International Journal of Basic & Clinical Pharmacology
Shaikh AI et al. Int J Basic Clin Pharmacol. 2024 Nov;13(6):872-876
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20243037

Original Research Article

An analysis of drug approvals in India over past 5 years

Aarmin I. Shaikh*, Chetankumar R. Acharya, Akash M. Shah, Manan G. Moradiya, Jay R. Patel, Aayushi H. Patel, Mehul V. Bhanderi

Department of Pharmacology, Government Medical College, Surat, Gujarat, India

Received: 10 September 2024
Accepted: 07 October 2024

***Correspondence:**
Dr. Aarmin I. Shaikh,
Email: aarminshaikh1998@gmail.com

ABSTRACT

Background: Drug development is a tedious process and takes a long time for approval by regulatory authorities. With time, Indian authorities have revised rules and regulations for conducting clinical trials as well as for the marketing of drugs, impacting the number of drugs being approved.
Method: The information about drug approvals from 2019–2023 was obtained from the CDSCO website. The single drug products were classified into 14 main anatomical therapeutic chemical (ATC) groups, while Fixed Dose Combinations (FDCs) were classified based on the system they act upon. Descriptive statistical analysis was done. The findings of our observational study were expressed as absolute numbers and percentages.
Results: Total 362 drugs were approved. Out of these, 135 were single drug products, and the rest were FDCs. The highest & lowest number of drugs were approved in the year 2022 and 2019 respectively. Maximum single drug product approvals were seen in Category L-antineoplastic and immunomodulating agents, while maximum FDC approvals were for drugs acting on the endocrine system.
Conclusion: There is a rising trend of approval for FDCs. The pattern of single drug products approval flattened over the years, coinciding with the implementation of new rules and regulations.

Keywords: CDSCO, New drug development, FDC, Drug approval, ATC group

INTRODUCTION

The approval process for new drugs in India is lengthy, spanning over a decade from research and development to market launch.[1] The government plays a crucial role in ensuring the effectiveness, safety, and quality of medications through stringent regulatory oversight. India's pharmaceutical industry historically excelled in producing high-quality, affordable generic drugs, enabled by process patents allowing legal reverse engineering of foreign drugs. However, since 2005 under World Trade Organization (WTO) agreements, India transitioned to recognizing product patents for new chemical entities (NCEs), marking the end of over 35 years of protection for reverse engineering practices. This policy shift facilitated multinational corporations (MNCs) to re-enter the Indian market, establishing their own manufacturing and R&D facilities, thereby enhancing domestic drug availability.[2] India's drug regulations originated during British colonial rule due to concerns over adulterated drugs, leading to the enactment of the Drugs and Cosmetics Act (DCA) in 1940 following recommendations by the Chopra Committee.[3] The Act was further detailed by the Drugs and Cosmetics Rules of 1945, which have since undergone numerous amendments to accommodate advancements in biomedical research and clinical trials. Key changes in 2008 and 2013 included the establishment of ethics committees registered with the Clinical Trials Registry India (CTRI) and mandatory audiovisual recording of informed consent.[4] In 2019, the New Drugs and Cosmetics Act was introduced after a major amendment with significant changes, separate ethics committees for biomedical and health

research were established, along with provisions for waivers in preclinical studies and conditional approvals for clinical trials if the drug is approved in certain developed countries. These updates have profound implications for India's pharmaceutical sector and drug development processes.[5]

The drug approval process differs across countries. In the USA, it's overseen by the United States Food and Drug Administration (USFDA); in Canada, by Health Canada; and in Japan, by the Pharmaceutical and Medical Devices Agency (PMDA).[6] In India, Central Drugs Standard Control Organisation (CDSCO), under the Drugs Controller General of India (DCGI), handles drug approval, with responsibilities divided between state and central authorities.[7] The CDSCO manages clinical trial approvals, regulation of standards, inspection of clinical trial sites, and international coordination, while State Drug Regulatory Authorities (SDRAs) oversee drug manufacturing, sales and distribution. Additionally, the submission of Periodic Safety Update Reports (PSURs) is mandatory for the marketing approval of new drugs.[3] In India, drug approval involves two phases: non-clinical studies for assessment of safety and efficacy, followed by clinical trials (Phases I-IV) after receiving necessary approvals.[8] Fixed dose combinations (FDCs), favoured for patient compliance, are classified as new drugs and require a clear declaration of their global regulatory status in the application, as per Form 44 under the Drug and Cosmetics Act of 1940 and Rules of 1945.[9]

To understand these effects, a review of drug approvals in India from 2019 to 2023 was conducted. The study aimed to examine the influence of regulatory amendments on the approval landscape and the broader implications for India's pharmaceutical industry.

