EuOrphan

SERVICE FOR THE SUPPORT OF THE EUROPEAN ORPHAN MEDICINE MARKET

softeco sismat information technology

EUORPHAN

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http://www.euorphan.com

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OBJECTIVES

The project aims at validating a service for the distribution of a complete set of information concerning medicines designated and/or commercialized both in EU and non EU countries for the treatment of rare diseases with the purpose of supporting:

* the European Legislation which came into force in April 2000, to encourage pharmaceutical companies to develop and market orphan medicines;
* the pharmaceutical companies, in defining business plans for new orphan medicines;
* the exchange of information and cooperation in R&D, authorization and manufacturing of new orphan drugs.

The EuOrphan service will ultimately provide social and ethical benefits, allowing access to quality and efficient healthcare to disadvantaged minorities of patients.

THE ORPHAN MEDICINE MARKET

Bringing new medicines to the market is expensive and time consuming. Unless there is sufficient financial incentive pharmaceutical companies may not be motivated to develop new medicines and treatments when the financial return is likely to be poor, as in the case of rare diseases.
EU legislation, through the 141/2000/EC Regulation, defined a legal framework to improve the development of drugs for the care of small populations (orphan drugs) by providing incentives to support the lack of return on investments.
The Regulation identifies two steps at the regulatory level for bringing such drugs to the market: the first is a designation procedure, to obtain the status of orphan drug; the second is the authorization procedure, to obtain the commercialization approval and reach the market.
EuOrphan services will place information related to both steps at disposal of physicians and patients who can benefit from up-to-date information on available treatments for rare diseases, of pharmaceutical companies which can use the information to steer their investments and of public health institutions which can find support in planning public health interventions.
Currently there are not specific services that support the stakeholders involved in the development, marketing and usage of medicines focused on rare diseases.
For instance, data concerning the drug market penetration, both at the EU and at national levels, as well as price sand reimbursement procedures, if available, may be collected only from several sources.
Moreover no unique source allows to obtain information for orphan medicines available outside Europe.

THE USERS

The services address four main user categories:

* Pharmaceutical companies, especially SMEs and biotechnological companies, which constitute a relevant sector of the pharmaceutical orphan market
* Public Health Institutions
* Physicians and Researchers
* Patients and Associations

DURATION AND FUNDING

EuOrphan is an e-TEN market validation project granted by the European Community, DG Information Society.
It started on 1stJanuary 2005 and lasts18 months.
A deployment phase during which the economical sustainability of EuOrphan services should be demonstrated will follow the market validation phase.

THE SERVICES

The EuOrphan services are based on up-to-date Web technology and are accessible through Internet using a common Web browser. Four main services are available, matching the users categories:

* Pharmaceutical companies are able to search and collect information useful for the definition of the business plans for the development of orphan medicinal products (e.g. market statistics, uncovered market sectors) and information for ensuring the compliance with regulatory requirements (e.g, epidemiological figures for the diseases, support in applying for a designation). Moreover the service will constitute a means to facilitate the recruitment of patients for clinical trials (small and geographically dispersed number of people)
* Public Health Institutions will benefit from the services provided by EuOrphan in terms of availability of data and statistics on orphan market at worldwide level to plan a rational usage of resources and public health interventions
* Physicians (both GPs and clinicians) and researchers will be able to look for updated information about the diseases and the medicines through direct access to new data, educational material and newsletters. The service will ultimately allow the improvement of the support to patients.
* Patients Associations and Patients will have the possibility to obtain clear information about new medicines, about their price in different countries and how to access them. Moreover they will be able to contact Sponsors and investigators of clinical trials, making the access to the studies easier, and public health institutions in order to organise pressure groups and stimulate additional studies.