



PHARMACEUTICAL MARKET ACCESS IN EMERGING MARKETS: CONCEPTS, COMPONENTS, AND FUTURE

¹Dr. B Lakshmi, ²Sai Kishore. V, ³Aditya Ingle ⁴Naphisabet Wankhar

¹HOD of Pharmaceutical Management, NIPER Hyderabad, ²Assitant Professor, NIPER Hyderabad,

³Student, NIPER HYDERABAD, ⁴ Student, NIPER Hyderabad

¹Department of Pharmaceutical Management,
¹NIPER Hyderabad, India

Abstract: This literature review explores the evolving landscape of pharmaceutical market access, with a focus on both developed and emerging markets. The significance of tailored market access strategies, especially in complex environments like Italy, is emphasized. The review delves into the challenges pharmaceutical companies face in emerging markets, highlighting growth opportunities. Key components of market access strategies, such as regulatory acceptance and stakeholder engagement, are identified. The discussion extends to the role of technology, including blockchain and AI, in transforming market access. The evolving dynamics of pricing, reimbursement, and health technology assessment are also explored. The conclusion anticipates future trends, envisioning collaborations between pharmaceutical companies and stakeholders to improve access, the transformative impact of digital technologies, and the growing role of AI in pharmaceutical research and development.

Keywords: Pharmaceutical market access, developing markets, developed markets, stakeholders, market access framework, rising healthcare costs, pricing, and reimbursement.

I. INTRODUCTION

The pharmaceutical industry is going through a paradigm shift, and the dynamics of the sector are increasingly being shaped by emerging markets (Kumar et al., 2014). Pharmaceutical corporations used to concentrate their efforts on well-established markets, but as emerging economies gain clout, the tide is turning. Rapid economic growth, shifting demographics, and the rise of the middle class in Asia, Latin America, Africa, and the Middle East are all factors driving up demand for pharmaceuticals and healthcare services (Sendyona et al., 2016a). Since the pharmaceutical sector is always changing, industry participants must predict emerging trends (Critchley & Zaric, 2019).

Gaining entrance to the market involves a calculated combination of different strategies rather than a single effort. Managing growing markets comes with its own set of difficulties, from cultural considerations to legal restrictions. Developing successful market access strategy requires an understanding of these obstacles (Jommi et al., 2012).

This analysis examines the process by which pharmaceutical companies commercialise their products, with a focus on developing nations with intricate regulatory frameworks and poor healthcare systems. New strategies including innovative finance, public-private partnerships, and digital health solutions are covered. Topics covered include healthcare technology's function, price, reimbursement, and regulations. The assessment anticipates the use of digital technology, artificial intelligence in drug research, and collaborations between governments and pharmaceutical corporations.

II. REVIEW OF LITERATURE

of five years. The time series monthly data is collected on stock prices for sample firms and relative macroeconomic variables for the period of 5 years. The data collection period is ranging from January 2010 to Dec 2014. Monthly prices of KSE -100 Index is taken from yahoo finance.

Pharmaceutical market access definition:

Ensuring patients have inexpensive access to pharmaceutical items is known as pharmaceutical market access. A wide range of parties are involved, including payers, patients, healthcare providers, and pharmaceutical corporations (Sendyona et al., 2016b).

Why it is important?

To guarantee that patients have access to the necessary medications
To encourage economic development and progress, and
To lessen the burden of illness (Koch, 2015).

Key challenges for pharmaceutical companies in emerging markets

Including the lack of a developed healthcare infrastructure, cost-cutting measures, intellectual property threats, complicated regulations, and rivalry from regional businesses. Growing demand, unexplored markets, government assistance, and joint ventures are important opportunities. Pharmaceutical companies will be well-positioned to expand in the upcoming years if they can overcome the obstacles and seize the opportunities (Tannoury & Attieh, 2017a).

Pharmaceutical market access strategy components:

Regulatory acceptance, cost and compensation planning for market access stakeholder participation
Additional factors: target patient population, disease location, and competitive landscape
This tactic guarantees that patients may obtain necessary supplies (Van Ommen et al., 2015).

How can pharmaceutical companies improve their market access in emerging markets?

