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Original Research Article

Delayed availability of new antimicrobials in India

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ABSTRACT

Background: Considering the interplay of multiple factors involved in regulatory drug approvals, commercial market launching, patent regulations and drug pricing regulations on the accessibility to new antimicrobial drugs, their affordability and availability and the consequent impact on efforts to tackle antimicrobial resistance (AMR), it is prudent to examine the regulatory approvals of new antimicrobial drugs and their availability in India compared to U. S. Food and Drug Administration (USFDA).

Methods: This was a cross-sectional study conducted in Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala, India between January 2025 and December 2025. Information on new antimicrobial agents (AMAs) approved for marketing by USFDA and CDSCO during the period 1970 to December 2025 were sourced from their respective websites.

Results: The number of antimicrobials approved in India is considerably less compared to U. S. (74.0%-182/246) vs (90.7%-223/246). Antibacterials comprise about 52.2% (95/182) total AMA approvals, antivirals 27.5% (50/182). About 27.5% (36/131) antibacterials not approved in India vs 9.9% (13/131) in U. S. About 25.4% (17/67) antivirals not approved in India vs 4.5% (3/67) in U. S. About three fourth (72.3%-115/159) CDSCO approvals were delayed compared to FDA approvals. More than three fourth (76.6%) antivirals (36/47), (73.2%) antibacterials (60/82), (80%) anti TB drugs (4/5), (100%) antifungals (10/10), (40.0%) antimalarials (2/5)-CDSCO approval delayed. Median delay in CDSCO approval among antimicrobials approved after FDA approval was 4.0 years. The median delay was 5.0 years for antibacterials, 3.0 years for antifungals, 3.0 years for antivirals, and 9.0 years for anti-tuberculosis drugs.

Conclusions: Along with a decrease in the number of new antimicrobial approvals in India, there appears to be delays in regulatory approval of antimicrobials as well when compared to USFDA. A reduction in the number of antimicrobials approved per year in India compared to U. S. may be interpreted as a reduction in the number of new antimicrobials submitted by pharmaceutical companies for CDSCO approval or increased time taken for the regulatory approval.

Keywords: Anti-infective agents, Drug approval, Drug and narcotic control, India, USFDA

INTRODUCTION

Antibiotic resistance is an anticipated natural phenomenon developing as a consequence of exposure of microbes to antibiotics over a period of time.[1] It may be considered as an adaptive response of microbes to deleterious environments.[2] Nonetheless, the use or rather misuse of antibiotics has culminated in the emergence of AMR as a major public health threat with predicted disastrous consequences in future.[3] A large part of this apprehension is owing to the absence of new antibiotics in developmental pipeline. Explanations offered for the lack of development of antibiotics are numerous but the political economy behind development and marketing of drugs might provide us with some clues.

Antimicrobials as a group are drugs required for the treatment of infectious diseases which is largely considered a third world problem.[4] A significant proportion of the population in these countries is below poverty line and therefore the overall purchasing power would be weaker.[5] A major share of the health care expenses in such countries, particularly those with weak public health care systems is out of pocket expenditure and they constitute the largest public health expenditures after personnel costs.[6] Also, in order to make drugs affordable, these countries resort to drug pricing controls and as such have weak patent barriers.[7] Even though they might be a party to trade-related aspects of intellectual property rights (TRIPS) agreement, the developing countries take advantage of the various flexibilities of TRIPS to ensure affordability of drugs for its citizens.[8] Thus, the incentives for a pharmaceutical company for developing drugs whose primary market will be the developing countries is limited.

Newly developed drugs enter markets of developed countries immediately after their approval whereas they are either not launched in developing countries or are launched after a considerable delay.[10-15] Multiple factors such as regulatory drug approvals, commercial market launching, patent regulations and drug pricing regulations impact accessibility, affordability and availability of new AMAs and efforts to tackle AMR. Hence it is prudent to examine the regulatory approvals of new AMAs and their availability in India compared to USFDA. The results of this study may contribute to understanding new antimicrobial approval patterns in India.

