REGULATORY STRATEGIES FOR ORPHAN DRUG DEVELOPMENT ON A GLOBAL SCALE

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ABSTRACT

INTRODUCTION

A medicinal product designated as an orphan drug is one that has been developed specifically to treat a rare medical condition referred to as "orphan disease. Orphan drugs are drugs intended to treat a rare disease.

KEY WORDS

Keywords: Rare disease, Orphan drugs, ODA

OBJECTIVES

1. To carry out the study of globalization in orphan drug development strategies in Different markets.
2. To study the Comparative regulatory frame work of orphan drugs.

METHODLOGIES

A review of the literature done by Studying and understanding different country orphan regulations.

RESULTS

1. This is the current scenario in-spite of the various incentives provided in the orphan drug act. However, in this work , we have tried to focus on Comparing regulations Adopted by various countries namely USA, EU, Canada and Australia & INDIA

SIGINIFICANT FINDINGS

1. The orphan drug regulations made by different countries have proven as promoters in development of orphan drugs. The orphan drug regulation in the US and the EU has been successful in providing treatments to the patients with rare diseases.
2. The orphan drug program can help the pharmaceutical companies in earning profit and recovering their investment even with small patient population in the developed countries.