THE PROCESS OF DEVELOPING NEW MEDICINES

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Annotation: *This article explores the complex and multi-stage process of developing new medicines, from the early stages of drug discovery to post-marketing surveillance. The paper discusses preclinical and clinical trials, regulatory requirements, and ethical considerations. Special attention is given to the technological and economic challenges faced by the pharmaceutical industry.*

Key words: *drug development, clinical trials, pharmacology, regulatory approval, pharmaceutical industry.*

INTRODUCTION

The development of new medicines is one of the most critical and resource-intensive activities in modern healthcare. It plays a central role in combating diseases, improving quality of life, and extending life expectancy. The process is characterized by high complexity, significant financial investment, and the need for strict regulatory compliance. On average, it takes between 10 and 15 years to bring a new drug from the initial research stage to market, with costs often exceeding billions of dollars.

The urgency for novel therapeutic solutions has increased dramatically due to the emergence of drug-resistant pathogens, global pandemics, and the growing burden of chronic diseases such as cancer, cardiovascular disorders, and diabetes. In this context, pharmaceutical innovation has become both a medical necessity and an economic challenge.

Drug development requires collaboration among multidisciplinary teams, including medicinal chemists, pharmacologists, toxicologists, clinicians, regulatory specialists, and data scientists. It is not only a scientific endeavor but also a carefully regulated process governed by agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Drug discovery and target identification

The process of developing a new medicine begins with identifying a biological target associated with a specific disease. This target is typically a molecule such as a protein, enzyme, or receptor that plays a critical role in the disease's progression. Advances in genomics, proteomics, and bioinformatics have significantly improved the ability to identify and validate such targets.

Once a target is identified, scientists explore various chemical and biological compounds to determine which might interact effectively with it. High-throughput screening (HTS) technologies allow researchers to test thousands to millions of

compounds rapidly. Computational drug design and artificial intelligence are increasingly employed to predict molecular interactions, optimize compound structures, and reduce the time required for initial discovery.

The drug discovery phase may last several years, with the aim of producing a “lead compound” — a promising candidate that exhibits desired biological activity and favorable pharmacological properties.

Preclinical development

Before a drug candidate can be tested in humans, it undergoes preclinical studies to assess its safety, toxicity, pharmacokinetics (how the drug is absorbed, distributed, metabolized, and excreted), and pharmacodynamics (how the drug affects the body).

Preclinical testing involves both in vitro experiments (using cell cultures) and in vivo studies (using animal models). These studies help determine the appropriate dosage range and identify potential side effects.

Ethical considerations are critical at this stage. Researchers must comply with animal welfare regulations and adhere to internationally accepted standards such as the 3Rs principle — Replacement, Reduction, and Refinement — to minimize animal suffering.

If the results demonstrate acceptable safety and efficacy, the sponsor company submits an Investigational New Drug (IND) application to the relevant regulatory authority, requesting permission to begin clinical trials in humans.

Clinical development

Clinical trials are divided into three main phases, each with distinct objectives:

• Phase I – Conducted with a small group (20–100) of healthy volunteers or patients, focusing primarily on safety, tolerability, and pharmacokinetics. This phase determines the safe dosage range.

• Phase II – Involves several hundred patients who have the disease or condition. The primary goal is to assess efficacy and further evaluate safety. Phase II studies help refine the optimal dose and regimen.

• Phase III – Large-scale trials involving thousands of patients, often across multiple countries. These studies confirm efficacy, monitor side effects, and compare the new medicine to existing treatments. The data gathered during Phase III form the basis for regulatory approval.

Clinical trials must follow strict ethical and scientific standards, including Good Clinical Practice (GCP) guidelines. Informed consent from participants is mandatory, and independent ethics committees oversee trial conduct to protect participants’ rights and safety.

Regulatory review and approval

After successful completion of clinical trials, the developer compiles all preclinical and clinical data into a comprehensive dossier — the New Drug Application (NDA) in the United States or Marketing Authorisation Application (MAA) in the European Union.

Regulatory agencies such as the FDA, EMA, or other national authorities thoroughly review the submission to assess whether the drug is safe, effective, and manufactured to high quality standards. The review process can take months to years, depending on the complexity of the drug and the urgency of its medical need.

In certain cases, expedited pathways like the FDA's "Fast Track," "Breakthrough Therapy," or "Emergency Use Authorization" can accelerate approval for medicines addressing serious or life-threatening conditions.

Manufacturing and quality control

Once approved, the medicine enters large-scale manufacturing.

Pharmaceutical production must comply with Good Manufacturing Practice (GMP) standards to ensure consistency, purity, and safety. Every batch undergoes rigorous quality control testing before release.

Scaling up from laboratory synthesis to industrial production is often challenging. Manufacturing processes must be optimized for efficiency while maintaining strict adherence to regulatory requirements.

