



ORIGINAL RESEARCH PAPER

Law

IMPROVING ACCESS TO ESSENTIAL MEDICINES IN INDIA: ADDRESSING POLICY GAPS, PUBLIC HEALTH CHALLENGES AND ECONOMIC BARRIERS

KEY WORDS: Essential Medicines, Healthcare System, Accessibility, Public Health, World Health Organisation (WHO), Generic Medicines, Disease Burden, Out-of-Pocket Expenditure, Essential Medicines List (EML) and Drug Controller General of India (DGCI).

Regan Kalate

Ph. D. Research Scholar, Dept. of Laws, Himachal Pradesh University, Summerhill, Shimla, Himachal Pradesh, India

ABSTRACT

The availability of essential medicines is a fundamental pillar of any effective healthcare system, particularly in a country as populous and diverse as India. Despite India's position as a global leader in the production of generic medicines, the challenge of ensuring that its own population has adequate access to essential medicines remains a significant concern. This research paper is rooted in this paradox, exploring the reasons behind the limited accessibility of essential medicines within India and the implications this has on public health. The study begins by providing a concise background on the concept of essential medicines, a principle introduced by the World Health Organization (WHO) to address priority healthcare needs globally. Essential medicines are those that should be available within the health system at all times, in adequate amounts, and in appropriate dosage forms, at prices that individuals and the community can afford. Despite the well-established global framework and India's robust pharmaceutical industry, the reality on the ground reveals significant gaps in the availability of these medicines to the Indian population. The urgency of this issue is highlighted by the extensive disease burden that India faces, spanning both communicable and non-communicable diseases. This paper analyses data from various studies to underscore the critical need for effective and widespread access to essential medicines as a means to address this burden. Additionally, the study examines the financial strain placed on Indian households due to high out-of-pocket expenditures on medicines, revealing a direct link between accessibility issues and the economic challenges faced by the population. In an effort to understand the governmental response to this challenge, the paper delves into the history and current implementation of the Essential Medicines List (EML) in India. The EML is intended to guide the procurement and distribution of medicines that are deemed essential for public health. However, this research critically evaluates the effectiveness of the EML, identifying significant gaps between policy and practice that have resulted in inadequate access to essential medicines for large segments of the population. The paper reviews evidence from previous research conducted in various parts of India, which consistently points to the limited availability of essential medicines, thereby highlighting the shortcomings in the current policy framework. These findings suggest that while the EML serves as a strong conceptual tool, its practical application requires significant improvements to meet the needs of the population effectively. Lastly, the research offers a series of recommendations aimed at enhancing the accessibility of essential medicines in India. These recommendations are designed to strengthen the implementation of the EML and ensure that essential medicines are available and affordable for all citizens, thereby improving overall health outcomes. The study seeks to contribute to the broader discourse on healthcare reform in India, particularly in the area of essential medicines. The insights and recommendations presented in this paper will guide policymakers, healthcare professionals, and other stakeholders in their efforts to create a more equitable and effective healthcare system in India.

INTRODUCTION

Admittance to fundamental prescriptions is a foundation of a working medical services framework, guaranteeing that populaces get the important therapies to keep up with and work on their wellbeing. The idea of Essential Medicines was first presented by the World Health Organisation (WHO) in 1977, and from that point forward, it has been a significant piece of worldwide wellbeing methodologies. Donela, 2017 The WHO, characterized it as those basic medicines that satisfy the priority health care needs of the population. Donela, 2017 In India, the accessibility of essential medicines stays at critical difficulties regardless of various drives pointed toward resolving these issues. According to WHO (World Health Organization) access to medicines is "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population". Mustafa, 2022

Tending to the variations in medication accessibility across various locales and guaranteeing that practical nonexclusive options are generally accessible are basic strides towards diminishing the financial weight on families and further developing by and large wellbeing results. In light of various exact explores, this exploration expects to give a far-reaching examination of the present status of the accessibility of essential medicines in India. With a point-by-point assessment, this study will add to the continuous endeavours to improve medical care conveyance and access in the country.

