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Europe Orphan Drug Market & Clinical Trial Insight 2015

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Abstracts

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The concept of rare diseases and the idea that a special attention needs to be given to this sector has been taking shape in Europe since the 1990s. Ever since then the political aspects and initiatives related to orphan medicinal products have been emerging at both the EU level and at the level of member states individually. Many member states in the EU have led the way during the 1990s in the space of orphan medicinal products, the result of which took the shape of the first European legislative text concerning rare diseases called the Orphan Medicinal Product Regulation. This Regulation was adopted in 1999 and came into effect in 2000.

In the European region, rare disease is considered to be a priority area and research in this field is given high importance by the EU Framework Programmes for Research and Technological Development (FP) ever since the early 1990s. Increasing the utilization of scarce resources and coordinating research efforts are the basic factors which have been responsible for success in the European rare diseases market. However, the absence of an exhaustive rare disease classification, standard terms of reference and a harmonized regulatory requirement, has always been a challenge in this region, which is currently impacting the global sharing of information, data and samples which would boost the research further.

It has been estimated that Europe has witnessed more than 100 therapies for rare diseases being approved since 2000, when the European Commission introduced incentives to encourage the development of these drugs. The share of R&D for orphan medicinal products development as a proportion of total biopharmaceutical industry's R&D has been increasing significantly over the years. This is strengthened by the fact

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that almost all companies which have been set up recently to develop orphan medicinal products have their extensive R&D plants and staff located in the European Union. This shows the significance of the region and its level of attractiveness.

Additionally, the investment in R&D by the European companies for developing orphan medicinal products has increased by more than 200%, while the total number of employees in these companies has recorded an increase of more than 150% since 2000. With the long durations of lead times in the biopharmaceuticals industry for R&D projects, it is most likely that the EU Regulation for Orphan medicinal products would have a significant impact in the coming years.

“Europe Orphan Drug Market & Clinical Trial Insight 2015” Report Highlights & Findings:

Europe Orphan Drug Market Overview

In-depth Insight on Regulatory Framework & for Orphan Drugs

Application Procedure for Seeking Orphan Drug Status

Comprehensive Insight on Orphan Drug Clinical Pipeline

Europe Orphan Drug Clinical Pipeline: 326 Drugs

Majority Orphan Designated Drugs in Phase-II: 111

Marketed Orphan Drugs in Europe: 130

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COMPANIES MENTIONED

AOP Orphan, Genethon, Genzyme Corporation, Glaxosmithkline, Merck, Novartis Pharmaceuticals, Orphan Europe, Pfizer, Prosensa, Shire, Teva Pharmaceutical

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About

The concept of rare diseases and the idea that a special attention needs to be given to this sector has been taking shape in Europe since the 1990s. Ever since then the political aspects and initiatives related to orphan medicinal products have been emerging at both the EU level and at the level of member states individually. Many member states in the EU have led the way during the 1990s in the space of orphan medicinal products, the result of which took the shape of the first European legislative text concerning rare diseases called the Orphan Medicinal Product Regulation. This Regulation was adopted in 1999 and came into effect in 2000.

The Regulation specifies the need to offer incentives for the development and marketing of drugs to treat, prevent, or diagnose rare conditions. It was laid down that without these incentives, it was unlikely that products would be developed for rare diseases as the cost of developing and marketing products for these disorders would not be recovered by sales. The Regulation specifies the designation criteria, outlines the procedure for designation, and provides incentives for products receiving an orphan designation (e.g. protocol assistance, market exclusivity, centralized procedure).

These incentives are aimed at helping sponsors to receive orphan medicinal product designations in the development of medicinal products with the ultimate goal of providing medicinal products for rare diseases to patients.Following are the criterion for a medicinal product to obtain an orphan drug designation:

> The medicinal product is intended to diagnose, prevent or treat a life-threatening or chronically debilitating condition (in humans).
>
> The condition affects not more than 5 in 10,000 people in the EU or without incentives, the marketing of that product would generate insufficient return to justify the necessary investment.
>
> There are no alternative methods of diagnosis, prevention or treatment of the condition or if an alternative method exists, the product will be of significant benefit to those affected by the condition.

The sponsor is required to fulfill or satisfy each and every clause of this framework. The

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non-fulfillment of any one of these clauses, would make the application not fit for approval. The designation of Orphan to the medicinal products is provided by the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA).

In some cases, the designation or orphan could be provided for a new orphan indication for an already authorized medicinal product. Thus, it is possible for a company which is researching the treatment of an orphan condition and screening known products used for the treatment of different conditions to apply for orphan product designation with respect to the use of the known product for the new treatment of the orphan condition. However, as the existing marketing authorization cannot be extended to cover the new orphan indication, a separate marketing authorization is required. Also, a common marketing authorization would not cover both Orphan and "non-orphan" indications.

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