Pharmaceutical companies can increase their market access in emerging markets and increase patient access to their products by learning about the local healthcare systems and markets, creating products and pricing strategies that are specific to these markets, forming alliances with local authorities and healthcare providers, and investing in market access capabilities (Bradfield & El-Sayed, 2009).

Emerging markets to drive global pharmaceutical growth in the next decade:

The pharmaceutical business has a fantastic opportunity in emerging markets. Although a precise definition is still lacking, emerging markets are generally understood by economists to be wealthy, developing countries where investment is expected to provide rising revenue despite significant risks. A market is categorized as emergent for several reasons, independent of the country's economic status, which makes the word applicable to all countries. Years after the second tier of nations emerged, Jim O'Neil, a former chairman of Goldman Sachs' asset management division, identified the leading emerging market economies as BRIC (Brazil, Russia, India, China, and South Africa), and later BRICS (Brazil, Russia, India, China, and South Africa) and MIST (Mexico, Indonesia, South Korea, and Turkey) (Bastone et al., 2023).

New market access models emerge to meet the needs of emerging markets:

Since emerging markets have a sizable and expanding population and a rising healthcare demand, they are becoming more and more significant for pharmaceutical companies. These markets do, however, also come with several difficulties, including restricted government funding for healthcare, intricate regulatory frameworks, and disjointed distribution networks.

Pharmaceutical companies are creating new market access strategies that are suited to the unique requirements of emerging economies to address these issues. Among these ideas are value-based pricing, digital health solutions, creative financing methods, and public-private partnerships (PPPs) (Lu et al., 2015).

Companies that concentrate on developing markets are still in their infancy and have not yet achieved the same level of recognition as companies in Western markets. These emerging markets include the Middle East, Latin America, Brazil, Russia, India, and China, or BRIC countries. Comparatively, the market access arrangements of pharmaceutical businesses (Kumar et al., 2014b). Pharmaceutical market access is the process of making both new and existing pharmaceuticals available to consumers and medical practitioners. This complex process involves a wide range of stakeholders, including governments, healthcare payers, patient advocacy groups, and pharmaceutical companies (Porokhnenko & Sapozhnikova, n.d.).

Regulatory affairs

There are several prospects for the implementation of global access policies due to the increased involvement of emerging market corporations in global health governance (Roemer-Mahler, 2014). Governments and health insurance companies are finding it difficult to keep up with the sharp rise in the price of new drugs (Van Der Gronde et al., 2017).

For the past ten years, the pharmaceutical industry's scientific productivity has been low due to a sharp increase in clinical trial attrition rates, more regulations, and tougher market circumstances (Moors et al., 2014). Understanding the evolution of the industry would necessitate analyzing corporate R&D activities in addition to the interactions between financial markets, emerging economies, tighter regulations, changing demographics leading to new diseases that need to be addressed, drug discovery technologies, and welfare-driven changes in healthcare delivery (Rafols et al., 2014).

The sector faces many obstacles, including ongoing patent expiration and regulatory obstacles; availability, cost, and reimbursement; and productivity in R&D (Gautam & Pan, 2016). Control frameworks that reflect and expand upon experiences in Europe and other emerging economies are being developed by a number of these countries, including China, India, South Africa, and others (Francer et al., 2014). In the past, the pharmaceutical industry's innovation and pricing structure has greatly improved public health. But there's no reason to assume that this will always be the case going forward. Specifically, the increase in the price of specialty medications indicates that a thorough evaluation of OECD nations' pricing policies for new products (Belloni et al., 2016).

Pricing and reimbursement

The cost of pharmaceuticals is a significant and divisive topic in middle- and low-income countries (MLICs). Since most patients pay for their medications out of cost without insurance, affordability depends on prescription prices that are in line with income (Danzon et al., 2015).

In Europe, national governments make the decisions on pharmaceutical reimbursement. The majority of the time, patients are responsible for some portion of the expense of outpatient medications; nonetheless, there are help shield patients from hefty out-of-pocket expenses (Vogler et al., 2017).

