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Short Review Paper

Short Review Paper on Drug Lag and Rare Disease Treatments in India: An Urgent Call for Actions

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Abstract

Drug lag, the delay in the availability of new medications, poses a significant challenge for patients with rare diseases in India. This paper examines the impact of drug lag on rare disease treatments in India, explores the regulatory and systemic factors contributing to these delays, and proposes strategies to mitigate the issue. By conducting a thorough examination of scholarly sources and policy analysis, the paper underscores the urgent need for regulatory reform and enhanced patient access to rare disease treatments.

Keywords: Drug lag, Rare diseases, India, Regulatory reform, Patient access, Orphan drugs, Clinical trials.

Introduction

Rare diseases, also known as orphan diseases, are conditions that impact a limited portion of the population. However, despite their low prevalence, they collectively affect millions worldwide, with more than 7,000 rare diseases impacting around 300 million people globally. Although each disease may only affect a few individuals, together, they present a substantial public health challenge.

In India, the landscape of rare diseases is particularly complex. With a population exceeding 1.4 billion, even rare diseases can affect large numbers. It is estimated that around 70 million Indians suffer from a rare disease. The country's healthcare infrastructure and policy frameworks are gradually evolving to address these conditions, yet awareness, diagnosis, and access to treatment remain significant hurdles for patients and their families[1].

Rare Diseases in India

India is home to a substantial number of individuals affected by rare diseases. Estimates suggest that there are approximately 70 to 90 million people in India living with a rare disease. This figure highlights the significant public health challenge posed by rare diseases in a country with a vast and diverse population.

In India, certain rare diseases are more prevalent due to various genetic, environmental, and socio-economic factors. Some of the most common rare diseases in the Indian context include: i. Thalassemia, ii. Hemophilia, iii. Cystic Fibrosis, iv. Gaucher Disease, v. Pompe Disease, vi. Duchenne Muscular Dystrophy (DMD), vii. Spinal Muscular Atrophy (SMA), viii. Primary Immunodeficiency Disorders[2].

Drug Approval Process in India

The Central Drugs Standard Control Organization (CDSCO) serves as India's primary regulatory authority, overseeing the approval, regulation, and monitoring of pharmaceuticals and medical devices.

The CDSCO ensures the safety, efficacy, and quality of drugs through a structured approval process. This process involves several key stages: Pre-Clinical Studies, Clinical Trials, New Drug Application (NDA), Approval, and Post-Marketing Surveillance. The New Drugs and Clinical Trials Rules, 2019 streamline India's regulatory framework for drug development and clinical trials.

Key features include faster approvals for new drugs, especially those approved in specific countries, and defined timelines for regulatory decisions[3].

Drug Lag in India

Drug lag is the delay in the release of new medications in certain regions following their approval elsewhere. This delay arises from multiple factors including Regulatory Differences, Administrative Issues, Economic Factors, Strategic Business Decisions, Local Clinical Trials and Post-Marketing Requirements, and Legal and Political Challenges[4].

The National Policy for Rare Diseases 2021, introduced by the Government of India, seeks to tackle the difficulties encountered by those with rare diseases. These diseases, which are frequently life-threatening and chronically debilitating, impact a minor segment of the population but have far-reaching consequences for patients and their families[5].

Comparison of Approval Timelines and Processes for Rare Disease Treatments

United States (FDA): The standard review process typically requires 10 months, whereas priority review shortens this to 6 months. Advantages include Fast Track designation, Breakthrough Therapy status, and Accelerated Approval pathways.and 7 years of market exclusivity under the Orphan Drug Act. Challenges include a high regulatory burden and high development costs[6].

European Union (EMA): Standard review takes up to 7 months, priority review takes 5 months. Benefits include Accelerated Assessment, 10 years of market exclusivity, and fee reductions. Challenges include lang3.ISCA-RJPcS-2024-006uage barriers and cultural differences[7].

Japan (PMDA): Standard review takes 12 months, priority review takes 6 months. Benefits include Priority Review and a 10-year re-examination period for orphan drugs. Challenges include language barriers and cultural differences[8].

India (CDSCO): Standard review takes 12-18 months, with priority review times varying. Recent policies offer expedited review for rare diseases, but there are limited market exclusivity and financial incentives. Challenges include inconsistent implementation and resource constraints[9].

Policy Recommendations to Address Drug Lag in India

To address drug lag and improve access to rare disease treatments in India, streamlining regulatory processes is essential. Recommendations include Harmonization of Regulations, Expedited Review Pathways, Adaptive Licensing, and Enhanced Regulatory Infrastructure[10.]

Encouraging pharmaceutical innovation and development of rare disease treatments in India requires targeted incentives such as Tax Incentives and Grants, Orphan Drug Designation, Public-Private Partnerships, and Intellectual Property Protections[11].

Conclusion

Drug lag significantly impacts patients with rare diseases in India, leading to delayed access to life-saving treatments, increased morbidity and mortality, and substantial physical, emotional, and financial burdens on patients and their families. By implementing policy recommendations, India can improve the lives of patients with rare diseases and ensure that they receive timely and effective treatments.

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