Why It Is So Important?

The COVID-19 pandemic has exacerbated global medicine

shortages, requiring increased transparency in the supply chain. Christine, 2021 India has emerged as a leading supplier of generic medicines in the world, yet majority of its population does not have access to essential medicines. Vandana Roy, 2013 Regardless of these endeavours, information from different areas uncovers constant holes in both accessibility and availability. Despite being the "pharmacy of the global south", over 65% of India's population does not have access to essential medicines, because health-care financing and provision is largely a private affair in most Low- and Middle-Income Countries (LMICs), and households incur catastrophic payments and make them vulnerable to poverty. Shivkant Selvaraj, 2014

The World Health Organization estimates that 1.3 to 2.1 billion people do not have access to essential medicines, and efficient procurement systems are an important priority for improving medicine affordability and accessibility. Vandana Roy, 2013 Recent figures published in Forbes shows that "at least 2 billion people don't have access to medicines and 1 billion people live in extreme poverty (less than \$1.25 per day) and 2.2 billion live on less than \$2 per day which is quite disturbing situation". Mustafa, 2022

In India, it is observed that 50-80% of the population has limited access to essential medicine. Sengupta, 2023 The, major infectious diseases include malaria, dengue, chikungunya, Japanese encephalitis, plague, jaundice, cholera, hepatitis, typhoid, HIV, tuberculosis, diarrheal diseases, influenza, and rabies. Kambrath, 2018 In 2019, Non-Communicable Diseases were responsible for approximately 41 million deaths globally, (71% of the NCDs fatalities

worldwide) with cardiovascular diseases being the leading cause of death, accounting for 32% of all deaths. Kosalram, 2023 The cumulative findings from 18 research papers conducted between 2009 and 2019 Kosalram, 2023 indicate that non-communicable diseases (NCDs) account for a significant number of deaths in India, with cardiovascular diseases (CVDs) being the leading cause. In 2020, the number of CVD-related deaths in India rose to 4.77 million, compared to 2.26 million in 1990, and 4200 per 10000 population. Kosalram, 2023 WHO, 2023 Hypertension is notably prevalent, affecting 31.5% of the urban population and 26.2% of the rural population, leading to substantial deaths and disabilities. Kosalram, 2023 Vector-Borne Diseases (VBDs) account for 17% of the globally estimated burden of all infectious diseases, and approximately 82% of the world's population lives in areas where they are at risk from at least one VBD. Dutta, 2019 Dengue cases increased from 16.44 million in 1990 to 28 million in 2019, a rise of 70% with an incidence rate it increased by approximately 4.73% over this period, whereas, lymphatic filariasis affected 37.20 million people in 2019. Dutta, 2019 Malaria causes around 1 million child deaths annually in developing countries, with India at high risk, while approximately 390 million dengue cases are reported globally each year; Japanese encephalitis, a mosquito-borne viral disease, affects around 70,000 people annually in Asia. Kambrath, 2018

According to WHO in India, the death rates per 100,000 population are 111 for ischemic heart disease, 64.2 for chronic obstructive pulmonary disease, 50.9 for stroke, 48.9 for diarrheal diseases, 31.8 for tuberculosis, 31.7 for neonatal conditions, 28.6 for lower respiratory infections, 19.8 for diabetes, and 19.6 for cirrhosis of the liver. WHO, 2023 Moreover, the annual rates are 0.05 new HIV infections per 1,000 uninfected people, 1.99 new TB cases per 1,000 people, and 3.64 new malaria cases per 1,000 people at risk, with diarrheal diseases being the leading cause of under-5 mortality. WHO, 2023 However, in contrast to the depiction above, the Central Government allocates only about 12% of its total health budget to medicines, with roughly 10% of this allocation used for procurement. This limited funding affects the availability of essential drugs. Donela, 2017

