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Review Article

Comparative Analysis of New Drugs Approval Process in India vs. CIS Countries (Russia & Kazakhstan)

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ABSTRACT

The approval process for new drugs is a critical regulatory pathway that ensures the safety, efficacy, and quality of pharmaceutical products before market authorization. Different countries adopt distinct regulatory frameworks based on their healthcare priorities, legal systems, and harmonization policies. This review article presents a comparative analysis of the new drug approval processes in India and the Commonwealth of Independent States (CIS) countries, particularly Russia and Kazakhstan. In India, the approval pathway is regulated by the Central Drugs Standard Control Organization under the provisions of the Drugs and Cosmetics Act and New Drugs and Clinical Trials Rules, 2019. In contrast, Russia and Kazakhstan follow regulatory procedures influenced by the Eurasian Economic Union (EAEU) guidelines and national regulatory authorities. The review compares major regulatory aspects including application submission, clinical trial requirements, dossier format, timelines, Good Manufacturing Practice (GMP) inspections, pharmacovigilance obligations, and marketing authorization procedures. The study highlights similarities and differences in regulatory expectations, approval timelines, and documentation standards among these regions. Furthermore, the increasing trend toward international harmonization and reliance mechanisms is discussed. Understanding these regulatory variations is essential for pharmaceutical companies seeking global market access and efficient regulatory strategy planning.

INTRODUCTION

1.1 Importance of New Drug Approval Systems

The approval of new drugs is a cornerstone of public health protection, ensuring that medicinal products made available to patients demonstrate acceptable standards of safety, efficacy, and quality. Regulatory authorities function as

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scientific gatekeepers, critically evaluating preclinical, clinical, and manufacturing data before granting marketing authorization [1]. Inadequate regulatory oversight can result in severe public health consequences, while overly restrictive systems may delay patient access to life-saving therapies [2]. With increasing therapeutic complexity, including biologics, targeted therapies, and advanced formulations, regulatory decision-making has evolved into a multidisciplinary scientific process integrating clinical medicine, toxicology, pharmacology, biostatistics, and regulatory science [3]. Modern drug approval systems therefore aim to balance patient safety with innovation facilitation [4].

1.2 Historical Evolution of Drug Regulation

Early drug regulation focused primarily on preventing adulteration and ensuring product quality, with minimal emphasis on therapeutic efficacy [5]. However, catastrophic events such as the thalidomide tragedy of the 1960s highlighted the need for rigorous pre-marketing clinical evaluation and post-marketing surveillance [6]. These events triggered global regulatory reforms, leading to mandatory clinical trials, strengthened pharmacovigilance systems, and risk-benefit–based regulatory decision-making [7]. As a result, national regulatory authorities adopted structured drug approval frameworks incorporating phased clinical trials, regulatory review timelines, and post-authorization safety monitoring [8].

1.3 Globalization of Pharmaceutical Development

The pharmaceutical industry has undergone extensive globalization, with drug discovery, clinical trials, manufacturing, and distribution occurring across multiple jurisdictions [9]. Multinational clinical trials have become standard practice, generating data intended for submission to several regulatory agencies simultaneously [10]. This globalization has created significant regulatory challenges due to divergent national requirements, documentation formats, and approval timelines [11]. Consequently, international harmonization initiatives such as the International Council for Harmonisation (ICH) have emerged to align technical requirements for drug registration [12]. Despite harmonization efforts, regulatory divergence remains a key obstacle to efficient global drug development [13].

1.4 Indian Drug Regulatory Framework

India is one of the world's largest pharmaceutical producers and exporters, supplying medicines to more than 200 countries [14]. The Indian drug regulatory system is governed by the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, with the Central Drugs Standard Control Organization (CDSCO) acting as the national regulatory authority [15]. The CDSCO oversees approval of new drugs, clinical trials, fixed-dose combinations, biologics, and import/export licenses [16]. Historically, the Indian regulatory framework faced criticism due to lack of defined timelines, inconsistent regulatory interpretation, and limited regulatory capacity [17].

1.5 New Drugs and Clinical Trials Rules (NDCTR), 2019

The introduction of the New Drugs and Clinical Trials Rules (NDCTR), 2019 marked a major regulatory milestone in India [18]. These rules replaced Schedule Y and introduced structured approval timelines, simplified clinical trial permissions, strengthened ethics committee oversight, and introduced compensation mechanisms for trial-related injury [19]. The NDCTR-2019 aimed to improve transparency, predictability, and ease of doing business while

maintaining subject protection [20]. However, studies indicate that operational challenges such as repeated deficiency queries, variability in expert committee review, and reliance on local clinical data continue to impact approval timelines [21].