Post-marketing surveillance (Phase IV)

The development process does not end with regulatory approval. In Phase IV, the medicine is monitored in the general population to detect any rare or long-term adverse effects that may not have been apparent during clinical trials.

Pharmacovigilance systems collect and analyze safety data, enabling regulatory agencies to take actions such as updating safety labels, restricting use, or withdrawing the product from the market if necessary.

Ethical, economic, and technological considerations

The development of new medicines raises important ethical questions, particularly regarding access, affordability, and the use of human and animal subjects in research. The high cost of drug development often translates into high market prices, which can limit access in low- and middle-income countries.

Technological advances — including artificial intelligence, CRISPR-based gene editing, and personalized medicine — are transforming the pharmaceutical landscape, offering new possibilities for faster, more precise drug development. However, they also bring challenges related to data privacy, bioethics, and regulatory adaptation.

CONCLUSION

The development of new medicines is a long, complex, and highly regulated process that combines cutting-edge science with rigorous ethical oversight. From the initial identification of a biological target to the large-scale manufacturing and post-

marketing surveillance, each stage is designed to ensure that a medicine is both effective and safe for human use.

The journey typically spans more than a decade and requires substantial investment, often exceeding billions of dollars. While the scientific challenges are formidable — ranging from understanding disease mechanisms to optimizing drug delivery — the economic and ethical considerations are equally significant. The high cost of research and development can create barriers to access, particularly in low-income regions, underscoring the need for global cooperation and equitable pricing models.

Technological innovations, such as artificial intelligence-driven drug discovery, advanced biotechnologies, and personalized medicine approaches, are accelerating timelines and improving success rates. These advances promise to transform the pharmaceutical landscape, making it possible to develop more targeted therapies with fewer side effects. However, they also demand adaptive regulatory frameworks and careful ethical consideration to prevent misuse or inequality in healthcare access.

Ultimately, the process of developing new medicines is not merely a technical endeavor — it is a societal commitment to improving health outcomes and quality of life worldwide. Continuous investment in research, transparent collaboration between industry and regulators, and a firm dedication to ethical principles will be essential to meet the medical challenges of the future.

REFERENCES:

1. Barrett J. (ed.), Fundamentals of Drug Development

2.Educational literature for students of pharmaceutical universities and faculties
Под редакцией академика РАМН,
профессора А.П. АРЗАМАСЦЕВА
“Фармацевтическая химия” Москва-2004

3. Под редакцией С.М. Дроговоз
Фармакология-сіто!
(фармакологическая логика) учебник Харьков 2007

1. Shaxnoza A. PROSODIC FEATURES OF SPEECH FORMS OF ADDRESS IN ENGLISH DISCOURSE IN COMPARISON WITH RUSSIAN //Journal of Modern Educational Achievements. – 2022. – Т. 1. – С. 33-38.

2. Shaxnoza A. PROSODIC FEATURES OF SPEECH FORMS OF ADDRESS IN ENGLISH DISCOURSE IN COMPARISON WITH RUSSIAN //Journal of Modern Educational Achievements. – 2022. – Т. 1. – С. 33-38.

3. Shaxnoza, Artikova. "PROSODIC FEATURES OF SPEECH FORMS OF ADDRESS IN ENGLISH DISCOURSE IN COMPARISON WITH RUSSIAN." Journal of Modern Educational Achievements 1 (2022): 33-38.

4. Shaxnoza, Artikova. "PROSODIC FEATURES OF SPEECH FORMS OF ADDRESS IN ENGLISH DISCOURSE IN COMPARISON WITH RUSSIAN." Journal of Modern Educational Achievements 1 (2022): 33-38.

5. Artikova S. M. О НЕОБХОДИМОСТИ ОБУЧЕНИЯ ИНОСТРАННЫМ ЯЗЫКАМ В РЕСПУБЛИКЕ УЗБЕКИСТАН //Theoretical & Applied Science. – 2020. – №. 5. – С. 79-83.

6. Artikova S. M. О НЕОБХОДИМОСТИ ОБУЧЕНИЯ ИНОСТРАННЫМ ЯЗЫКАМ В РЕСПУБЛИКЕ УЗБЕКИСТАН //Theoretical & Applied Science. – 2020. – №. 5. – С. 79-83.

7. Artikova, S. M. (2020). О НЕОБХОДИМОСТИ ОБУЧЕНИЯ ИНОСТРАННЫМ ЯЗЫКАМ В РЕСПУБЛИКЕ УЗБЕКИСТАН. Theoretical & Applied Science, (5), 79-83.

8. Artikova, S. M. (2020). О НЕОБХОДИМОСТИ ОБУЧЕНИЯ ИНОСТРАННЫМ ЯЗЫКАМ В РЕСПУБЛИКЕ УЗБЕКИСТАН. Theoretical & Applied Science, (5), 79-83.