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Regulatory pharmacy strategies for reducing drug development costs in underserved population

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Abstract

The rising costs of drug development present a critical challenge, particularly for underserved populations, who often struggle to access essential medicines. This paper examines several regulatory strategies to reduce these costs, such as adaptive regulatory frameworks, incentives for orphan drug development, leveraging real-world evidence (RWE), public-private partnerships (PPPs), and promoting generic drug development. These strategies offer pathways to balance innovation with affordability, thereby addressing health disparities.

Keywords: Regulatory; Drug Development Costs; Pharmacy Strategies; Underserved Populations

1. Introduction

Pharmaceutical innovations have drastically transformed healthcare over the last fifty years, enabling the treatment and prevention of many diseases that were once difficult or impossible to manage (Morgan et al, 2020). These advances have become so integral to modern healthcare that equitable access to them is now considered a fundamental human right, which presents a significant social and policy challenge, particularly due to the costs involved (WHO, 2017). The global expenditure on pharmaceuticals illustrates the magnitude of this challenge. In 2017, pharmaceutical spending worldwide reached a staggering $1.135 trillion, marking a 56% increase from a decade earlier(IQVIA, 2018). While this surge in spending is partly driven by the increasing demand for medicines, the escalating prices of pharmaceuticals remain a pressing concern for health system managers. The pricing strategies employed by pharmaceutical companies have raised questions regarding their fairness, as drug prices are often perceived to exceed the value they provide and may not align with fair compensation for investments in research and development (Morgan et al, 2020).

This situation poses a growing challenge across the globe, as it threatens the sustainability of the very systems that are designed to support pharmaceutical innovation. Addressing this issue requires balancing the need to foster continued innovation in drug development with ensuring that medicines are affordable and accessible to all populations, regardless of economic status. The development of new pharmaceuticals is an arduous, expensive process, taking up to 10 to 15 years and costing between $1.3 billion and $2.8 billion per drug (DiMasi, Grabowski, & Hansen, 2016). These staggering costs limit access to essential medications for underserved populations, exacerbating global health inequities. According to the World Health Organization (WHO), over two billion people globally lack access to basic medicines, with affordability being a significant barrier (WHO, 2018). Pharmaceutical companies, driven by profit motives, often prioritize drugs targeting high-income markets, neglecting conditions that disproportionately affect low-income regions (DNDi, 2020). Drug development is a costly and complex process, often taking over a decade and costing billions of dollars. According to estimates, the average cost of developing a new drug range from $1.3 billion to $2.8 billion, depending on the therapeutic area and success rates (DiMasi, Grabowski, & Hansen, 2016).

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Generating social value from pharmaceutical innovations requires policies that can simultaneously encourage investment in research and development while ensuring that new treatments become accessible to the public (Morgan et al, 2020). A key mechanism used to promote such investment is the patent system, which grants temporary market power to companies, enabling them to recoup their research costs and secure profits. This exclusivity period incentivizes pharmaceutical companies to invest in areas with significant unmet medical needs, where high development costs and risks might otherwise deter investment (Morgan et al, 2020). However, the system is designed so that, after a certain time, the patent expires, allowing competitors to enter the market and produce generic versions of the drug, which often leads to a decrease in prices and increased access for consumers (Morgan et al, 2020).

2. Challenges in Drug Development for Underserved Populations

Drug development is an expensive process, with the preclinical research, clinical trials, and regulatory approval processes driving up costs significantly. Studies suggest that developing a new drug may cost between $1.3 billion and $2.8 billion (DiMasi, Grabowski, & Hansen, 2016). The process of developing a new drug is an immensely complex and resource-intensive endeavour. It demands not only a significant financial investment but also the commitment of vast human resources and advanced technological capabilities (Dickson et al, 2009). Each stage of drug development—from initial discovery, through preclinical trials, and into clinical testing—requires adherence to rigorous regulations that govern safety, efficacy, and manufacturing practices. These strict standards are designed to ensure that any new drug is safe for use in the general population. However, they also contribute substantially to the overall costs associated with bringing a new chemical entity (NCE) to market (Dickson et al, 2009). The need for large-scale clinical trials, adherence to Good Manufacturing Practices (GMP), and the rigorous evaluation of both short-term and long-term effects mean that pharmaceutical companies often face long development timelines, sometimes lasting over a decade, and substantial financial outlays. This has led to a steady increase in the costs of research and development (R&D) for new drug candidates.

