# Orphan Drugs and Regulatory Boards in Global Market

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## Abstract

*The prevalence of rare diseases among the global population has been increasing in recent years. To tackle this issue, both developing and developed countries have formulated regulations that promote the availability of drugs for rare diseases, as well as make sure that these drugs are easily available to the patient. Currently, the average approval time for orphan drugs for rare diseases is faster than non orphan ones. as well as make sure that these drugs are easy available to the patients. Findings: Factors of increment of orphan drug's market are: market exclusivity for orphan drug developers, the rising prevalence of rare diseases and favorable Government policies. The orphan drug market is experienced a increment 11,5%. Factors that are responsible for the growth of this market is around 13 months and the same for orphan drugs is much less at around 10 months. The European Union has implemented similar policies FDA for the development of theese drugs, and the European Governments have individualy implemented these polices in their countries, some of these are Italy's AIFA 5% Fund, Belgium's special solidarity found, and France's temporary authrizations for use. Even the countries in Asia Pacific have also followed similar steps with countries like Japan, South Korea and Taiwan with nitiatives like the revised orphan drug Regulations and Orphan Drugs Guidelines (2003). These initiatives offered tax credits and subsidies to both the patients as well as the Pharmaceutical Companies. These policies in various countries around the world have evolved the market studied, that has been growing at a healthy rate in recent years orphan drugs can be defined as a molecule intended to treat a rare disease. The rare disease, as the name suggests, has a low prevalence rate and has been defined differently across geographical locations.*

**Keywords:** Orphan Drugs, Pharma Market, Globalisation, Public Procurement, Transparence, Regulatory Boards.