From Lab to Market: The Complete Journey of Drug Licensing

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Abstract

The journey of a drug from the confines of a laboratory to the shelves of a pharmacy is a complex, multi-phase process governed by rigorous scientific, regulatory, and ethical standards. Drug licensing is not merely a bureaucratic hurdle—it's a critical safeguard that ensures new medications are safe, effective, and beneficial to public health. This article explores the complete lifecycle of drug development and licensing, from initial discovery to market approval.

Keywords: Psychiatric disorders, • Celiac disease

Introduction

The journey begins with drug discovery, where researchers identify potential compounds that could treat a specific disease or condition. Preclinical research is essential to determine whether a drug is safe enough to be tested in humans. Only a small fraction of compounds make it past this stage. If preclinical results are promising, the drug sponsor submits an Investigational New Drug (IND) application to regulatory authorities (e.g., FDA in the U.S., CDSCO in India). Upon approval, the drug enters clinical trials, which are conducted in three main phases [1].

This phase determines how the drug behaves in the human body and identifies any immediate adverse reactions. Licensing does not guarantee affordability or availability, especially in low-income countries. This phase is the most expensive and time-consuming. Conditional approvals based on early data, with ongoing monitoring. It provides comprehensive data needed for regulatory approval [2].

Once clinical trials are successfully completed, the drug sponsor submits a New Drug Application (NDA) or Marketing Authorization Application (MAA) to the relevant regulatory body. If the drug meets all safety, efficacy, and quality standards, it receives marketing approval—the official license to be sold and prescribed [3].

Approval is not the end of the journey. The drug enters Phase IV, also known as post-marketing surveillance, which includes**,** This phase ensures continued safety and allows regulators to withdraw or restrict a drug if serious issues arise. Some countries participate in mutual recognition agreements, allowing drugs approved in one region to be fast-tracked in another [4].

Recent debates around emergency use authorizations (e.g., during the COVID-19 pandemic) have highlighted tensions between speed and safety. Conditional approvals based on early data, with ongoing monitoring. Adaptive licensing: Conditional approvals based on early data, with ongoing monitoring [5].

Conclusion

Drug licensing is a meticulous process that balances innovation with public safety. While it may seem slow or bureaucratic, each step is designed to protect patients and ensure that new treatments truly deliver on their promise. Licensing does not guarantee affordability or availability, especially in low-income countries. Conditional approvals based on early data, with ongoing monitoring. As science evolves and global health challenges intensify, the licensing journey must adapt becoming faster, more transparent, and more equitable.

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