A critical issue arising from this trend is the question of who will ultimately bear the financial burden for such expensive pharmaceutical R&D. Historically, the cost has largely been borne by the pharmaceutical companies themselves, recouped through the market exclusivity granted by patents (Dickson et al, 2009).. These patents allow companies to charge premium prices for new drugs during a limited period before generic competition enters the market. However, with the rising costs of drug development and the increasing complexity of modern therapeutics, there is growing concern about whether this model remains sustainable (Dickson et al, 2009).

These costs are passed on to consumers, making essential drugs unaffordable for underserved populations. As a result, pharmaceutical companies may prioritize drugs for profitable markets, neglecting treatments for conditions that disproportionately affect low-income regions.

Public healthcare systems, insurance companies, and patients themselves are all impacted by the high prices of new medications, raising questions about affordability and access. The societal benefits of innovative drugs are clear, but finding a balance between rewarding the innovation of pharmaceutical companies and ensuring that life-saving treatments remain accessible to all segments of the population is an ongoing challenge.

The sheer cost of drug development poses a major obstacle, especially for treatments targeting less profitable diseases or conditions prevalent in low-income countries. Estimates show that only 1 in 5,000 compounds makes it from the discovery phase to market, underscoring the inefficiency of the current drug development pipeline (Kaitin, 2010). Clinical trials, which are necessary to establish the safety and efficacy of new drugs, are particularly expensive. A single phase III clinical trial can cost between $11 million and $53 million (Getz et al., 2015).

For pharmaceutical companies, this high cost disincentivizes investment in diseases that affect smaller or poorer populations. As a result, conditions such as malaria, tuberculosis, and neglected tropical diseases (NTDs) remain underfunded and undertreated. The WHO notes that NTDs continue to cause significant morbidity and mortality in low-income countries despite the availability of cost-effective interventions (WHO, 2021). Underserved populations experience profound health disparities due to limited access to affordable medications. Diseases that disproportionately affect these populations, such as HIV, malaria, and tuberculosis, often go untreated because pharmaceutical companies find these markets unprofitable (UNAIDS, 2019). According to the Global Health Observatory, access to essential medicines remains inadequate in over 30% of the world's population, particularly in Africa and Southeast Asia (WHO, 2020).

Moreover, existing healthcare infrastructure in low- and middle-income countries (LMICs) often lacks the capacity to support the distribution and administration of new drugs. Without comprehensive health systems, even affordable medications may fail to reach the populations that need them most (Wirtz et al., 2017).

3. Regulatory Hurdles

The regulatory approval process, while necessary to ensure drug safety and efficacy, contributes significantly to the overall cost of drug development. Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require extensive data on a drug's performance across multiple clinical trials (FDA, 2020). These trials often require significant investment and take years to complete, further delaying access to life-saving treatments in underserved populations.

For instance, the regulatory process for HIV antiretroviral drugs in the 1990s took an average of seven years from clinical testing to market approval, delaying access to essential therapies for millions of people (UNAIDS, 2019). Although regulatory agencies have made strides in streamlining approval processes, particularly for orphan drugs and diseases with unmet medical needs, the regulatory burden remains substantial.

4. Regulatory Pharmacy Strategies to Reduce Drug Development Costs

Adaptive regulatory frameworks provide a flexible approach to drug development, allowing for the expedited approval of drugs that show early promise in clinical trials. The EMA's adaptive pathways pilot program, launched in 2014, aimed to expedite the approval of drugs for patients with unmet medical needs (EMA, 2021). Similarly, the FDA's Breakthrough Therapy Designation offers a fast-tracked approval process for drugs that demonstrate substantial improvement over existing therapies (FDA, 2020). By allowing for early approval based on preliminary data, adaptive pathways reduce the need for extensive, long-term clinical trials, thereby lowering development costs (Eichler et al., 2015). These frameworks are particularly beneficial for drugs targeting underserved populations, where the financial risk of lengthy trials often deters investment. For instance, the Breakthrough Therapy Designation has been instrumental in accelerating the approval of oncology drugs, many of which treat rare cancers that disproportionately affect low-income populations (Brahmachari, 2017).

