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Review Article

Role of CDSCO in Drug Approval in India

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ABSTRACT

The research is guided by seven secondary objectives mapping regulatory pathways for different drug categories (NCEs, foreign-approved drugs, generics, biosimilars, FDCs, and imported drugs); assessing efficiency and transparency through timeline analysis, bottleneck identification, and evaluation of the SUGAM portal; identifying systemic challenges including human resource shortages, infrastructure limitations, conflicts of interest, and coordination failures with State Drug Controllers; evaluating the Pharmacovigilance Program of India (PvPI), post-marketing study completion rates, and recall mechanisms; conducting comparative performance analysis across key regulatory metrics; analyzing recent reforms under the New Drugs and Clinical Trials Rules of 2019; and providing actionable recommendations for strengthening CDSCO. Key findings indicate that while CDSCO has evolved from a passive licensing body to a more active gatekeeper—particularly following the 2005 Schedule Y revisions, the 2019 New Drugs and Clinical Trials Rules, and the SUGAM portal—persistent challenges remain. These include chronic understaffing compared to mature regulators, weak pharmacovigilance with adverse drug reaction reporting rates below 1% of expected levels, proliferation of irrational fixed-dose combinations, and limited transparency in decision-making. Historical tragedies such as the substandard glycerin deaths (1970s) and recent cough syrup fatalities in Gambia and Uzbekistan (2022) underscore the catastrophic consequences of regulatory gaps. The study concludes that meaningful reform requires optimal staffing levels, risk-based inspection approaches, enhanced public-private partnerships for pharmacovigilance, legislative changes to ensure regulatory independence, and greater public disclosure of review documents and approval decisions. This thesis provides a comprehensive foundation for future research and policy advocacy aimed at transforming CDSCO into a world-class regulator capable of protecting public health while supporting India's role as a global pharmaceutical leader.

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INTRODUCTION

The Central Drugs Standard Control Organization (CDSCO)

Organizational Structure and Statutory Mandate

The Central Drugs Standard Control Organization (CDSCO) serves as the apex national regulatory authority for pharmaceuticals and medical devices in India, operating under the Directorate General of Health Services within the Ministry of Health and Family Welfare. Headquartered in New Delhi, CDSCO maintains an extensive network of zonal offices, port offices, and laboratories strategically located across the country to facilitate drug regulation at points of import, manufacturing, and distribution. The organization derives its statutory mandate primarily from two foundational legal instruments: the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945, which together establish the legal framework for import, manufacture, distribution, and sale of drugs in India. Under this legal framework, CDSCO is responsible for approving new drugs, conducting clinical trial oversight, regulating blood banks, setting standards for drugs, and coordinating with State Drug Control Authorities on enforcement matters.

India's Position as "Pharmacy of the World"

India has earned the designation "pharmacy of the world" due to its preeminent position as the largest global provider of generic drugs, supplying over 50 percent of global demand for various vaccines and approximately 40 percent of generic drugs to the United States pharmaceutical market. The Indian pharmaceutical market is currently valued at over \$50 billion USD and continues to experience rapid growth, driven by increasing domestic healthcare demand, expanding export

markets, and the expiration of patents on numerous blockbuster drugs. This immense production capacity, while economically advantageous, carries profound public health responsibilities regarding drug safety, efficacy, and quality that must be rigorously enforced through effective regulation. Without a robust regulatory framework, the risk of substandard, spurious, misbranded, or otherwise unsafe drugs reaching patients—both within India and across international borders—increases substantially, potentially causing widespread harm and undermining trust in Indian pharmaceuticals.

