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Introduction

Welcome to the Indian Journal of Legal Affairs and Research (IJLAR), a distinguished platform dedicated to the dissemination of comprehensive legal scholarship and academic research. Our mission is to foster an environment where legal professionals, academics, and students can collaborate and contribute to the evolving discourse in the field of law. We strive to publish high-quality, peer-reviewed articles that provide insightful analysis, innovative perspectives, and practical solutions to contemporary legal challenges. The IJLAR is committed to advancing legal knowledge and practice by bridging the gap between theory and practice.

Preface

The Indian Journal of Legal Affairs and Research is a testament to our unwavering commitment to excellence in legal scholarship. This volume presents a curated selection of articles that reflect the diverse and dynamic nature of legal studies today. Our contributors, ranging from esteemed legal scholars to emerging academics, bring forward a rich tapestry of insights that address critical legal issues and offer novel contributions to the field. We are grateful to our editorial board, reviewers, and authors for their dedication and hard work, which have made this publication possible. It is our hope that this journal will serve as a valuable resource for researchers, practitioners, and policymakers, and will inspire further inquiry and debate within the legal community.

Description

The Indian Journal of Legal Affairs and Research is an academic journal that publishes peer-reviewed articles on a wide range of legal topics. Each issue is designed to provide a platform for legal scholars, practitioners, and students to share their research findings, theoretical explorations, and practical insights. Our journal covers various branches of law, including but not limited to constitutional law, international law, criminal law, commercial law, human rights, and environmental law. We are dedicated to ensuring that the articles published in our journal adhere to the highest standards of academic rigor and contribute meaningfully to the understanding and development of legal theories and practices.

FROM APPROVAL TO ACCOUNTABILITY: A SOCIO-LEGAL CRITIQUE OF CDSCO DRUG REGULATORY FRAMEWORK IN INDIA

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ABSTRACT

The Drugs and Cosmetics Act of 1940 established a complicated federal system for drug controls in India, with CDSCO serving as the highest regulatory body backed by SRDAs. The role of CDSCO and its medication approval procedure is severely examined in this research. It highlights concerns about procedural irregularities and a lack of transparency. The article has concentrated on a few major problems that impair CDSCO's overall effectiveness and have an impact on the public interest. The article highlights cases in which the court identified regulatory shortcomings, capricious approvals, and a failure to protect public health. The article argues that the effectiveness of India's drug regulatory system is significantly hindered by a lack of transparency, inadequate coordination, and weak institutional capacity. It emphasizes the need for reforms aimed at standardizing regulatory practices, strengthening human resources, and enhancing transparency in the drug approval process. Drawing from comparative practices such as those followed by the USFDA, the study advocates for greater public disclosure of regulatory decisions and documentation to ensure accountability and restore public trust in the system.

Keywords – CDSCO, Drugs, Health, SRDA, Regulation, Clinical trial

INRODUCTION

The Drugs and Cosmetics Act of 1940 and several ministries, such as the Ministry of Health and Family Welfare, oversee the complicated process of drug regulation in India. The law establishes a network of regulatory bodies to oversee the procedure at both the federal and state levels. The Central Drugs Standard Control Organization (CDSCO) was established at the central level by the Drugs and Cosmetics Act, 1940. The Drugs Controller General of India (DCGI), acting on the advice of the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC), is the primary regulatory body within CDSCO. Inspections, recalls, and market surveillance are just a few of the specific responsibilities assigned to CDSCO's zonal offices, which are dispersed throughout the nation. State Drug Regulatory Authorities (SDRAs) are statutory organizations established at the state level by the Drugs and Cosmetics Act of 1940. SDRAs are responsible for certain parts of drug regulation and fall under the purview of each state's health department. In reality, CDSCO is in charge of creating policies and granting licenses and manufacturing permits, while SDRAs appear to be in charge of some implementation under CDSCO's supervision.

Drug Regulation in India and Role of CDSCO

The Drugs and Cosmetics Act, 1940 (DC Act) and its accompanying Drugs and Cosmetics Rules, 1945 (DC Rules) provide the basis of most drug regulations in India. However, state governments also have significant power over drug regulation in India since "public health" is a state issue under the country's constitution. As a result, there is now no explicit and legislated division of authority between the federal government and the states. The root cause of many issues with drug regulation in India is the absence of a powerful regulatory authority.