Out of Pocket Expenditure

Developing countries have a major percentage, around 20 to 60 percent, of healthcare costs spent on essential drugs and a much higher percentage (50 to 90%) as an out-of-pocket expenditure. Thipathi, 2018 India's financial resource allocation for health has been low, and households spend a disproportionate share of their consumption expenditure on health care, moreover the health insurance covers a limited population, and most expenditure on health is borne by out-of-pocket expenditure. Vandana Roy, 2013

The per capita public spending on medicines in Rajasthan increased significantly from 2010-2014, leading to a decline in poverty due to lower OOP spending on medicines. Selvaraj, 2014 Private health expenditure accounts for nearly 70% of total health spending, with drugs representing a significant portion, ranging from 20% to 65%, Cameron, 2013 spending on medicines ranks second in expenditure after food in India. Singh, 2013 The high cost of medicines in India, combined with relatively low public health investment, is worsening access to essential medications. A single hospitalization can push 35% of people below the poverty line, and out-of-pocket medical expenses alone can drive 2.2% of the population into poverty within a year. World Bank, 2013

Essential Medicines List

Initially the essential medicines were merely a concept for well-established policy, that later on converted to essential medicines list in 1977 with a regular revision after every two years. Jha, 2022 They ought to be accessible at all times, in suitable dose forms, in sufficient quantities, with guaranteed quality, and at reasonable costs. The WHO Model Essential Medicines List (EML) guides

countries in developing and updating their national EMLs to enhance medicine procurement supply and prescription practices. Satheesh, 2023 In India the first National Essential Medicine List (NEML) prepared in 1996 and revised in 2003, 2011, 2015, and recently in 2022.

The availability and utilization of essential medicines in India face significant challenges, as highlighted in multiple research papers. Studies reveal that essential medicines are inadequately available in various Indian states, with stock-outs lasting from 4 to 14 weeks, showcasing governance issues and procurement disparities. Wadhwa, 2024 The delay in updating the National List of Essential Medicines (NLEM) can hinder access to crucial medications, impacting patient care and affordability, especially in low-resource settings. Satheesh, 2023 Furthermore, research indicates that prescribers often deviate from the NLEM, with over half of prescriptions including non-NLEM drugs, potentially leading to increased costs and decreased effectiveness of treatments. Ratinder Jha, 2022 Initiatives like the Pradhan Mantri Bhartiya Jan Ausadhi Pariyojana (PMBJP) aim to enhance access to affordable generic medicines, but challenges such as limited drug coverage and stock-outs persist, necessitating policy reforms for improved procurement and distribution of essential drugs. Lavtepatil, 2022

The selection criteria for essential medicines in India are influenced by various factors, that include addressing priority public health needs, demonstrating proven efficacy and safety, offering good cost-effectiveness, aligning with treatment guidelines, remaining stable under typical storage conditions, receiving approval from regulatory authorities like the DCGI, and being adaptable to local health needs and emerging conditions. Parmar, 2022

What Does Studies Depict

Research Study/conducted in a few particular Indian states has shown how important these stores are to increasing the accessibility of necessary medications; however, stock-outs continue to be a problem, especially in rural and underdeveloped areas. While the evidence is limited, data from several Indian states demonstrate significant variations in the availability and stock-outs of essential medicines. For example, the mean availability of essential medicines was 43% in Bihar compared to 88% in Tamil Nadu. Selvaraj, 2014

Even in capital city, Delhi, the typical accessibility of fundamental meds in open area offices was viewed as around 41.3%, for certain basic medications being actually inaccessible in overviewed offices. Kotwani, 2013 The study further revealed, the mean availability of 33 surveyed medicines was only 34.0%, with some medicines having 0% availability at certain facilities. Specifically, five medicines, including beclomethasone inhaler and dispersible zinc tablet, were not available at any of the surveyed public facilities. Kotwani, 2013