METHODS

This was a cross-sectional study conducted in Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala, India between January 2025 and December 2025. Information on new AMAs approved for marketing by USFDA and CDSCO during the period 1970 to December 2025 were sourced from their respective websites.[16,17] US FDA website provides details including drug name, active ingredients, strength, dosage form/route, marketing status, approval dates and history, letters, labels, reviews and therapeutic equivalents. The CDSCO website provides information on drug name, strength, indication and date of approval. FDA approval was chosen as the comparator for CDSCO approval because U. S. has become the country of choice for new drug launches and hence a reliable estimate of the time difference and pattern of drug approvals can be obtained. Only approvals of oral or injectable new molecular entities were considered for this examination as AMR is primarily observed on systemic use. Information relating to the name of the approved drug, indication and date of marketing approval was obtained from the data available in websites. For drugs which were approved during 1970 to December 2025 by either of the regulatory agencies but whose respective date of approval could not be sourced from the data of drugs approved during 1970 to December 2025, details of approval were sourced from data of drugs approved before 1970, from respective websites. New antimicrobials in this study, refers to products that contain active moieties that have not been approved by FDA or CDSCO previously, either as a single ingredient drug or as part of a combination product. Combination agents or (Fixed drug combinations) FDCs was considered as new AMA only if at least one of the components have not been previously approved. Topical AMAs and AMAs for veterinary use were excluded. For analysis purpose, anti-TB (antituberculosis) drugs are analyzed separately from antibacterial drugs and antimalarials were analyzed separately from antiprotozoals.

RESULTS

A total of 246 antimicrobial agent approvals by either USFDA or the Central Drugs Standard Control Organization (CDSCO) was examined in this study. Of these 223 (90.65%) AMAs were approved by FDA and 182 (73.98%) were approved by CDSCO. Overall, 64.63% (159/246) AMAs were approved by both FDA and CDSCO while 9.35% (23/246) AMAs were not approved by FDA and 25.2% (62/246) were not approved by CDSCO till date (31 December 2025).

Out of 246 antimicrobials included in this analysis, the largest category were antibacterials (53.25%-131/246) followed by antivirals (27.23%-67/246). Antiprotozoals, antimalarials, anti TB drugs and anthelminthics together accounted for the remaining proportion (Table 1).

Across categories of AMAs, approval by both regulatory agencies was most common for antivirals and antifungals. A large proportion of antibacterials were not approved by CDSCO compared to FDA. Among antimicrobials approved by both agencies (n=159), CDSCO approvals were granted ahead of FDA approval for 36 (22.6%) agents whereas approvals were delayed compared to FDA approvals for 115 agents (72.33%).

Time-lag analysis was performed for 159 AMAs approved by both FDA and CDSCO. Median differences between FDA and CDSCO approvals varied across antimicrobial categories (Table 2). The overall median time difference in FDA and CDSCO AMA approvals was 4.0 years. When CDSCO approvals were granted ahead of FDA approval, the median time difference was 5.5 years. When CDSCO approvals followed FDA approval, the median time difference was 4.0 years. Among antibacterial agents, the median difference was 5.0 years, with similar median values observed for approvals granted earlier and later by CDSCO. CDSCO approvals of all antifungals approved by both agencies were delayed relative to FDA approval with a median delay of 3.0 years. The number of antimalarials and anti-tuberculosis drugs were small and larger time differences were observed in these categories.

Table 1: Approval status of categories of antimicrobials.

Category of AMA, (N)	Not approved by FDA (%)	Not approved by CDSCO (%)	Approved by both (%)
Anthelminthic (7)	0 (0)	2 (28.6)	5 (71.4)
Anti TB (6)	1 (16.7)	0 (0)	5 (83.3)
Antibacterial (131)	13 (9.9)	36 (27.5)	82 (62.6)
Antifungal (15)	1 (6.7)	4 (26.7)	10 (66.7)
Antimalarial (10)	3 (30.0)	2 (20.0)	5 (50.0)
Antiprotozoal (10)	2 (20.0)	3 (30.0)	5 (50.0)
Antiviral (67)	3 (4.5)	17 (25.4)	47 (70.1)
Total (246)	23 (9.3)	64 (26.0)	159 (64.6)

Table 2: Median time difference between FDA and CDSCO approvals by antimicrobial category.

Antimicrobial category	Drugs approved by both CDSCO and FDA, (N)	Median time difference (in years)*	Median lead when CDSCO approved earlier (in years)	Median delay when CDSCO approved later (in years)
All antimicrobials	159	4.0	5.5	4.0
Antibacterials	82	5.0	5.0	5.0
Antivirals	47	3.0	4.0	3.0
Antifungals	10	3.0	–	3.0
Antimalarials	5	8.0	3.0	33.5
Anti-TB drugs	5	15.0	18.0	9.0

*Absolute median difference between FDA and CDSCO approval years. -indicates that no drugs in that category received CDSCO approval earlier than FDA approval.