In many markets, like China, brand equity is highly valued. This is further supported by sporadic incidents in the past involving real problems with the quality of generic drugs (Anderson, n.d.). The high and rising prevalence of non-communicable diseases (NCDs) like diabetes and hypertension make the prices of medications a particular concern in low- and middle-income countries (LMICs), where they can make up as much as 70% of all healthcare spending (Godman et al., 2018)

Reimbursement organizations and insurance agencies frequently bargain buy costs that are less than the listed pricing of pharmaceuticals (list prices). These agreements could be in the form of discreet discounts, post-purchase rebates, or reimbursements (Iyengar et al., 2016). Due to poor quality control, the pharmaceutical business in emerging nations has been plagued by scandals involving subpar products and corruption, which may have deterred new investment (Tannoury & Attieh, 2017). According to Martikainen, Kivi, and Linnosmaa, the countries with the highest wholesale pricing for recently released reimbursable medications were where producers were allowed to choose their prices (Lakdawalla, 2018).

Health technology assessment

Mobile devices have the power to completely transform the healthcare industry, especially in low- and middle-income nations with limited resources where services and infrastructure for the sector are often inadequate (Chib et al., 2015). In the pharmaceutical industry, the technology or its application must be significantly original and unique. The application of such a technology can change how capable the manufacturing industry is, enhancing the quality and safety of products (O'Connor et al., 2016).

The foundation of health technology assessment, and hence early HTA, is that it combines information from different data sources and pragmatically conducted clinical trials to guide health policy (Ijzerman et al., 2017). HTA can aid in the selection of cost-effective health technologies, the allocation of limited resources increased efficiency and effectiveness of services, and quality assurance of care (Oortwijn et al., 2010). HTA includes all clinical operations, including surgery and diagnostics, as well as medications and medical equipment. HTA contributes to price and reimbursement decision-making by giving accountable entities and organizations reliable, fast, and accurate information about emerging medical technologies (Dankó, 2014). In Poland, an HTA is deemed comprehensive if it includes an economic analysis, a clinical effectiveness study, and an impact analysis on the healthcare system (Angelis et al., 2018). Standards for digital health tech evidence are developed by national and international HTA organizations; one example is NICE's Evidence Standards Framework (Vis et al., 2020).

Stakeholder engagement

A key component of an organization's social effect is stakeholder engagement. Multinational firms rely on increasingly complicated methods for their engagement initiatives (Davila et al., 2018). CSR practices in the context of the pharmaceutical industry, a sector that demonstrates the challenges of stakeholder management to company managers in a particularly dramatic way, have not been thoroughly studied (O'Riordan & Fairbrass, 2014).

To bring the EHHC's (European Heart Health Charter) goal of preventing cardiovascular illness in Switzerland into reality, a multistakeholder framework was established by a core group headed by a global pharmaceutical corporation (Rühli et al., 2017). The pharmaceutical industry is influenced by a variety of factors. As a result, businesses can withstand the intense competition and public scrutiny by implementing sound management practices as well as by comprehending and involving their diverse stakeholders and effectively addressing their concerns (Demir & Min, 2019).

The entire range of R&D is not fully covered by the norms of practice now in place for patient interaction with different stakeholders. The purpose of the EUPATI guidelines is to assist patient participation throughout the whole process of research and development of medications (Warner et al., 2018).

Market access communications

In the healthcare industry, decision-making is a multifaceted process that begins with the creation of evidence, is followed by consideration of each potential intervention, and is ultimately communicated to important stakeholders (Van Nooten et al., 2012).

Blockchain technology could help the healthcare sector manage information security by enabling the analysis and sharing of patient data while protecting its security and privacy (Farouk et al., 2020). A significant factor in the availability and accessibility of care facilities for remote areas is information and communication technologies (Kamsu-Foguem & Foguem, 2014).

Future headlines

Pharma companies partner with governments and other stakeholders to improve access to medicines in emerging markets

To address numerous obstacles in the process of creating goods for underprivileged populations, particularly pharmaceuticals, institutions establish entities known as public-private partnerships (PPPs) (Woodson, 2016). Public-private collaborations help both developed and developing nations by transferring knowledge and

cutting-edge medical innovations. For instance, Text4Baby, a mobile health application (mHealth) that offers free health information to pregnant moms through text messages, is an example of a PPP that expands its service by connecting with hundreds of partners (Stevens & Huys, 2017).