Other studies conducted in different parts of India also show similar results as 39% in Bhiwani city and its administrative areas, 58% in Chhattisgarh, 84 and 90% respectively in Belagavi and Bagalkote districts of North Karnataka, Punjab was 45.2% and in Haryana it was 51.1%. Wadhwa, 2024 A study conducted in Maharashtra shows that despite the limited coverage of essential medicines and prevalence of Fixed Dose Combinations (FDCs) in the PMBJP list, only 47% of surveyed essential drugs were available in PMBJP outlets, with 3-6 month stockouts and generic medicine costs ranging from 0.01 to 0.47 days' wages for the lowest-paid unskilled worker. Lavtepatil, 2022 The WHO report also confirms that nearly 68% of people in India have limited or no access to essential medicines. World Medicines Situation, 2004 Moreover, some researches shows declining trend in the availability of free medicines from 1986 to 2004, along with a rising number of people not receiving any medications for

outpatient care. UNDG,2003

These examinations additionally have shown that this error is much of the time more articulated in country regions contrasted with metropolitan focuses. Moreover, the monetary weight of medical care stays high in India, with personal costs representing a critical part of medical care use. This weight excessively influences low-pay families, pushing numerous underneath the neediness line because of clinical costs. Meds comprise the biggest portion of these costs, stressing the requirement for better admittance to reasonable medications.

The Way Forward

Access to essential medicines in India is challenged by factors like inadequate stocking, poor supply chain management, ineffective prescription practices, and lack of trust in medicine quality, all exacerbated by weak procurement systems and inadequate financial protection for households. Selvaraj, 2014 Also the governance issues, and challenges at the facility and user levels do play a pivotal role in hindrance. India's current drug policy is facing significant challenges, particularly in terms of access to essential medicines. Wadhwa, 2024 The current state of limited access to medicines highlights the critical need for a new approach where public health concerns take precedence over commercial interests in drug pricing and accessibility.

The primary focus should be on the implementation of comprehensive price controls on all essential drugs, using the National Essential Drugs List (EDL) as the foundation. This ensures that price controls target the most vital and life-saving medicines, with a uniform markup of 100% applied across the board. Moreover, the selection process for essential medicines should be systematic and based on public health needs, ensuring that the most relevant and effective medicines are included in the essential medicines list.

Increasing public sector financing for the procurement of essential medicines is also crucial. The State Government of Rajasthan in India introduced the Mukhyamantri Nishulk Dawa Yojana (MNDY) in 2011 to address the issues and started the procurement of medicines and surgical items through an open tender (two bid) system and also procured high-end medicines for cancer and other complex diseases directly from the importers. Selvaraj, 2014 This would help ensure that sufficient quantities of medicines are available to meet the needs of the population. Implementing controls on taxes and duties related to essential medicines can help reduce costs and improve accessibility for the population.

The sustainable financing of drug procurement would ensure that medicines reach the intended beneficiaries, but an inefficient medicine supply chain management system may result in poor-quality medicines, life-threatening shortages, antimicrobial resistance and avoidable fatalities. Sevaraj, 2014 The procurement and delivery systems for essential medicines are often inadequate, leading to non-availability of required medicines, which jeopardizes the credibility of the public health system. Donela, 2017

However, merely placing essential drugs under price control is insufficient, as pharmaceutical companies often shift production to non-essential drugs when essential ones are regulated. To counter this, continuous monitoring of entire therapeutic categories is necessary, with a dynamic list of price-controlled drugs that can be updated regularly to reflect market trends.

The distribution of essential medicines is often uneven, with rural areas facing more significant challenges in accessing these drugs compared to urban centres. Donela, 2017 Thus, there is a dire need for efficient distribution systems to ensure that essential medicines reach all areas, particularly

underserved and rural regions. This may involve improving logistics and supply chain management. The National Health System and Resource Centre's guidelines for state district drug warehouses aim to prevent overstocking, inventory costs, stock-outs, and drug deterioration through improved distribution monitoring. Guidelines, National Health Mission, 2021 The NHSRC's free drug guidelines emphasize three to five-day cycle times for quality checks and timely reporting to ensure continuous, punctual delivery of essential medicines to healthcare facilities. Operational Guidelines, National Health Mission, 2021

An independent mechanism for data collection on the pharmaceutical market is also essential. Currently, the government relies on commercial data sources, which is inadequate for effective policy-making. Establishing its own system for tracking drug pricing and availability would allow the government to make informed decisions and adjust policies as needed.