DISCUSSION

Markets in developed countries encourage the development of drugs for the treatment of non-communicable diseases (NCDs) which are their primary health concern.[18] NCDs require lifelong treatment and as such profits earned on these are huge when compared to antimicrobials which are given as a short course of few days.[19] Furthermore, developed countries have strict patent regulations, reimbursement programs and high willingness to pay. Drug prices in U. S. are the highest in the world, and this enables the pharmaceutical companies to recover more than their drug development costs.[20]

The Indian pharmaceutical market scenario is quite unique when compared to other developing countries. From the absence of any pharmaceutical patent barriers in the early 1970s to being a signatory of TRIPS in 1995, the country has gone through a major market transformation.[21] The pharmaceutical market in India consists of major multinational corporations who have research and development wings as well as branded pharmaceuticals in their portfolio, and indigenous pharmaceutical companies who mostly concentrate on branded generics or generics.[22] In the years before 2005, well before India officially started recognizing patent applications, India was a large supplier of generic drugs to the developing countries at cheap affordable prices.[23] Speculations are rife that pharmaceutical patenting regulations and colluding India to agree to TRIPS arrangements were largely aimed at curbing the generic drug market principally supported by Indian pharmaceuticals.[24] Nevertheless, in spite of apprehensions predicting post TRIPS hike in pharmaceutical prices, the country seems to have fared well in that arena.[4] Rather the concerns appear to have taken another perturbing direction of delayed launch of new drugs which deserves significant attention in the background of emergence of AMR as a public health concern.

Curbing the development of AMR requires a multifaceted approach, including examining the circumstances of their use, ensuring their judicious use, monitoring dispensing to ensure judicious use, and educational and managerial interventions.[25] Along with those efforts towards encouraging development of new antimicrobials to tackle the emerging AMR is necessary.[12] Also, the development and approval of new antimicrobials need not necessarily mean that it translates into their availability to the needy in developing countries, given the patent barriers and drug pricing controls in these countries which reduce the profit quotient to the developer. Launch of a new drug in a market is a decision which occurs only when a pharmaceutical company considers the launch as a financially profitable venture. Financial profitability plays the most important part in the decision, and the profit has to justify the drug launch costs which include regulatory costs as well as marketing costs.[26]

Launch of a new drug in a country is also controlled by many factors such as demand and size of the market, drug pricing regulations and patent system in the country. [26] Along with a decrease in the number of new antimicrobial approvals in India, there appears to be delays in regulatory approval of antimicrobials as well when compared to USFDA. A reduction in the number of

antimicrobials approved per year in India compared to U. S. may be interpreted as a reduction in the number of new antimicrobials submitted by pharmaceutical companies for CDSCO approval or increased time taken for the regulatory approval. As this study has considered regulatory approval data from 1970 to 2025, drugs for which there was a regulatory delay at CDSCO, reduction in the number of antimicrobials submitted for regulatory approval or rejection of applications submitted for approval may be assumed. In order to ascertain the reason, an examination of status of applications submitted for regulatory approvals is necessary. Such an examination can also aid in exploring whether the antimicrobials referred to as "not approved" in this study data are rather drugs that were not submitted to CDSCO for approval.

A significant time difference is observed between regulatory approvals in both the countries which is suggestive of delay in submission of applications for CDSCO approval. This delay despite the high infectious disease burden in India and the consequent increase in market demand, points to need for alternative explanations for the delays in submission and demands examination of determinants of decision to introduce a new drug into Indian market.

Previous studies have highlighted the impact of market characteristics including price regulations, strength of patent laws, market demand and size, unmet medical needs, per capita income, willingness to pay, presence of national drug policies and essential medicines list as determinants of market entry.[1,2] How these macroeconomic factors impact entry of new antimicrobial drugs into Indian pharmaceutical market needs to be explored.

A reduction in the number of antimicrobial approvals during various time periods is observed in the data. An explanation to such time related approval variations may be obtained by examination of the market characteristics and regulations pertaining to new drug approvals during those periods. There are regulatory changes in the Indian context as the period before entering the TRIPS regime, the supreme court mandated stopping of all drug trials in 2013 and such interventions that might have affected regimes of drug introduction into the country.[23] Therefore, an examination considering these time frames is called for.