On the regulatory front, the Central Drugs Standard Control Organization (CDSCO), headed by the Drug Controller General of India (DCGI) is primarily responsible for coordinating the activities of the SDRAs, formulating policies, and ensuring uniform implementation of the DC Act throughout India. The DCGI is responsible for handling matters of product approval and approval standards, clinical trials, introduction of new drugs, and import licenses for new drugs. A drug may be licensed for manufacturing in a state only once it has been approved by CDSCO. Bans on drugs

issued by CDSCO, although rare, are also authoritatively binding on the SDRAs. According to the Minister of Health and Family Welfare, between 2013-2015, only three drugs were banned citing risk to human beings and availability of safer alternatives in the country.[1]

Chapter II of the DC Act constitutes three agencies for assisting and advising the central and state governments. The Drugs Technical Advisory Board (DTAB) advises the governments on technical matters arising out of drug control administration. The Drugs Consultative Committee (DCC) advises the governments and the DTAB on matters tending to secure uniformity in drug control administration throughout the country. The Central Drugs Laboratory (CDL) functions as the central drug testing laboratory for CDSCO. While the DTAB includes two central government nominees from among persons in charge of drug control in the states, it is the DCC that is the larger representative body, having representatives from all the states in the country. Suggestions and recommendations originating at the DCC go through the DTAB and become executive guidelines or rules, if they are approved by CDSCO.

State Drug Regulatory Authorities (SDRAs) established under the DC Act are responsible for licensing of manufacturing establishments and sale premises, undertaking inspections of such premises to ensure compliance with license conditions, drawing samples for testing and monitoring of quality of drugs, taking actions like suspension/cancellation of licenses, surveillance over sale of spurious and adulterated drugs, instituting legal prosecution when required, and monitoring of objectionable advertisements for drugs.

[1] Lok Sabha Unstarred Question No. 1042, answered by the Minister of Health and Family Welfare on 4 December 2015

Figure 1: Division of responsibilities between CDSCO and SDRAs

Operational Dynamics of CDSCO

CDSCO approves new drugs based on a combination of non-clinical data, clinical trial data (focusing on safety and efficacy) from abroad as well as in India, and the regulatory status of the drug in other countries.[2] The law around new drug approvals is contained in Rules 122 A, 122 B, 122D, 122 DA, 122 DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and 122 E of Schedule-Y of the DC Rules. The law permits a waiver of requiring local clinical trials if the Licensing Authority decides it is in the public interest to grant permission to import / manufacture the new drug on the basis of data available from other countries. Applications for approval of New Drugs are evaluated by the 12 Subject Expert Committee (SEC) (formerly referred to as New Drug Advisory Committees (NDAC)), consisting of experts usually drawn from Government Medical Colleges and Institutes across India. The approval or otherwise is granted based on the recommendations of these committees.

The drug approval process in practice has had its fair share of criticism, notably in the 2016 ban by the central government on fixed dose combinations (FDCs), with the government overruling prior approvals given by the DCGI and state licensing authorities, and without seeking advice from DCC and DTAB. According to critics of the ban, mainly from amongst pharmaceutical companies,

[2] Lok Sabha Unstarred Question No. 1393, answered by the Minister of Health and Family Welfare on 18 July 2014