Rational drug use optimizes treatment effectiveness, reduces adverse reactions, and is cost-efficient by ensuring appropriate prescriptions and preventing complications from unnecessary medication. Donela, 2017 Additionally, reducing the number of irrational drugs in the market would simplify the implementation of price controls and enhance their effectiveness. Promoting rational drug prescribing and use is another critical aspect of improving drug policy. Standard treatment guidelines for common illnesses should be formulated and widely disseminated, along with prescriber information and an annual national formulary provided to all registered practitioners at no cost.

The Drug Controller General of India (DGCI) must exercise greater caution in registering new drugs, focusing on public health benefits and risks. The presence of a large number of drugs in the market, coupled with aggressive marketing strategies by pharmaceutical companies, can lead to confusion and irrational use of medicines. Donela, 2017 Manufacturers of new drugs should provide cost data, and even if these drugs are not under price control, they should conform to voluntary regulations capping. This would prevent the trend of overpricing new medicines at the entry level.

There is a lack of a strong drug regulatory authority, which can lead to issues in the quality and safety of medicines available in the market. Donela, 2017 Thus, strengthening the National Pharmaceutical Pricing Authority (NPPA) is crucial. Currently, the NPPA is understaffed, and its coordination with state drug control authorities is weak. Enhancing its capabilities and establishing Drug Price Control Order (DPCO) cells in each state under the NPPA's aegis would improve enforcement. Furthermore, introducing mechanisms to verify the declared landed cost of imported medicines would prevent pricing manipulation by importers.

The revival of Public Sector Units (PSUs) in the pharmaceutical sector is an urgent necessity. These units, once pioneers in drug production, have been in decline and now produce very little. Reviving them would provide a counterbalance to the high prices charged by private companies and ensure continued production of essential medicines when private firms discontinue them due to price controls. Also, the enhancing of capacity and capability of indigenous pharmaceutical manufacturing can help ensure a steady supply of essential medicines at reasonable prices.

Conclusion

India's status as a leading producer of generic medicines contrasts sharply with the persistent issue of limited access to essential medicines within the country. Despite the World Health Organization's framework and the Essential Medicines List (EML) designed to guide medicine availability, significant gaps remain in its practical implementation. This research

highlights the disparity between policy and practice, revealing that high out-of-pocket costs and inadequate distribution systems contribute to the accessibility issues faced by the population. Addressing these challenges requires a comprehensive review and strengthening of the EML, improved procurement and distribution processes, and strategies to reduce financial burdens on households. By implementing these recommendations, India can better align its pharmaceutical prowess with the actual healthcare needs of its population, ultimately fostering a more equitable and effective healthcare system. This study aims to provide actionable insights to policymakers and stakeholders to enhance access to essential medicines and improve public health outcomes.