Introduction of pharmaceutical patent regulations was predicted to facilitate entry of new pharmaceuticals into Indian market. On the contrary, a median delay of 4.0 years for regulatory approval of AMAs is observed. This delay may be due to a shrink in market demand and size due to high monopoly prices.[2] The price control regulations existent in India can also dilute the incentives of patent rights. Quite the reverse, along with strong patent laws existent in U. S., pharmaceutical companies also enjoy free pricing i.e. they can set drug prices, which serves as an incentive for faster drug launches.

Furthermore, antimicrobials do not need repeat purchases as they are used for a short period of time and thus lack first mover advantage as in the case of drugs for NCDs.[19] Moreover, people of lower socio-economic strata, who have low purchasing power constitute the major market for antimicrobials.[14]

Availability of a new antimicrobial agent may mean more effective treatment options and have the potential to decrease morbidity, mortality, health expenditure and increase quality of life of patients in need. Existing literature that examines the causes of drug launch delays in Indian market utilizes data from 1995 to 2011 and hence this dilemma necessitates further exploration to aid in tackling AMR effectively.[1,2,5]

Limitations

The analysis was done on the assumption that the delay in drug approvals was due to delays in submission of applications for regulatory approval. An examination of whether the drugs were submitted for regulatory approval in respective countries is called for. Whether the delayed drug approvals were due to long regulatory processes also has to be examined. Whether the drugs were launched in market post regulatory approval and time difference between regulatory approval and market launch was also not examined (Obtaining details of date of market launch requires access to antimicrobial sales data which is not available in public domain). This analysis assumes that patterns of drug regulatory approvals across all drug categories are similar. For an accurate comparative analysis, it is necessary to examine characteristics of drug approvals across various drug categories in the above years. Exploration of whether the delay is due to market characteristics of India is indispensable before arriving at conclusions from this study. Analysis of the time differences between submission of applications for patent approvals and regulatory approvals in both countries and examination of role of patent barriers and price regulations in these delays is also required. The reasons for presence of drug approval delays despite a favorable environment for conducting clinical trials in India and acceptance of clinical trials conducted in other countries for regulatory approvals also has to be explored.

CONCLUSION

This study shows that there is considerable difference in the timeline of approval of antimicrobials by USFDA and the CDSCO during the period 1970-2025. While many antimicrobials were approved by both regulatory agencies, many approvals by CDSCO occurred later than FDA approval with a median delay of about four years. In addition, some drugs which were approved by FDA had not received CDSCO approval during the study period. The findings of this study indicates that introduction of

new AMAs into Indian market may be influenced not only by regulatory review processes but also by market conditions such as pricing policies, patent systems and commercial considerations that influence company decisions to seek approval by CDSCO in India. By the examination of long-term patterns in antimicrobial approvals across the two regulatory systems, this study adds empirical evidence of differences in the timings of access to newer antimicrobial therapies in India. The study points to the need for further research on the policy, regulatory and market factors that affects the availability of newer antimicrobials in countries with a high burden of infectious diseases and rising antimicrobial resistance.