METHODS

The information about drug approvals was primarily obtained from the CDSCO website (as accessed on 31 May 2024).[10] The drugs approved between 1st January 2019 to 31st December 2023 that were intended for human use were included. For analysis, both approved single drug products as well as combinations were taken into consideration.[8]

Single drug products were classified into fourteen main groups as per the Anatomical Therapeutic Chemical (ATC) classification system.[11] FDCs were classified based on the system they act upon.

Statistical analysis

Descriptive statistical analysis was done using Microsoft Excel 2021. The values were expressed as percentage, mean±standard deviation (SD), median and range. The trend of drug approval over the years was depicted as a line diagram.

RESULTS

Over the last 5 years, CDSCO has approved a total of 362 drugs with a mean of 72.8±14.84 (SD) approvals per year (median approvals per year: 72; range: 49-89). The year-wise distribution of the total number of approvals is shown in table 1. Out of these 362 approvals, 135 were single drug products and the remaining 227 were FDCs (Table 1).

Table 1: The year-wise distribution of the total number of approvals.

Year	Single drug products	Fixed dose combinations	Total no of approvals %
2023	27	53	80 (22.10)
2022	30	59	89 (24.58)
2021	25	47	72 (19.89)
2020	27	45	72 (19.89)
2019	26	23	49 (13.54)
Total	135	227	362 (100)

Table 2: Drug products approved per year in terms of mean, median and range.

	Mean±SD*	Median	Range
Total no. of approvals (n= 362)	72.4±14.84	72	49-89
Single drug product approvals (n=135)	27±11.15	27	25-30
Combination drug product approvals (n=227)	45.8±13.67	47	23-59

*SD: standard deviation.

Table 3: Combination drug products approved in India categorised based on the system they act upon.

System	No. of approvals (%)
Endocrinology	54 (23.79)
Cardiovascular system and blood	42 (18.50)
Respiratory system	34 (14.98)
Miscellaneous	23 (10.13)
Infectious diseases	16 (7.05)
Pain management and anaesthesia	15 (6.61)
Gastrointestinal system	13 (5.72)
Genitourinary system	12 (5.29)
Sensory organs	8 (3.52)
Oncology	3 (1.32)
Central nervous system	3 (1.32)
Psychiatry	2 (0.88)
Dermatology	2 (0.88)
Veterinary	2 (0.88)
Musculoskeletal system	0 (0)
Total	227 (100)

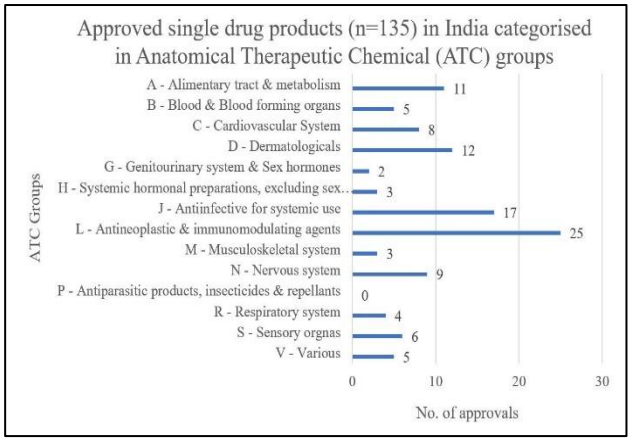

Figure 1: Approved single drug products (n=135) in India categorised in anatomical therapeutic chemical (ATC) groups.

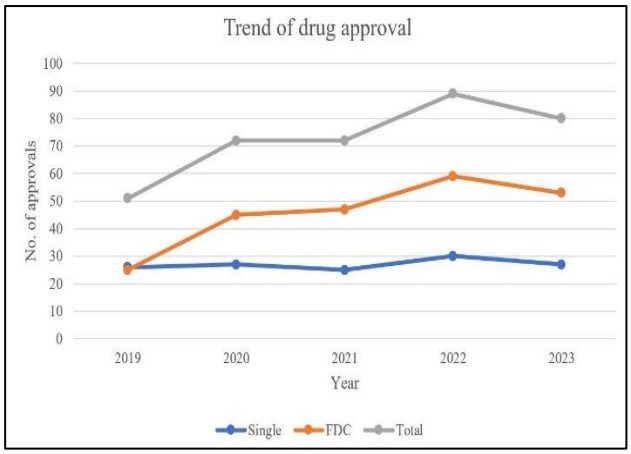

Figure 2: Trend of drug approval.

