and financial autonomy has undermined control over recruitments, expenditure in critical areas such as drug laboratories, and flexibility in prioritizing regulatory areas for investment and long term planning. A statutory overhaul is also a necessary corollary to this. The DCA, as it currently stands, is a skeletal legislation which is supported by a complex and increasingly unwieldy body of subsidiary legislations (notifications). Many of the recommendations made in this paper can only be effective if there is a clear statutory commitment.

Finally, we underline that this study, in many ways breaks new ground. First, the administrative functioning and challenges faced by SDRAs have been studied in a systematic manner. Second, comparative perspectives both from regulatory leaders like USA and UK and other developing countries like China and Indonesia have also enriched our understanding of common challenges and search for credible solutions. Third, more than 100 stakeholders including regulators, manufacturers, industry associations, civil society organizations and academicians were interviewed for this study. 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. Ultimately, we hope this study will invigorate and contribute the discussion on regulatory reform of this critically important sector.

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SNAPSHOT OF POLICY RECOMMENDATIONS

Issue	Recommendation	Intended impact
Lack of uniformity in legal interpretations of the Drugs and Cosmetics Act, 1940	<p>Make CDSCO the controlling and reporting authority for SDRAs,</p> <p style="text-align: center;">Or</p> <p>Empower and strengthen SDRAs to become regulatory partners of CDSCO</p>	<p>Harmonised application of drug regulatory standards throughout the country.</p> <p>Coherence in regulatory decision-making between the national regulatory authority (CDSCO) and state regulatory agencies (SDRAs); and convergence of drug regulatory standards among SDRAs</p>
Lack of independence and autonomy to the drug regulator	Financially independent and technically autonomous (politically accountable to the Parliament) statutory regulatory agency	Greater flexibility and increased operational effectiveness of both CDSCO and SDRAs
Disparity in the practice of inspection amongst SDRAs	<p>Workforce rationalization and adoption of SOPs</p> <p>Risk-based inspections should be adopted as a statutory principle for organizing inspection protocols</p>	Risk-based inspections would facilitate prioritization of regulatory work in resource constraint settings and SOPs could facilitate harmonization of regulatory procedures
Lack of key infrastructure especially at the level of SDRAs	Strengthening laboratories, universal digitalization process by adoption of XLN software system, and adequate transportation	<p>Survey of state government laboratories would ascertain minimum laboratory facilities (instrumentation and manpower) that should be adopted for each of the states which can become the basis for resource allocation</p> <p>Uniformed digitalization drive will strengthen the harmonization of regulatory work among the states and centrally integrated data bank</p>

Issue	Recommendation	Intended impact
Need to match the number of regulatory personnel to the scale of activities, and address great disparity in pay, work conditions and training facilities	Requirement of additional human resources and conducting periodic training programs with uniform training modules to officials of CDSCO and SDRAs	<p>Achieving a staff strength reflecting current and projected scales of operations</p> <p>Periodic training would enhance capabilities of the already existing officials and further help in bringing uniformity in regulatory functions</p>
Financial dependence of the CDSCO and SDRAs on government funding	<p>Financial autonomy in revenue generation and disbursement</p> <p>Adoption of sustainable financial models that are partly funded by budgetary allocation and partly by a user fee model</p>	Flexibility in planning and operationalization of institutional plans with removal of complicated and lengthy approval systems for financial disbursement
Need for a more transparent regulatory decision-making	Standardize operational protocols and provide key access points for public information	This would help strengthen the trust and perception, consistency in decision-making and establishing precedent for the benefit of public and various stakeholders
Need for adequate channels for public outreach and international cooperation	<p>CDSCO and SDRAs should proactively develop a plan for public engagement</p> <p>Publicity should be given to regulatory decisions ensuring transparency and interface with the public needs</p> <p>Active participation of regulatory agencies in international forums</p>	<p>Increasing public engagement would facilitate bridging the gap between the regulators and the public.</p> <p>Advocacy campaigns would also encourage voluntary compliance within industry</p> <p>International cooperation would help the agencies in adopting international best practices to further streamline the procedures</p>

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