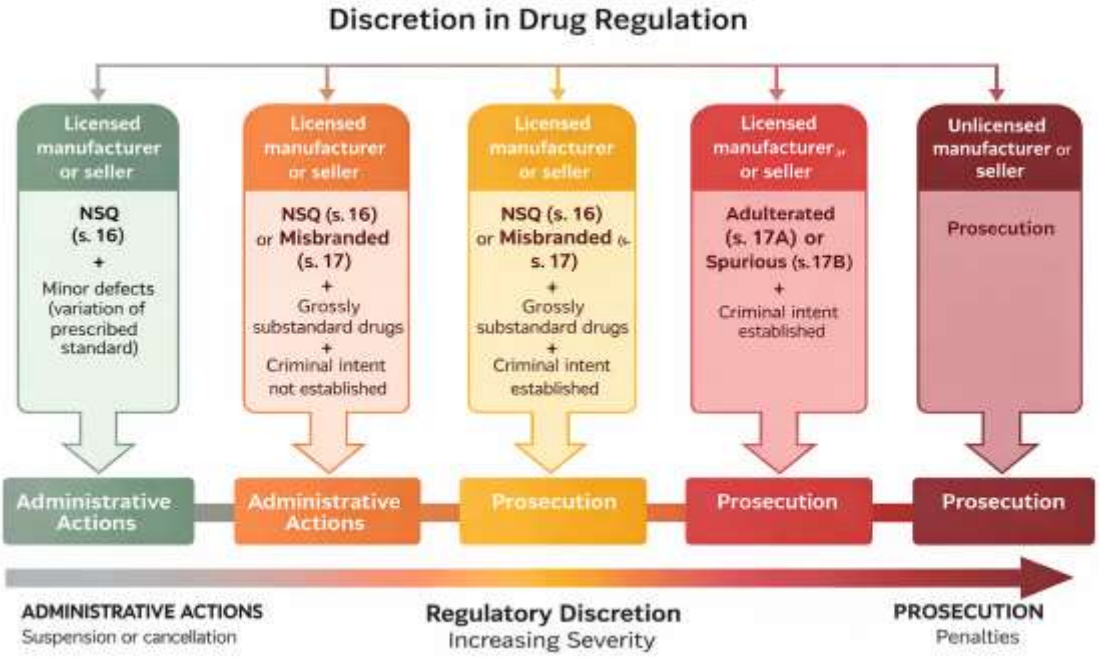
there was a blatant flouting of the rule of law in the announcement of the ban. They said that besides due process, principles of natural justice were also ignored, with manufacturers not being given a chance to be heard, and reasoned orders not being given. The government has defended itself against the allegations, but is already facing litigious challenges in several states from several multiple pharmaceutical companies.[3] Overall, this has put considerable cloud over the new drugs approval and regulatory process in India, and with the ban being issued by the government rather than by CDSCO, this particularly casts a shadow on the legitimacy of CDSCO as a regulatory body.

Issues

1. Uneven Implementation of Penalties - While much of the drug regulation process has been codified, the officers are bestowed with wide discretion at two major junctures in the regulatory process. Firstly, a Drug Inspector may revoke the order issued under Section 23 upon being satisfied that the defect in the drug/cosmetic can be and has been remedied. Secondly, once a Drug Inspector has submitted the inspection report to the Licensing Authority, the Licensing Authority decides whether the violation is serious enough to warrant prosecution. The Licensing Authority may choose between suspension of the license, revocation of the license and prosecution of the licensee. However, neither the DC Act nor the DC Rules provide any metrics to guide this discretion. This has resulted in an uneven implementation of penalties where a repeat offender may get away with suspensions in one state but might be prosecuted in another. A study shows that the identification of a drug as spurious or NSQ (not of standard quality) depends on the Drug Inspector's reading of Form 13.[4] This points to the potential of uneven implementation even within states. Conversely, the absence of clear definitions and standards in the DC Act have also caused harsh punishments for violations lacking criminal intent. In May 2018, the Small and Medium Pharma Manufacturers Association (SMPMA) demanded the implementation of the DCC guidelines for taking action on spurious or NSQ drug samples

[3] Lok Sabha Unstarred Question No. 82, answered by the Minister of Health and Family Welfare on 29 April 2016
[4] Chokshi, M, et al (2015),"Drug Quality and Safety Issues in India," ICRIER, Working Paper 310, September, available at; https://icrier.org/pdf/Working_Paper_310.pdf, last accessed: 2 February 2019

in light of enhanced penalties under the DC (Amendment) Act of 2008.[5] It was highlighted that the absence of a clear definition of NSQ in the legal framework leads to the same punishment being meted out for spurious, adulterated drugs, as well as for drugs that are merely defective. They argued that issues like decreased potency, disintegration, etc. should not be treated at par with adulterated or spurious drugs. To deal with the problem of uneven penalties for violations across states, CDSCO released "Guidelines For Taking Action on Samples of Drugs Declared Spurious or Not of Standard Quality In The Light of Enhanced Penalties Under the Drugs And Cosmetics (Amendment) Act, 2008". Among other things, the guidelines attempt to harmonize the system of penalties with the degree of offence introducing parameters such as criminal intent and sufficiency of administrative action for judging the seriousness of the offence. However, in the absence of regular trainings, the implementation of these guidelines is stuck in limbo.