Historical Evolution and Regulatory Tragedies

Drug regulation in India remained relatively permissive throughout much of the 20th century, with limited pre-market oversight and minimal post-marketing surveillance requirements compared to Western regulatory systems. The Bhopal gas tragedy of 1984, involving the release of methyl isocyanate gas at a Union Carbide pesticide plant, served as a catastrophic wake-up call regarding industrial safety and chemical regulation, indirectly influencing pharmaceutical oversight. The early 2000s witnessed revelations of widespread unethical clinical trials being conducted in India, including trials on illiterate patients without proper informed consent, pediatric trials for adult indications, and numerous unreported deaths. These tragedies and scandals forced a fundamental reevaluation of regulatory oversight, prompting CDSCO to evolve from a passive licensing body that primarily processed applications into a more active gatekeeper responsible for proactive safety monitoring.

Key Regulatory Milestones

The introduction of Schedule Y to the Drugs and Cosmetics Rules in 2005 represented a watershed moment, establishing comprehensive



requirements for clinical trial approval, ethical review, and Good Clinical Practice standards in India. The New Drugs and Clinical Trials Rules of 2019 consolidated and modernized the regulatory framework, introducing provisions for accelerated approval pathways, compensation for trial-related injuries, and waiver of local clinical trials for drugs approved in certain foreign jurisdictions. The establishment of the SUGAM online portal represented a significant technological advancement, enabling transparent electronic submission, processing, and tracking of drug applications while reducing opportunities for corruption and delay. Despite these advancements, CDSCO continues to face persistent criticism from industry stakeholders, public health advocates, and parliamentary committees regarding excessive approval delays, lack of transparency in decision-making, and chronic understaffing compared to mature regulators like the US Food and Drug Administration (USFDA) or European Medicines Agency (EMA) [1].

Importance of Understanding CDSCO's Role

Understanding the precise role of CDSCO in drug approval is essential not only for pharmaceutical companies seeking market access but also for public health policymakers designing effective regulatory systems. Clinicians require knowledge of the approval pathway to understand the evidence base underlying prescribed medications and to communicate appropriately with patients about drug safety. Patients, as ultimate consumers of approved drugs, have a legitimate interest in understanding how their medications were evaluated and what post-marketing surveillance systems exist to detect adverse events.

Public Health Protection as Paramount Objective

Protecting public health constitutes the paramount objective of any drug regulatory system, as unsafe or ineffective drugs can cause preventable morbidity, mortality, and long-term disability across populations. The Substandard Glycerin tragedy of the 1970s, which caused over 300 deaths in Mumbai due to contaminated glycerin used in pediatric formulations, stands as an early example of catastrophic quality control failures with devastating human consequences.

More recently, deaths linked to contaminated cough syrups exported to Gambia and Uzbekistan in 2022 highlighted that such failures continue to occur, with investigations revealing unacceptable levels of diethylene glycol and ethylene glycol in products marketed to children. Without rigorous pre-market approval requirements and robust post-marketing surveillance systems, these types of tragedies become more frequent and widespread, potentially affecting vulnerable populations including children, elderly patients, and immunocompromised individuals. CDSCO's core function is to ensure that every drug sold in India has demonstrated acceptable safety and efficacy through well-conducted clinical trials or, in the case of generic drugs, through demonstrated bioequivalence to approved reference products [2].

Historical Legacy of Inadequate Oversight

Prior to the 2005 amendments to the Drugs and Cosmetics Rules, India did not explicitly require mandatory clinical trial approval for new drugs that had already received approval in foreign countries, creating a dangerous loophole exploited by manufacturers. This loophole allowed drugs that had been withdrawn from Western markets due to safety concerns to be introduced into the Indian market without independent evaluation of risk-benefit profiles for Indian populations. Between 2005 and 2015, extensive investigations revealed thousands of cases of unethical clinical



trial practices occurring across India, including trials conducted on illiterate patients who could not read consent forms, trials on vulnerable populations without adequate safeguards, and deaths not properly reported to regulatory authorities. Specific violations included enrolling children in trials intended for adult drugs, failing to obtain proper informed consent from trial participants, conducting trials without Institutional Ethics Committee approval, and systematically underreporting serious adverse events including deaths. This pattern of unethical conduct created a legitimacy crisis for Indian clinical research, damaging India's reputation as a destination for ethical clinical trials and undermining public confidence in the pharmaceutical industry. Strong regulation by CDSCO is necessary to restore and maintain ethical standards, ensure protection of human subjects participating in clinical research, and rebuild public trust in the drug approval system.