1.6 Overview of CIS Countries and Pharmaceutical Regulation

The Commonwealth of Independent States (CIS) emerged following the dissolution of the Soviet Union and includes countries with shared historical and regulatory legacies [22]. Among these, Russia and Kazakhstan represent the most significant pharmaceutical markets due to population size, economic capacity, and healthcare expenditure [23]. Historically, CIS regulatory systems were centralized, state-controlled, and less transparent compared to Western regulatory authorities [24]. However, increasing integration into the global pharmaceutical market has driven substantial regulatory modernization [25].

1.7 Drug Regulatory System in Russia

Russia regulates medicinal products under Federal Law No. 61-FZ "On Circulation of Medicines", enacted in 2010 [26]. This law governs all aspects of drug development, including clinical trials, state registration, manufacturing, quality control, and pharmacovigilance [27]. The Russian Ministry of Health acts as the primary regulatory authority, supported by expert organizations responsible for scientific evaluation [28]. Drug registration in Russia traditionally required local clinical trials, extensive documentation, and Russian-language submissions, contributing to prolonged approval timelines [29]. Recent reforms have focused on aligning Russian regulatory practices with international standards, including partial adoption of ICH guidelines and electronic submission systems [30].

1.8 Drug Regulatory System in Kazakhstan

Kazakhstan historically regulated medicines through national legislation administered by the Ministry of Health and subordinate regulatory bodies [31]. The regulatory framework emphasized state expertise, price control, and centralized procurement [32]. Due to limited domestic pharmaceutical capacity, Kazakhstan has relied heavily on imported medicines, increasing the importance of efficient regulatory processes [33]. Prior to regional harmonization, approval timelines were often lengthy and unpredictable [34].

1.9 Eurasian Economic Union (EAEU) and Regulatory Harmonization

A major regulatory transformation occurred with the establishment of the Eurasian Economic Union (EAEU), comprising Russia, Kazakhstan, Belarus, Armenia, and Kyrgyzstan [35]. The EAEU introduced harmonized rules for medicinal product registration through Decision No. 78 (2016) [36]. Under the EAEU framework, a single reference country conducts scientific assessment, while other member states participate through mutual recognition procedures [37]. This system aims to reduce duplication, improve regulatory efficiency, and align with international best practices [38].

1.10 Impact of EAEU on Russia and Kazakhstan

The EAEU regulatory framework significantly altered national drug approval systems in Russia and Kazakhstan [39]. While Russia acts as a leading reference authority, Kazakhstan benefits from reliance on regional assessments [40]. However, transition challenges include conversion of national registrations to EAEU format, language requirements, GMP inspection coordination, and procedural ambiguity during

implementation [41]. Studies report that these challenges have affected approval timelines and industry compliance [42].

1.11 Comparative Perspective: India vs Russia & Kazakhstan

India follows a centralized national regulatory system, whereas Russia and Kazakhstan operate under a regionalized EAEU framework supported by national authorities [43]. Indian approvals emphasize ethics committee oversight and local clinical trials, while CIS approvals focus on dossier completeness and expert evaluation [44]. Differences also exist in approval timelines, documentation requirements, and post-approval obligations such as variations management and pharmacovigilance reporting [45].

1.12 Importance of Comparative Regulatory Analysis

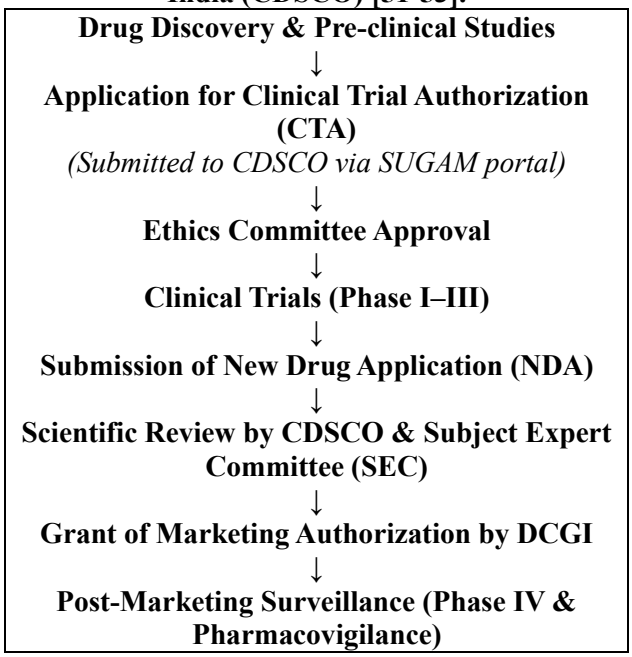
Comparative regulatory analysis provides valuable insights into regulatory efficiency, transparency, and harmonization potential [46]. For Indian pharmaceutical companies targeting CIS markets, understanding regulatory expectations in Russia and Kazakhstan is essential for strategic planning and compliance [47]. Such studies also support regulatory capacity building and policy reforms by identifying gaps and best practices [48].