REFERENCES

1. Donela V. V. Mounika, M. Shiny, A. Leela Deepthi and P. Phaneendra, "A Review on Essential Medicines and Rational Usage of Drugs" WJPR 407-420 (2017), Volume 6, Issue 5.
2. Ibid.
3. Christine Årdal, Enrico Baraldi, Peter Beyer, Yohann Lacotte, DG Joakim Larsson, Marie-Cécile Ploy, John Arne Rottingen & Ingrid Smithg, Supply chain transparency and the availability of essential medicines, BWHO 319-320 (2021), doi: <http://dx.doi.org/10.2471/BLT.20.267724>.
4. Vandana Roy, A Way to Low Cost, Quality Medicines: Implementation of an Essential Medicines Policy in Public Health Facilities in Delhi (India), IJRPS 397-410 (2013), Vol. 4(3).
5. Sakthivel Selvaraj, Indranil Mukhopadhyay, Preeti Kumar, Malini Aisola, Pritam Datta, Pallav Bhat, Aashna Mehta, Swati Srivastava, Chhaya Pachauli, Universal access to medicines: evidence from Rajasthan, India, WHOEAJPH (July-December 2014), Vol. 3 (3-4).
6. Sujitha Valiya Kambrath and Meera Deshmukh, The burden of Infectious diseases in India – An overview, IJCRLS 2237-2240 (June 2018), Vol. 07, No. 06.
7. Non-Communicable Diseases (NCDs) encompass a wide range of conditions, including chronic respiratory illnesses like asthma and COPD, cancers, diabetes, and cardiovascular diseases, which cover ailments such as strokes and heart attacks.
8. Ramesh S, Kosalram K. The Burden of Non-Communicable Diseases: A Scoping Review Focus on the Context of India, JEHP (February 2023), Published by Wolters Kluwer – Medknow, Volume 12.
9. Supra Note 12.
10. Dutta O, Prasanth A, Kumari A, Akanksha K, Deebe F, Salam N, Burden of Dengue, Leishmaniasis and Lymphatic Filariasis in India and its States from 1990–2019: Analysis from the Global Burden of Disease Study, GBD (October 2019), PLOS ONE.
11. Supra Note 5.
12. Prabal Vikram Singh, Anand Tatambhotla, Rohini Kalvakuntla, Maulik Chokshi, Understanding Public Drug Procurement in India: A Comparative Qualitative Study of Five Indian States, BMJ Open Accessible Medical Research (2013); accessed online at [https://bmjopen.bmj.com/content/bmjopen/3/2/e001987.full.pdf\(bmj.com\)](https://bmjopen.bmj.com/content/bmjopen/3/2/e001987.full.pdf(bmj.com)), on 17th Jan. 2024.
13. Health, Nutrition, Population Sector Unit, India, World Bank. India: Raising the Sights—Better Health Systems for India's Poor. New Delhi, India: The World Bank, 2001; as cited Ibid.
14. Pallavi Jha, Sneha Ambwani, Surjit Singh, Pankaj Bhardwaj, Shobhan Babu Varthya and Jaykaran Charan, Availability of the Essential Medicines in Community Pharmacies: A Cross-Sectional Study, JPP 92–94 (2022) Vol. 13(1).
15. Gautam Sathesh, M.K. Unnikrishnan, Vivekanand Jha, Abdul Salam, India's Latest Essential Medicines List: Gaps, Strengths and Opportunities in Evidence-Based Decision Making, BMJEEM (01-Feb-2023).
16. Medha Wadhwa, Poonam Trivedi, Devang Raval, Somen Saha, Hitesh Prajapati, Rupal Gautam, K V Jagadeesh, Kavitha Rajshekhar, Factors Affecting the Availability and Utilization of Essential Medicines in India: A Systematic Review, JPBS (April 2024).
17. Supra Note 31.
18. Sonam Lavtepatil and Soumitra Ghosh, Improving Access to Medicines by Popularising Generics: A Study of India's People's Medicine' Scheme in Two Districts of Maharashtra, BMCHSR Health (2022).
19. Arpit Parmar, Santanu Nath, Susanta Kumar Padhy, List of Essential Psychotherapeutic Medicines 2019 of India: When Science Was Left Behind, JPP (March-April 2022), Vol. 64, Issue 2; and also, Harmeet Singh Rehan, Indranil Banerjee, Umesh D. Suranagi, Are We Moving Towards a New Definition of Essential Medicines? JPP (October-December 2015), Vol. 6, Issue 4.
20. The World Medicines Situation, 2004, World Health Organization; visited at https://iris.who.int/bitstream/handle/10665/68735/WHO_EDM_PAR_2004.5.pdf on 18th Jan. 2024.
21. UNDG Indicators for Monitoring the Millennium Development Goals. New York: United Nations, 2003.
22. Operational Guidelines Free Drugs Service Initiative. National Health Mission, Ministry of Health and Family Welfare, Government of India. 1st Edition. 2021.