Globalization and Export Obligations

India exports pharmaceuticals to over 200 countries worldwide, including highly regulated markets such as the United States, European Union member states, Japan, Australia, and Canada, each with its own regulatory requirements and inspection regimes. Any failure in drug safety or quality at Indian manufacturing facilities leads directly to import alerts, product bans, supply disruptions, and significant reputational damage to both individual companies and the Indian pharmaceutical industry as a whole. The USFDA has frequently issued import alerts against major Indian pharmaceutical companies including Ranbasaki Laboratories (now part of Sun Pharma), Sun Pharmaceutical Industries, and others for data integrity issues, manufacturing violations, and failure to comply with Good Manufacturing Practice standards. These import alerts result in

significant economic consequences, including lost revenues, increased regulatory scrutiny, mandatory third-party audits, and in some cases, criminal prosecution of company executives. CDSCO must harmonize its approval processes with International Council for Harmonisation (ICH) guidelines to ensure that drugs approved in India are also acceptable to foreign regulators, avoiding duplicative testing requirements and reducing barriers to export.

Without such alignment, Indian pharmaceutical exporters face regulatory barriers that increase costs, delay market access, and place them at competitive disadvantage relative to manufacturers from countries with more harmonized regulatory systems.

India's Unique Disease Burden and Demographic Diversity

India's unique disease burden includes endemic diseases such as dengue fever, chikungunya, scrub typhus, visceral leishmaniasis, and specific strains of tuberculosis that are less common or entirely absent in Western countries where most new drug development occurs. Drugs or vaccines developed for these diseases may never have been tested abroad due to lack of commercial incentive or absence of patient populations in Western countries where clinical trials would be conducted. CDSCO must therefore possess the indigenous regulatory capacity and scientific expertise to evaluate clinical trial data generated specifically in Indian populations, accounting for genetic, dietary, environmental, and lifestyle differences that substantially affect drug metabolism and safety profiles.

Genetic polymorphisms affecting drug-metabolizing enzymes differ significantly between Indian and Western populations, meaning that drugs found safe and effective in predominantly



Caucasian populations may have different risk-benefit profiles when used in India. Dietary practices, including prevalence of vegetarianism and use of specific spices and herbs, can interact with drug metabolism in ways not captured by clinical trials conducted in populations with different dietary patterns. Environmental factors including air pollution, water quality, and prevalence of infectious diseases can affect drug absorption, distribution, metabolism, and excretion, necessitating locally generated safety and efficacy data [3].

Fixed-Dose Combinations as a Special Challenge

India has witnessed a proliferation of Fixed-Dose Combinations (FDCs)—formulations containing two or more active pharmaceutical ingredients combined in a single pill—many of which lack adequate scientific justification for the combination. The number of FDCs approved in India dramatically exceeds that approved in any other major pharmaceutical market, with thousands of unique combinations available, many of which have never been subject to rigorous clinical evaluation. In 2016, the Government of India banned over 300 irrational FDCs following CDSCO review, including combinations such as painkillers combined with antidepressants and antibiotics combined with antidiarrheals, which lacked therapeutic rationale and posed potential safety risks. Many prohibited FDCs continued to be marketed despite the ban, requiring litigation and regulatory enforcement actions to achieve compliance, demonstrating the challenges of post-approval surveillance and enforcement. This situation demonstrates the ongoing need for vigilant regulation to prevent irrational, potentially harmful combinations from flooding the market and exposing patients to unnecessary risks without corresponding therapeutic benefits.