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REFERENCES

1. Noncommunicable diseases. Available at: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases. Accessed on 27 February 2026.
2. Gargate N, Laws M, Rahman KM. Current economic and regulatory challenges in developing antibiotics for Gram-negative bacteria. npj Antimicrob Resist. 2025;3(1):50.
3. Parasrampuria S, Murphy S. Comparing U. S. and International Market Size and Average Pricing for Prescription Drugs, 2017-2022: Issue Brief. Washington (DC): Office of the Assistant Secretary for Planning and Evaluation (ASPE); (HHS ASPE Reports); 2024.
4. Patent Reform and Public Health: India's TRIPS Journey in Pharmaceutical Law | International Journal of Scientific Development and Research. Available at: https://ijsdr.org/viewpaperforall.php?paper=IJSDR2510049. Accessed on 27 February 2026.
5. CBCL. Regulating the Generic Drugs Market: Eliminating the difference between Branded and Unbranded Generics. NLIU CBCL. 2022. Available at: https://cbcl.nliu.ac.in/competition-law/regulating-the-generic-drugs-market-eliminating-the-difference-between-branded-and-unbranded-generics/. Accessed on 27 February 2026.
6. Mehta A, Nancy, Sonkala S, Mishra AK. Harmonizing Access to Medicine: Exploring India's Process Patent in Intellectual Property Rights Amid Global Pressures. Int Tinnitus J. 2024;28(1):60-4.
7. Balancing Innovation with Access to Generic Medicines. Available at: https://www.iiprd.com/from-pharmacy-of-the-world-to-patent-prison-indias-shift-under-trips/. Accessed on 27 February 2026.
8. Chaudhuri S. Are Medicine Prices High And Unaffordable After Trips? Evidence From Pharmaceutical Industry In India. Commentary on India's Economy and Society Series. 2019;10.
9. Bhaduri S, Brenner T. Determinants of drug launch delay in pre-TRIPS India: A survival analysis approach. Working Papers on Innovation and Space. 2011. Available at: https://ideas.repec.org//p/pum/wpaper/2011-05.html. Accessed on 27 February 2026.
10. Bhaduri S, Ray AS. A game theoretic model of drug launch in India. Health Econ Policy Law. 2006;1(Pt 1):23-39.
11. Cockburn IM, Lanjouw JO, Schankerman M. Patents and the Global Diffusion of New Drugs. American Economic Review. 2016;106(1):136-64.
12. Danzon PM, Wang YR, Wang L. The impact of price regulation on the launch delay of new drugs--evidence from twenty-five major markets in the 1990s. Health Econ. 2005;14(3):269-92.
13. Kataria BC, Mehta DS, Mehta SJ. Drug Lag For Antimicrobial Agents: Comparison of the US, EU and India Approvals. National J Med Res. 2012;2(03):264-8.
14. Narayan S. Price Controls on Pharmaceutical Products in India. Singapore: NUS Institute of South Asian Studies. Institute of South Asian Studies. 2007;46.
15. Joosse IR, Mantel-Teeuwisse A, Ham HA van den, Arevalo LC. Availability of essential medicines for non-communicable diseases: a scoping review of challenges and opportunities. BMJ Glob Health. 2025;10(11):e019634.
16. Approved New Drugs. Available at: https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/. 2026. Accessed on 27 February 2026.
17. Drugs@FDA: FDA-Approved Drugs. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed on 27 February 2026.
18. Pharma Innovation vs Patient Access: Why Drugs Lag in India. Available at: https://www.mrmed.in/health-library/health-care/pharma-innovation-vs-patient-access-india. Accessed on 27 February 2026.
19. Shrestha J, Zahra F, Cannady J. Antimicrobial Stewardship. In: StatPearls. Treasure Island (FL): StatPearls Publishing. 2025. Available from: http://www.ncbi.nlm.nih.gov/books/NBK572068/. Accessed on 27 February 2026.
20. Dutescu IA, Hillier SA. Encouraging the Development of New Antibiotics: Are Financial Incentives the Right Way Forward? A Systematic Review and Case Study. Infect Drug Resist. 2021;14:415-34.
21. Jekunen A. Decision-making in product portfolios of pharmaceutical research and development-managing streams of innovation in highly regulated markets. Drug Des Devel Ther. 2014;8:2009-16.
22. Lanjouw J. Patents, Price Controls and Access to New Drugs. NBER. Available at: https://share.google/UenTDhGWEyLr1dCZs. Accessed on 27 February 2026.

23. Roy Chaudhury R, Mehta D. Regulatory developments in the conduct of clinical trials in India. Glob Health Epidemiol Genom. 2016;1:e4.
24. Shafiq N, Pandey AK, Malhotra S, Holmes A, Mendelson M, Malpani R, et al. Shortage of essential antimicrobials: a major challenge to global health security. BMJ Glob Health. 2021;6(11):e006961.
25. Majumder MAA, Rahman S, Cohall D, Bharatha A, Singh K, Haque M, et al. Antimicrobial Stewardship: Fighting Antimicrobial Resistance and Protecting Global Public Health. Infect Drug Resist. 2020;13:4713-38.
26. Drug Patent Watch. Transform Data into Market Domination. 2025. The Price of a Miracle: A Strategic Blueprint for Optimal Pharmaceutical Launch Pricing. Available at: https://www.drugpatentwatch.com/blog/the-price-of-a-miracle-a-strategic-blueprint-for-optimal-pharmaceutical-launch-pricing/. Accessed on 27 February 2026.

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