[5] Yadav, L (2018), "SMPMA urges DCGI to act against NSQ drug manufacturers as per DCC guidelines", 17 May, Pharmabiz, available at: http://www.pharmabiz.com/NewsDetails.aspx?aid=108929&sid=1, last accessed 10 July 2019

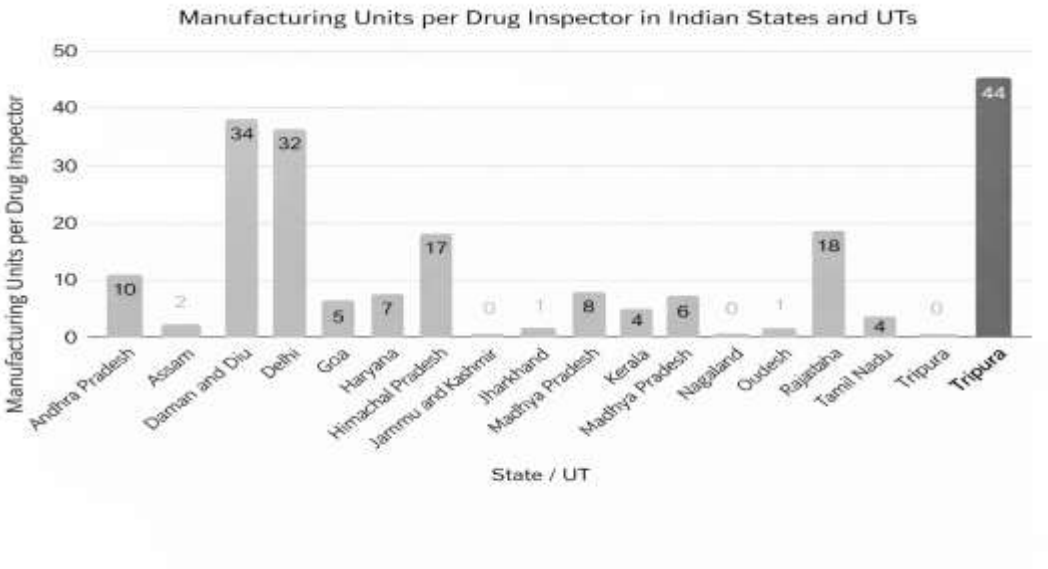
To deal with the problem of uneven implementation, the DTAB agreed to various recommendations such as minimum experience for Licensing Authorities, creation of Intelligence cells in each state, deputation of state regulatory officials to the central regulatory system and vice-versa, cadre restructuring in Drugs Controlling Authorities etc.[6] However, concrete implementable steps are yet to be taken by CDSCO or the Ministry of Health and Family Welfare. In a recent meeting of the DTAB, it was acknowledged that despite the Guidelines, the implementation was non-uniform across states. It was recommended that the Guidelines be standardized and incorporated into the DC Rules.[7]

2. Overworked Administration - The DC Act and DC Rules mandate the inspection of all retailers and manufacturers at least once a year. In 2003, the Mashelkar Committee identified a lack of trained personnel as one of the major issues in Indian drug regulation. The recommendations fixing a formula for adjudging the required number of Drug Inspectors in a state were reiterated in the 59th Parliamentary Committee Report of 2013. According to the formula, there needs to be one drug inspector for every 50 manufacturing units and one for every 200 sale/distribution retailers. In a Lok Sabha answer, the government conceded that the current strength of drug inspectors was much below the 3200 required per Mashelkar's formula.[8] The three states with the highest number of sale/distribution outlets namely, Maharashtra (92359), Gujarat (39364) and Punjab (25917), have 161, 98 and 46 sanctioned positions for Drug Inspectors respectively. Per the Mashelkar formula, the required strength should have been 461, 196 and 129, respectively. Assuming each Drug Inspector can inspect 50 manufacturing units per year, Maharashtra, for example, with 3139 drug producing companies[9] would need 63 Inspectors for manufacturing licensees alone.