Weak Pharmacovigilance Infrastructure

Pharmacovigilance—the science and activities relating to detection, assessment, understanding, and prevention of adverse drug reactions—remains critically weak in India compared to mature regulatory systems. India's adverse drug reaction (ADR) reporting rate is estimated at less than one percent of expected numbers based on World Health Organization (WHO) reporting norms, indicating massive underreporting of drug safety problems. CDSCO oversees the Pharmacovigilance Program of India (PvPI), established in 2010 and operating through a network of ADR monitoring centers across the country, but underreporting and lack of healthcare provider awareness remain persistent challenges. Dangerous drugs may remain on the market for years before safety signals are detected through pharmacovigilance systems, during which time preventable adverse events continue to occur. Regulation must extend beyond pre-market approval to include continuous monitoring throughout the drug life cycle, with mechanisms for updating product labeling, restricting use, or withdrawing drugs when new safety concerns emerge [4]. The primary objective of this thesis is to critically evaluate the end-to-end drug approval process administered by CDSCO, encompassing pre-clinical trial permissions, clinical trial oversight, new drug application (NDA) review, and post-marketing surveillance systems. This evaluation is conducted in comparison with global best practices as exemplified by mature regulatory authorities including the USFDA, EMA, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). The evaluation employs multiple metrics including approval timelines, stringency of evidence requirements, transparency of decision-making, and effectiveness of post-market safety monitoring.



Mapping Regulatory Pathways

The first secondary objective is to map the regulatory pathway for different categories of drugs in India, recognizing that distinct regulatory requirements apply to each category. For New Chemical Entities (NCEs) developed domestically, the pathway requires comprehensive pre-clinical data, phased clinical trials culminating in Phase 3 confirmatory studies, and a New Drug Application supported by complete clinical study reports.

For new drugs already approved in foreign countries such as the United States, European Union, or Japan, the pathway may qualify for waiver of local clinical trials under certain conditions specified in the New Drugs and Clinical Trials Rules of 2019. Generic drugs require demonstration of bioequivalence to a reference product approved in India, with different requirements depending on the complexity of the molecule and therapeutic category. Biosimilars require a distinct pathway including comparative analytical studies, non-clinical studies, and clinical studies to demonstrate similarity to a reference biologic product. Fixed-Dose Combinations (FDCs) require justification for the combination, data demonstrating that each component contributes to the claimed effect, and evidence that the combination does not increase risk beyond that of individual components. Imported drugs must meet all requirements applicable to domestically manufactured drugs, with additional requirements related to manufacturing site inspection and certification by the regulatory authority of the country of origin.

Assessing Efficiency and Transparency

The second secondary objective is to assess the efficiency and transparency of CDSCO's approval process through systematic analysis of multiple

performance indicators. Average approval timelines from application submission to market authorization are analyzed by drug category, distinguishing between standard approvals, priority reviews, and accelerated approvals. Bottlenecks and delays at various stages of the approval process are identified, including delays in Subject Expert Committee (SEC) reviews, requests for additional data, and final approval processing. The impact of online systems, specifically the SUGAM portal for electronic application processing, is evaluated for its effect on reducing processing time, improving transparency, and reducing opportunities for corruption. Public availability of approval decisions, clinical trial data, inspection reports, and review summaries is assessed against international transparency standards established by organizations such as the WHO and the International Coalition of Medicines Regulatory Authorities (ICMRA).

Identifying Systemic Challenges

The third secondary objective is to identify systemic and structural challenges facing CDSCO that impede optimal regulatory performance. Human resource shortages are analyzed by comparing the number of scientific reviewers employed by CDSCO against the volume of applications received, with benchmarking against reviewer-to-application ratios at USFDA and EMA. Infrastructure limitations, specifically laboratory facilities for drug testing and quality control, are assessed for their capacity to handle the volume of samples requiring analysis. Conflicts of interest arising from CDSCO's dual role as both policymaker (setting regulatory standards) and enforcer (inspecting and sanctioning non-compliant manufacturers) are examined. Coordination failures between CDSCO and State Drug Controllers, who share



responsibility for drug regulation under India's federal structure, are identified as sources of inconsistent enforcement and regulatory gaps.

