REGULATORY REQUIREMENTS FOR EXPEDITED DRUG APPROVAL PROGRAMS

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ABSTRACT

Accelerated approval processes bring innovative pharmaceuticals to market faster than ever before. Different approval methods are being used by regulatory authorities in the United States (US) to reduce the time it takes to perform a clinical review. Traditional drug discovery is an expensive and time-consuming process. According to one study, the pharmaceutical industry spends an average of $3 billion on R&D operations, and it takes more than ten years to develop and launch one new drug. Patients cannot afford to wait ten years for a life-saving medicine. As a result, regulatory authorities and pharmaceutical companies are adopting a strategy in the field of new drug research that expedites the licencing of select pharmaceuticals that cure severe illnesses and solve unmet medical needs. Expedited approval processes may attract interest as a way to significantly cut the time and cost necessary for the creation of new drugs. For a better understanding, this article is pre-selected with several expedited approval processes in the US and EU, with an illustration of these quick approval processes using the COVID-19 vaccine, Comirnaty, and Crizotinib medicine.

Key words: Expedited Approval, Fast Track Approval, Accelerated Approval, Breakthrough Therapy, Priority Review.

INTRODUCTION

Modern medicine and science have made incredible strides in improving and extending lives. Nonetheless, many diseases and conditions still lack adequate therapy. Life expectancy has increased and improved dramatically thanks to advances in science and medicine. But there is still a severe dearth of treatment for many diseases and disorders.

The term "expedited drugs" generally refers to drugs that are approved and made available to patients more quickly than usual. This can happen through a variety of pathways, such as the Food and Drug Administration's (FDA) Accelerated Approval Program, which allows for expedited approval of drugs that treat serious conditions and fill an unmet medical need. These pathways are designed to help patients get access to new treatments faster, while still ensuring that the drugs are safe and effective.

According to the FDA, expedited programs are designed to facilitate and expedite the development and review of drugs that are intended to treat serious conditions and that demonstrate the potential to address unmet medical needs. These programs allow the FDA to work more closely with drug developers to identify the most efficient paths for clinical development and to expedite the development and review of drugs that are intended to treat serious conditions. In the case of COVID-19, the FDA has used its expedited programs to speed up the development and review of drugs and vaccines that are intended to treat or prevent the disease. These programs have allowed drug developers to submit applications for approval more quickly and have allowed the FDA to review these applications more quickly. This has helped to speed up the availability of drugs and vaccines that can help to prevent or treat COVID-19.[4]

In order to treat urgent or life-threatening diseases and fill an unmet medical need, new medicinal products are developed and approved through expedited approval procedures. Drug discovery and review processes are being sped up by regulatory agencies like the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in order to treat serious diseases and meet unmet medical needs. Regulatory bodies in the US and EU have established quick assessment and approval processes in order to hasten access. By lowering the time and expense needed for the discovery of novel drugs, these routes can also be of great assistance to pharmaceutical

companies. These approaches include various forms and degrees of clinical evidence in comparison to the conventional approval process.

AIDS has become an epidemic in the US by 1988. In Rockville, Maryland, in front of the USFDA, a crowd demonstrated. The demonstrators shouted, "42,000 patients died from AIDS." The FDA wasn't present. Over 62,000 Americans had died from AIDS by the end of 1988, according to the Centers for Disease Control and Prevention. The demonstrators asked the FDA to "Stop placebo-group studies in clinical trials investigating Acquired Immune Deficiency Syndrome (AIDS) drugs to speed up the availability of new drugs to the patients that showed efficacy." A few days after the protest, the FDA declared that, in light of the findings of Phase II clinical trials, it would begin to consider licensing drug items for serious or life-threatening disorders.

The Food and Drug Administration (FDA) of the United States is in charge of policing everything, including prescription pharmaceuticals, medical equipment, and cosmetic products. The FDA has come under intense pressure in recent years to expedite the licensing of specific drugs in order to combat the ongoing COVID-19 outbreak. The FDA must make sure that the items it approves are both safe and effective despite the need to speed up the process. Knowing the FDA's fast approval procedure can help payers, providers, and consumers understand that the drugs undergoing this process are still safe and helpful to patients. 74% of medications will be approved through an accelerated method by 2021, claims Regulatory Focus.[3]

There are numerous phases on the way from the initial proof of a potential therapeutic benefit to the approval of a drug; this process can take up to 15 years and cost more than $1.3 billion. The regulatory approval process in the United States has been changed to make it easier to develop novel, safe, and effective substances quickly. This will enable research breakthroughs to be realized more quickly through the creation of new drugs, diagnostics, and devices. In order to give rapid approval for novel medications that are thought to bring major therapeutic advancements or address the most pressing unmet needs, a number of paths have been devised over the years.[5]

If you're working on a project related to expedited drugs, you may want to look into specific examples of drugs that have been expedited by the FDA, such as remdesivir or the Pfizer-BioNTech COVID-19 vaccine. You may also want to research the specific

expedited programs that the FDA has in place and how they work. Additionally, you may want to look into the benefits and drawbacks of expedited drug development and review, as well as the ethical considerations involved in the use of expedited drugs.

There are several pathways that can be used to expedite the approval of drugs. One of the most well-known is the FDA's Accelerated Approval Program, which is designed to allow for faster approval of drugs that treat serious conditions and fill an unmet medical need. Drugs that are approved through this program are generally based on surrogate endpoints, which are measures that are thought to predict clinical benefit, such as tumor shrinkage or improvement in laboratory values. However, these drugs are still required to undergo further testing to confirm their clinical benefit. Another pathway for expedited approval is the FDA's Breakthrough Therapy designation, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. This designation is based on preliminary clinical evidence that suggests that the drug may offer substantial improvement over existing therapies. Finally, the FDA's Fast Track designation is intended to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. Drugs that receive this designation are eligible for more frequent meetings with the FDA to discuss the drug's development and review process.[6]