   The problem is compounded by the number of positions lying vacant. As per CDSCO's response to our RTI, of a sanctioned strength of 287 drugs inspectors at the central level,

[6] DTAB meeting on 16 June 2017.
[7] DTAB meeting 29 November 2018, Agenda no 2.
[8] Lok Sabha Unstarred Question no. 4752 answered by the Minister of State in the Ministry of Health and Family Welfare on 23 March, 2018.
[9] Data from Lok Sabha unstarred Question 5761, dated 2 May 2013

64 positions are lying vacant. Similarly, at the level of DDC (I), of a sanctioned strength of 28 at the centre, 9 positions are lying vacant. In 2015, Chattisgarh reported approximately 700 pending license applications because the post of Deputy Drug Controller had been vacant for a year.[10] Himachal Pradesh reports a vacancy in 6 out of 22 sanctioned posts for Drug Inspectors.[11] Similarly, 13 out of 84 sanctioned posts in Jammu & Kashmir,[12] 15 out of 38 in Karnataka and 6 out of 23 in Tripura are reported vacant.[13]



3. Inefficient Administration - According to the Ministry of Health and Family Welfare, CDSCO, in recognition of its limitations in conducting Risk Based Inspection of pharmaceutical manufacturing units in the country, designed a special training programme for officers drawn from CDSCO, Drug Testing Laboratories and state Regulators. The trainees were subjected to assessment both before and after the training. A team of five officers each headed by a mid level officer was deputed to carry out inspections of

[10] Jaiswal, A (2015), "With no Dy Drug Controller, over 700 drug license applications pending in Chhatisgarh", Times of India, 10 December, available at: https://timesofindia.indiatimes.com/city/raipur/With-no-dy-drug controller-over-700-drug-licence-applications-pending-in-Chhattisgarh/articleshow/50125538.cms, last accessed 15 July 2019
[11] As of 24 December 2018, according to the website: http://www.hp.gov.in/dhsrhp/drug%20inspector.pdf
[12] As available at https://dfcojk.org/details.php
[13] As available at https://health.tripura.gov.in/drugregulation

manufacturing units for a period of three days. At least five rounds of such inspections involving 136 units have been carried out so far.[14]

Responses to pointed questions posed in RTI applications about the number and nature of training sessions conducted by CDSCO for in-house officers reveals that only eight training programmes have been conducted in the period between April 2015 and January 2019. Of these, half (4 training programmes) were clearly identified as induction training programmes for new recruits.

S No	Training Programme	Course duration	Participants
1	Training for drugs inspectors	One month	87 Drug Inspectors
2	Investigation techniques and launching of prosecution for drugs inspectors	3 weeks	57 Drug Inspectors
3	Good clinical practices	3 days	61 Drug Inspectors
4	Risk based inspection of manufacturing facilities	4 batches of 6 days each	240 Assistant Drug Controllers, Drug Inspectors, Assistant Drug Inspectors and Government Analysts

Training programmes could be held more regularly and be tailored to respond on a needs-basis, depending on the skills and techniques that drugs controllers, drugs inspectors, and government analysts are likely to need on the field. The development of the training programme on risk-based inspection was a case in point of such responsive design. However, a one-time training programme is not likely to serve much purpose in ensuring the robust functioning of the regulatory machinery.

[14] Lok Sabha Unstarred Question no. 440 answered by the Minister of State in the Ministry of Health and Family Welfare on 16th December 2016.

Judicial take on working of CDSCO

The author has summarized using table a list of cases where court highlighted fault of CDSCO–

CASE	YEAR	COURT	FAULT IDENTIFIED
Swasthya Adhikar Manch v. UOI — WP(C) 33/2012	2012–2013	Supreme Court	Failure to regulate clinical trials; "deep slumber"; DCGI powers revoked by Health Secretary.
Kalpana Mehta v. UOI — WP(C) 558/2012 & 921/2013	2012–2018	Supreme Court (Constitution Bench)	Irregular HPV vaccine approval by DCGI; failure to obtain consent from minors; file production ordered.
Dinesh Thakur v. UOI — WP(C) 2016	2016	Supreme Court	Illegal drug approvals; missing files; no drug recall framework; lack of statutory basis for CDSCO.
Jitendra Chouksey v. UOI (Delhi HC)	2025	Delhi High Court	Inadequate evaluation before approving diabetes drugs for off-label weight loss use.

CONCLUSION

The solution to combat the arbitrariness with which DCGI approves new drugs for Indian population is to insist on transparency at every level of drug approval process. Bureaucrats who are aware that their decisions are going to be publicly accessible are more likely to behave themselves and will follow the law. The USFDA publishes on its website different reviews of new drug application which includes a medical review, pharmacology review etc. Detailed notes on approval of proprietary name, labelling and all communications between the USFDA and the pharmaceutical company are also made publicly available. Creating pressure on Ministry of Health to publish all records pertaining to drug approval can led to more transparency and helps us to maintain standards followed by developed countries.