Evaluating Post-Approval Surveillance

The fourth secondary objective is to evaluate the post-approval surveillance mechanisms employed by CDSCO, specifically the Pharmacovigilance Program of India (PvPI). The effectiveness of PvPI in detecting adverse events is assessed through analysis of adverse drug reaction reporting rates, timeliness of signal detection, and actions taken in response to identified safety concerns. The rate of post-marketing studies mandated by CDSCO as a condition of approval is quantified, along with the proportion of such studies that are actually completed and submitted for review. The recall mechanism for unsafe drugs is evaluated for its effectiveness, including the legal authority to compel recalls, timeliness of recall initiation, and completeness of recall execution.

Comparative Performance Analysis

The fifth secondary objective is to compare CDSCO's performance with mature regulators including USFDA, EMA, and PMDA across key regulatory metrics. Timelines for standard approvals, accelerated approvals, and priority reviews are compared across regulators to identify relative performance and areas for improvement. Stringency of clinical trial data requirements, including standards for data quality, statistical analysis, and safety reporting, is compared to identify gaps in Indian requirements. Transparency of decision-making, including public disclosure of review documents, approval summaries, and inspection reports, is benchmarked against transparency policies of comparator regulators.

Analyzing Recent Regulatory Reforms

The sixth secondary objective is to analyze recent regulatory reforms, particularly the New Drugs and Clinical Trials Rules of 2019, and assess their impact on drug approval in India. Provisions for waiver of local clinical trials for drugs approved in certain foreign countries are analyzed for their effect on access to innovative medicines and their potential risks. Compensation requirements for clinical trial-related injury or death are evaluated for their adequacy in protecting trial participants and their implementation in practice. Accelerated approval pathways for orphan drugs and rare diseases are assessed for their accessibility and effectiveness in bringing treatments for rare diseases to the Indian market [5-10].

Secondary Objective Seven: Providing Actionable Recommendations

The seventh secondary objective is to provide actionable, evidence-based recommendations for strengthening CDSCO's regulatory capacity and performance. Optimal staffing levels and organizational restructuring proposals are developed based on benchmarking against comparator regulators and workload analysis. Adoption of risk-based inspection approaches, prioritizing manufacturing sites and products based on risk factors rather than fixed schedules, is recommended to improve inspection efficiency. Enhanced public-private partnerships for pharmacovigilance, leveraging healthcare providers, academic institutions, and industry resources, are proposed to improve adverse event reporting. Legislative changes to enable greater independence from political interference, including protections for regulatory decision-makers and transparent appointment processes, are recommended.



CONCLUSION

The Central Drugs Standard Control Organization stands at a critical juncture in India's public health history. As the nation solidifies its position as the "pharmacy of the world," the regulator's ability to ensure drug safety, efficacy, and quality directly impacts not only India's 1.4 billion citizens but also patients in over 200 countries that rely on Indian pharmaceuticals. This thesis has systematically examined CDSCO's drug approval role across two decades of regulatory evolution, from the permissive era prior to 2005 through the transformative New Drugs and Clinical Trials Rules of 2019 to the present day. The analysis reveals that CDSCO has made substantial progress in several critical areas. The introduction of Schedule Y in 2005 established a formal framework for clinical trial approval and ethical oversight, closing dangerous loopholes that had previously allowed untested drugs to enter the Indian market. The 2019 Rules introduced accelerated approval pathways for orphan drugs, provisions for waiving local clinical trials for drugs approved in recognized foreign jurisdictions, and compensation requirements for trial-related injuries. The SUGAM online portal has improved application processing transparency and reduced opportunities for corruption. These achievements demonstrate CDSCO's capacity for meaningful reform when political will and administrative resources align.

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