In terms of overall new drug approvals, the highest 89 approvals were observed in year 2022. The mean, median and range of drug product approvals are shown in Table 2.

The single drug product approvals were categorised in terms of ATC groups. The analysis is shown in Figure 1. The ATC groups containing over 10% of total single drug product approvals were: L (antineoplastic and immunomodulating agents) with 25 (18.51%) drugs and J (anti-infectives for systemic use) with 17 (12.59%) drugs. Out of total single drug product approvals, 25 (18.51%) drugs were not classified into ATC groups (Figure 1).

FDCs were classified based on the system they act upon. Their analysis is depicted in Table 3. The highest number of FDC approvals - 59, were seen in 2022. The highest number of FDC approvals - 54 were for endocrine diseases, which was about 23.79% of total FDC approvals, followed by 42 (18.50%) drugs for cardiovascular and blood related diseases and 34 (14.98%) drugs for respiratory diseases (Table 3). The time-trend curve for all the approved drug products during the period from 2019 to 2023 is depicted in Figure 2. Additionally, it displays the drug products containing both - single or a combination of drugs, which are plotted individually. The plot shows an overall rising trend, with the highest approvals in 2022 (n=89) (Figure 2).

Since 2019, a rising trend has been seen for approval of both single and combination products. Similarly, this trend also peaks in 2022, then recedes in the subsequent year. With the exception of 2019, combination drug products have received more approvals than single drug products nearly every year.

DISCUSSION

The pharmaceutical industry ranks among the world's largest businesses. It is consistently at the forefront of innovation, developing new drugs while staying updated with the ever-evolving regulatory and technical aspects of the industry. Recent progress in global pharmaceutical manufacturing focuses on harmonising drug regulations. The International Conference on Harmonisation (ICH) guidelines help lower the costs associated with preparing registration dossiers and ensure that marketed products maintain high standards of quality, safety and efficacy. These efforts are highly beneficial for both drug developers and regulatory authorities.[12]

In India, drug approvals are primarily regulated by the Ministry of Health and Family Welfare (MoHFW) and the Ministry of chemicals and fertilizers. The CDSCO and MoHFW oversee the licensing, quality control and distribution of drugs. Additionally, there are various other regulatory bodies involved in drug regulation.[5]

The study identified a total of 362 approvals by the DCGI from 2019 to 2023, the period under the study. An average rate of approval, per year turns out to be 72.[4] (median approvals per year: 72; range: 49–89). A study by Chawan et al of drugs approved from 1999 to 2015 showed an increasing trend followed by a fall in subsequent years.[8] A similar study by Karve et al of drugs approved from 2009 to 2019 showed a drastic decline in the number of drug approvals. This study also reported a median of 42 approvals, which was lower than that reported in our study.[5] Our study showed that, total number of drug approvals has increased over the years. Approvals of new single drug products have not shown a significant increase, but the number of FDCs approved has significantly increased.

It is well-known that the approval rate of drugs is directly related to the incidence and prevalence of diseases in a specific geographic region. It is a known fact that the incidence of cancer is increasing in India. Also, the incidence of infectious diseases like respiratory infections, genitourinary infections etc. is high in India.[13] Our study results support this, showing that oncology is the therapeutic area with the highest number of single drug approvals, followed by infectious diseases. Due to the COVID-19 pandemic, a greater number of single drug

product approvals are seen in ATC group J-anti-infective in 2020.

Combination therapy is often suitable for chronic conditions where it is genuinely needed.[9] The rise in FDC approvals for drugs treating endocrine and cardiovascular diseases aligns with the increasing prevalence of diabetes and hypertension in India. Owing to the challenges associated with creating new chemical entities, the pharmaceutical sector finds it simpler to create FDCs, which is also reflected in our study.[14]

Developing a new drug is a lengthy and costly process, so Indian companies are focusing on FDCs to differentiate their products in a competitive market. This strategy may be essential for survival amid increasing competition among drug manufacturers. Prior to 2005, due to India's process patent system, numerous brands for single drug molecules existed, making it challenging for pharmaceutical companies to distinguish their products from competitors. To stand out, companies are pursuing innovations. Drug development is a risky, unpredictable and expensive process requiring both scientific excellence and a deep understanding of the business environment. Consequently, many Indian companies are shifting towards contract manufacturing, outsourcing, contract research or collaborations with multinational corporations.[2]