PPPHs (Private-public partnerships for health) have increased awareness of specific diseases through public relations and brand creation, making it easier to raise funds—as shown with "the big three"—AIDS, TB, and malaria (Kostyak et al., 2017). PPP can help support and sustain the development of academic drug discovery skills that benefit society by enhancing the value derived from publically funded research, in addition to assisting the pharmaceutical sector in increasing its productivity (Yildirim et al., 2016).

Digital technologies transform pharmaceutical market access in emerging markets

Blockchain technology has been used in the pharmaceutical industry, enabling quality assurance and tracking of the entire medication production process (Plotnikov & Kuznetsova, 2018). Businesses that have implemented digital technology at higher levels, both in terms of breadth and depth, can provide more innovative products and services. Businesses that combine radical innovation with service innovation maximize the potential of the technologies they have put into use far more (Blichfeldt & Faullant, 2021).

The portfolios of the pharmaceutical sector have begun to shift recently as a result of investments made in the creation of new medications and vaccines in response to COVID-19, which have been made possible by the additional tools and resources made possible by the digital transformation (Kim et al., 2022).

AI and machine learning play a growing role in pharmaceutical market access

Pharmaceutical R&D is changing as a result of AI and ML, which are also boosting productivity and quickening the process of finding new drugs. After 15 to 20 years of use in drug discovery, AI/ML is already beginning to influence the planning, execution, and analysis of clinical trials. Clinical trial applications of AI and ML may be accelerated by the COVID-19 pandemic. It's critical to deconstruct AI and ML and apply them sparingly in the creation of new drugs (Kolluri et al., 2022). Drug research and development methods need to be rethought in light of AI and computer algorithms, taking into account both their potential and limitations. However, given the current omics expertise, they can be used to steer drug development and discovery pipelines by accounting for a range of molecular diversity among individuals and communities, which may be a sign of treatment response or adverse effects (Koromina et al., 2019). Every stage of computer-aided drug design involves the application of AI and ML techniques, and their combination produces powerful molecules with a high success rate. Further advancements have been made in the integration of AI and ML with high-dimensional data and its potent potential. Through increased success rates and improved output prediction, AI/ML integrated models have the potential to substantially reduce the cost of clinical trials (Selvaraj et al., 2022).

III. METHODOLOGY:

The literature search was limited to articles published from 2009 - 2023. The search for articles was done online by using the search words 'Pharmaceutical market access, emerging markets, Pharmaceutical market concept, Pharmaceutical market component, Pharmaceutical Market future' in the title and keywords in research databases at Wiley, Elsevier, Taylor & Francis, ERIC, Springer, SAGE, Frontiers, Google Scholar.