Orphan drugs, developed to treat rare diseases, have been a focus of regulatory incentives since the passage of the Orphan Drug Act in 1983 (U.S. Congress, 1983). The Act provides a range of benefits to pharmaceutical companies, including tax credits, grants for clinical research, and seven years of market exclusivity. These incentives have led to a significant increase in orphan drug approvals, with over 600 orphan drugs approved since the Act's passage (FDA, 2020). Rare diseases, which affect fewer than 200,000 people in the United States, often overlap with underserved populations, particularly in LMICs, where conditions such as sickle cell disease and certain types of cancer are more prevalent (NIH, 2022). Expanding similar incentives to include diseases that disproportionately affect low-income regions could encourage pharmaceutical companies to invest in treatments for NTDs, which currently receive limited funding. The success of orphan drug incentives in high-income countries suggests that similar models could be applied globally to reduce development costs and increase access to essential medications (Kesselheim, Avorn, & Sarpatwari, 2017).

Real-world evidence (RWE) is increasingly recognized as a valuable tool for reducing the cost and time associated with drug development. RWE includes data from sources such as electronic health records, insurance claims, and patient registries, offering insights into a drug's performance in real-world settings (Sherman et al., 2016). By complementing traditional clinical trial data, RWE can streamline regulatory approval processes and reduce the need for large, expensive trials. Regulatory agencies, including the FDA and EMA, are now incorporating RWE into their decision-making processes. According to a study by Sherman et al. (2016), the use of RWE has the potential to reduce clinical trial costs by up to 40%. This is particularly relevant for underserved populations, where conducting large-scale clinical trials may be logistically and financially challenging. RWE can provide valuable insights into how a drug performs in diverse, real-world populations, helping to ensure that treatments are safe and effective across different demographics (FDA, 2020).

Public-private partnerships (PPPs) have been highly effective in reducing drug development costs, particularly for diseases that disproportionately affect underserved populations. The Drugs for Neglected Diseases initiative (DNDi) is one such PPP, bringing together governments, non-profit organizations, and pharmaceutical companies to develop affordable treatments for neglected tropical diseases (DNDi, 2020). Through collaboration, DNDi has been able to reduce the cost of drug development by sharing resources, expertise, and financial risk. For example, DNDi's partnership

with Sanofi resulted in the development of fexinidazole, a new treatment for sleeping sickness, which was developed at a fraction of the cost of traditional drug development (DNDi, 2020). This model could be expanded to other diseases that affect underserved populations, offering a cost-effective solution to the high financial barriers associated with drug development. Generic drugs play a crucial role in reducing the cost of medications and improving access to essential medicines. In the United States, the Hatch-Waxman Act of 1984 facilitated the development of generic drugs by allowing manufacturers to submit abbreviated new drug applications (ANDAs), significantly reducing the time and cost required to bring generics to market (U.S. Congress, 1984). Since its enactment, the availability of generic drugs has increased dramatically, with generics accounting for approximately 90% of all prescriptions filled in the U.S. (FDA, 2020). For underserved populations, the promotion of generic drugs is essential for reducing drug costs. Expanding regulatory frameworks that encourage the approval of generics, particularly for diseases prevalent in low-income regions, could help ensure broader access to affordable medications. According to the WHO, promoting the use of generic drugs in LMICs could reduce drug prices by up to 80% (WHO, 2018).

5. Conclusion

Regulatory pharmacy strategies play a critical role in reducing drug development costs and improving access to essential medications, particularly for underserved populations. Adaptive regulatory frameworks, incentives for orphan drug development, the use of real-world evidence, public-private partnerships, and the promotion of generic drugs are all viable approaches for addressing the high costs of drug development. While challenges remain, such as balancing safety and speed, addressing global regulatory disparities, and ensuring affordable pricing, these strategies provide a pathway to greater equity in drug development and access. Strengthening post-market surveillance, expanding regulatory collaboration, and leveraging digital technologies will further enhance these efforts, ultimately contributing to a healthier and more just global society.

Recommendations

Based on the reviewed study, the following is recommended;

- Compare the effectiveness of regulatory strategies across different global regions.

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