An additional aspect of FDCs in India is the contentious issue surrounding their approval by different state licensing authorities. There is a lack of uniformity across states regarding the permission to manufacture these combinations. As a result, a product might be approved by one state licensing authority while being rejected by another.[15]

There is significant potential to enforce rules and regulations that will guide, monitor and control the activities of healthcare providers in the country, aiming to meet international standards. Implementing the recommendations of the Mashelkar committee and establishing the central drug authority promptly are crucial for overseeing the manufacture, quality and supply of drugs. Beyond drug approvals, numerous issues affect the healthcare system and drug availability. Comprehensive regulatory changes are necessary to keep pace with industry trends and ensure uniform standards for producing quality drugs. Strengthening regulatory infrastructure is essential to guarantee high-quality products and prevent the production of counterfeit drugs.[15]

The study has following limitations

Biologicals (monoclonal antibodies) were not included in the study as they were not included in drug approval lists by CDSCO. Authors also excluded veterinary drug products from the current analysis, which were approved by the DCGI during 2019-2023. This study focused solely on FDCs approved by the DCGI office. As a result, our list might not contain all combinations that have been approved by state licensing authorities.

CONCLUSION

A rigorous drug approval process, including a stringent regulatory framework, ensures high-quality drug approvals but may delay the timely introduction of new pharmaceuticals.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Mohs RC, Greig NH. Drug discovery and development: Role of basic biological research. Alzheimers Dement Transl Res Clin Interv. 2017;3(4):651–7.
2. Kataria BC, Bhavsar VH, Donga BN. Contemplation on approved drugs in India from 1999 through 2011. Asian J Pharm Clin Res. 2012;5(3):25-9.
3. Roy AM, Jones R, Mathew A. A comparative study of cancer drug approvals in India and high-income countries. J Cancer Policy. 2022;1:33.
4. Lahiry S, Sinha R, Choudhury S, Mukherjee A, Chatterjee S. Paradigm shift in clinical trial regulations in India. Indian J Rheumatol. 2018;13(1):51.
5. Karve AV, Sheth AP, Perveen SS. An analysis of drug approvals in india over past 10 years. J Res Educ Indian Med. 2014;20(3-4):141-52.
6. Bandarapalle K, Kumarachari RK, Sri KT, Neeraja B, Likhitha C, Chaitanya K, et al. A Review on regulatory affairs and regulatory requirements for drug approval. Future J Pharm Health Sci. 2024;4(1):26–38.
7. Ministry of Health and Family Welfare. Govt of India. Notification. The Gazette of India: Extraordinary, Part II, Section 3, Subsection (I), New Delhi. 2019. Available at: https:// cdsco. gov.in/ opencms/ export.
8. Chawan V, Gawand K, Phatak A, Badwane S. An overview of drugs approved in India from 1999 through 2015. Int J Basic Clin Pharmacol. 2015;697–700.
9. Chaudhry S. Fixed dose combinations in India- what a way to go! Indian J Pharm Pharmacol. 2023;10(1):45–9.
10. Approved New Drugs. 2024. Available at: https://cdsco.gov.in/opencms/opencms/en/Approval.
11. ATCDDD-Guidelines. 2024. Available at: https://atcddd.fhi.no/atc_ddd_index. Accessed on 17th March 2024.
12. Singh J. International conference on harmonization of technical requirements for registration of pharmaceuticals for human use. J Pharmacol Pharmacother. 2015;6(3):185–7.

13. India-Sample Registration System (SRS)-cause of death in India 2017-2019. Available at: https://censusindia.gov.in/nada/index.
14. Gupta Y, Ramachandran S. Fixed dose drug combinations: issues and challenges in India. Indian J Pharmacol. 2016;48(4):347.
15. The Central Drugs Standard Control Organization (CDSCO). Mashelkar committee report. 2012. Available at: http://cdsco.nic.in. Accessed on 17th March 2024.

Cite this article as: Shaikh AI, Acharya CR, Shah AM, Moradiya MG, Patel JR, Patel AH, et al. An analysis of drug approvals in India over past 5 years. Int J Basic Clin Pharmacol 2024;13:872-6.