Analysis

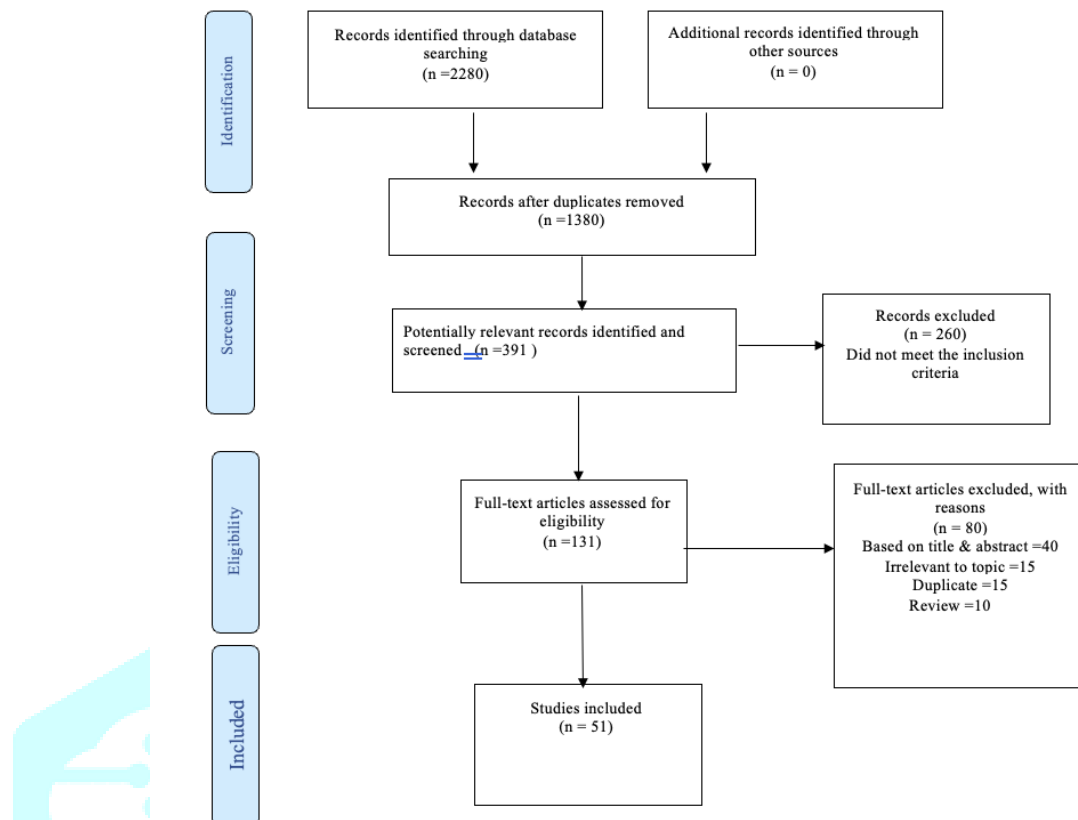
The method used is the Preferred Reporting Item for Systemic Reviews and Meta analytic (PRISMA) method. All articles that have passed the selection process were then reviewed and summarised based on the objectives, year of publication, number of citations and suggestions for further research.

Inclusion & Exclusion criteria

The be included in the current study, studies have to meet some criteria:

- (a) Studies have included some kind of selection criteria (Pharmaceutical market access, emerging markets, Pharmaceutical market concept, Pharmaceutical market component, Pharmaceutical Market future). These criteria limited the number of studies
- (b) Accordingly excluded the studies in which it based on irrelevant information there is no proper Title, Abstract or review.

PRISMA Flow Diagram



Final data set

The research database search resulted in all keyword search results obtained from 2280 research articles. After scanning the title, there was the same article in two different databases. The results after deducting the duplicates are 1380 articles. A total of 391 articles were screened. 260 Articles excluded that they did not meet the inclusion criteria.

Articles accessed for eligibility are 131 articles. A Total number of 80 articles were excluded based on title and abstract (40) Irrelevant to the topic (15) Duplicate (15).

The final data set consists of 51 articles.

The oldest included study was published in the year 2009 and the most recent study was conducted in 2023. The Entire process is shown in the figure.

IV. DISCUSSION:

The discussion revolves around the multifaceted landscape of pharmaceutical market access, emphasizing the industry's pivot towards emerging markets. Challenges in Italy underscore the need for nuanced strategies, unexplored in existing literature. The evolving dynamics of pricing, reimbursement, and health technology assessment are explored, shedding light on their critical roles. Stakeholder engagement emerges as a key factor, with a focus on CSR practices in the pharmaceutical sector. The discussion anticipates future headlines, envisioning collaborative efforts to improve access, the transformative impact of digital technologies, and the growing role of AI in pharmaceutical R&D.

V. CONCLUSION:

In conclusion, this literature review provides a comprehensive overview of the evolving pharmaceutical market access landscape. The industry's shift towards emerging markets, coupled with challenges in Italy, underscores the need for tailored strategies. Key components, including regulatory affairs, pricing, reimbursement, health technology assessment, and stakeholder engagement, are integral to successful market access. The discussion anticipates future trends, emphasizing collaborations to enhance access, the transformative potential of digital technologies, and the increasing influence of AI in pharmaceutical research and development. This synthesis of current knowledge sets the stage for continued exploration of innovative approaches to navigate the complexities of pharmaceutical market access in a rapidly evolving global landscape.

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