

Unpacking the Role of Regulatory Affairs in Ensuring Affordable Access to New Drugs

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Introduction

The healthcare landscape is ever-evolving, with new drugs and treatments continually being developed to address a wide array of diseases and medical conditions. However, the availability of these new therapies hinges not only on scientific innovation but also on the regulatory frameworks that govern the approval, pricing and distribution of these medications. Regulatory affairs play a crucial role in this process, serving as the bridge between scientific advancements, government policies and the public's access to affordable medications. Regulatory agencies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other national health authorities are tasked with ensuring that new drugs meet the necessary safety, efficacy and quality standards. But their role extends far beyond simply approving new drugs—they also shape the conditions under which these drugs are made accessible to the public, balancing the need for innovation with the goal of ensuring affordability for all [1].

Regulatory affairs encompasses the processes through which new products—drugs, biologics and medical devices—are approved for use within a particular market. Regulatory professionals are responsible for ensuring that these products comply with legal and scientific standards set by national and international agencies. Their tasks involve preparing and submitting documentation to regulatory bodies, liaising with authorities to provide necessary information and staying updated on changing regulations that affect product development and marketing. The regulatory framework for pharmaceuticals is designed to ensure that drugs are safe, effective and of high quality before they are released to the public. However, regulatory affairs professionals are also involved in shaping the broader policies that govern drug access, pricing and reimbursement. Their work can have significant implications for the affordability and availability of drugs, especially in the context of global health disparities [2].

Description

The regulatory pathway for a new drug involves several key stages, each designed to ensure that a drug meets rigorous standards. These stages include preclinical testing, clinical trials (Phase I-III) and regulatory submission for approval. Once a drug is approved, it enters the market and may be subject to ongoing monitoring for safety and efficacy (Phase IV). Before clinical trials can begin, a drug is tested in the laboratory and on animals to evaluate its safety profile. If these tests are successful, the drug can proceed to human trials. In human trials, the drug undergoes a series of phases (I-III) to assess its safety, dosage, efficacy and side effects in humans. Only after successful trials can a drug be submitted for regulatory approval. A drug company submits a comprehensive dossier to regulatory agencies, which includes data from preclinical and clinical trials, manufacturing information and proposed labeling. Regulatory authorities review this data to ensure the drug's safety and efficacy

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before granting approval. If a regulatory agency grants approval, the drug is authorized for sale and distribution. However, the company must also ensure compliance with regulations regarding marketing practices, pricing and post-market surveillance. Different countries and regions have varying regulatory frameworks, although many regulatory agencies work in coordination with one another. For example, the FDA in the U.S. and the EMA in the European Union have slightly different standards and approval processes. However, through harmonization efforts like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), there is an effort to standardize regulations and make the global drug development process more efficient [3].

While regulatory agencies are responsible for ensuring the safety and efficacy of new drugs, they do not directly control the pricing of medications. However, regulatory affairs professionals play a key role in shaping the conditions under which drugs are priced and made accessible to the public. Drug pricing is influenced by a variety of factors, including research and development costs, market competition, patent protections and reimbursement policies. One important aspect of regulatory affairs is patent law. A patent grants a company exclusive rights to manufacture and sell a drug for a limited period (usually 20 years), which allows them to recoup the costs of development. During this period, the drug is protected from generic competition, which can significantly increase its price. Once the patent expires, generic manufacturers can enter the market, leading to competition and a decrease in the price of the drug. While patents help incentivize innovation, they can also limit access to affordable medications, particularly in low- and middle-income countries. Regulatory affairs professionals may engage in negotiations and discussions with regulators to ensure that the intellectual property protections granted to a new drug are balanced with the need for access to affordable therapies. In some cases, regulators may allow for exceptions to patent protections, such as the issuance of compulsory licenses, to facilitate access to essential medications in certain regions [4].

Regulatory agencies also have special programs to incentivize the development of orphan drugs—medications that treat rare diseases affecting fewer than 200,000 people in the U.S. or a similarly small population in other countries. Because the market for these drugs is limited, there is often little financial incentive for companies to develop them without regulatory incentives such as extended patent protection, tax credits, or grants. These incentives help make orphan drugs more financially viable for pharmaceutical companies, but they also raise concerns about affordability. Orphan drugs are often priced much higher than other medications and in the absence of market competition, these high prices can place a significant financial burden on healthcare systems and patients. Regulatory affairs professionals are involved in crafting policies that ensure that orphan drugs are priced in a way that balances innovation with affordability and accessibility. One of the most significant challenges faced by regulators is striking a balance between fostering pharmaceutical innovation and ensuring that new drugs remain affordable. The high cost of drug development, particularly for cutting-edge therapies such as biologics and gene therapies, often leads to exorbitant drug prices. While these therapies can offer groundbreaking benefits for patients, they may also be financially out of reach for many people. Regulatory agencies, therefore, must carefully evaluate the potential benefits of new therapies against their cost and the societal need for access. In some cases, regulatory agencies may approve a drug under expedited pathways, such as the FDA's "Breakthrough Therapy" or "Accelerated Approval" designations, to fast-track access to life-saving medications. However, these programs can sometimes bypass extensive cost-effectiveness evaluations, potentially leading to high prices for new therapies [5].

Conclusion

The role of regulatory affairs in ensuring affordable access to new drugs is multifaceted and complex. Regulatory agencies are tasked not only with ensuring that drugs are safe and effective but also with navigating the broader landscape of drug pricing, market access and reimbursement policies. As the pharmaceutical industry continues to innovate, regulatory affairs professionals will play a crucial role in balancing the need for scientific progress with the goal of making essential medications accessible and affordable for all populations. While the regulatory process itself cannot directly control drug prices, the policies and decisions made by regulatory agencies can have a significant impact on the affordability and availability of medications. By collaborating with policymakers, industry stakeholders and public health organizations, regulatory professionals can help create a framework that encourages innovation while ensuring that new therapies reach patients who need them most. In an era of rapidly advancing medical technologies and rising healthcare costs, the importance of regulatory affairs in promoting access to affordable medications cannot be overstated. As we continue to grapple with global health challenges, the work of regulatory professionals will be integral in shaping a future where life-saving treatments are within reach for everyone, regardless of their economic circumstances.

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Conflict of Interest

There are no conflicts of interest by author.

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