1.13 Research Gap and Rationale

Although numerous studies examine Indian or CIS regulatory systems independently, comprehensive comparative analyses focusing on India versus Russia and Kazakhstan remain limited [49]. Existing literature often lacks detailed evaluation of EAEU implementation challenges and their implications for global pharmaceutical development [50].

2. METHODOLOGY

Flow Chart 1: New Drug Approval Process in India (CDSCO) [51-53].



The new drug approval processes in India, Russia, and Kazakhstan follow a structured, stepwise regulatory pathway but differ in governance, procedural emphasis, and harmonization approach. In India, the process is centrally regulated by CDSCO under the NDCTR-2019 framework, beginning with pre-clinical studies, followed by clinical trial authorization, ethics committee approval, phased clinical trials, submission of a New Drug Application, and grant of marketing authorization by the DCGI, with strong emphasis on ethical oversight and post-marketing pharmacovigilance. In Russia, new drug approval is governed by Federal Law No. 61-FZ and involves mandatory local clinical trials, submission of a CTD-formatted dossier, expert scientific evaluation, and state registration of the medicinal product in the State Register of Medicines (GRLS), reflecting a more expert-driven and nationally controlled review system. Kazakhstan, operating largely under the EAEU harmonized regulatory framework, follows a regional pathway that includes dossier submission

to a reference EAEU authority, expert evaluation, mutual recognition

Flow Chart 2: New Drug Approval Process in Russia [54-56].

Pre-clinical Development

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Submission of Clinical Trial Application to Ministry of Health (MoH)

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Local Clinical Trials in Russia

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Preparation of Registration Dossier (CTD Format)

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Expert Evaluation by Scientific Expert Organization

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State Registration of Medicinal Product

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Inclusion in State Register of Medicines (GRLS)

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Post-Marketing Pharmacovigilance

Flow Chart 3: New Drug Approval Process in Kazakhstan (EAEU Route) [57-59].

Pre-clinical & Clinical Development

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Submission of Application to Reference EAEU Authority

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Expert Evaluation by EAEU Regulatory Body

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Mutual Recognition Procedure (MRP)

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Grant of EAEU Marketing Authorization

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National Approval in Kazakhstan

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Post-Marketing Surveillance & Variations Management

Aim:- To compare and critically analyze the new drug approval processes in India and CIS countries (Russia & Kazakhstan) to identify opportunities for harmonization and regulatory efficiency.

Objectives:-

1. To review the existing regulatory frameworks and legal provisions governing new drug approvals in India, Russia, and Kazakhstan.
2. To analyze and compare procedural pathways, dossier requirements, and approval timelines across these regions.
3. To identify regulatory challenges, bottlenecks, and differences in clinical trial and GMP inspection requirements.
4. To assess the impact of harmonization initiatives such as EAEU regulations and India's NDCTR 2019 on drug approval efficiency.
5. To propose recommendations for improving transparency, efficiency, and alignment of India's and CIS countries' drug approval processes.

CONCLUSION

The comparative evaluation of new drug approval processes in India, Russia, and Kazakhstan demonstrates that although all three regulatory systems aim to ensure drug safety, efficacy, and quality, they differ significantly in procedural requirements, documentation standards, review timelines, and regulatory frameworks. India follows a relatively structured and evolving regulatory system under CDSCO with increasing alignment toward international standards such as ICH guidelines. Conversely, Russia and Kazakhstan operate through regulatory mechanisms influenced by the Eurasian Economic Union, emphasizing regional harmonization and unified pharmaceutical regulations. Differences in clinical trial requirements, language specifications, GMP inspections, and pharmacovigilance obligations present both

opportunities and challenges for pharmaceutical manufacturers seeking multinational approvals.

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