BIOSIMILARS IN EUROPE, AN OUTLOOK

An in-depth look at future biosimilar drug launches — growth hormones, somatostatin and analogues, EPO, insulin, infertility drugs, G-CSF, interferons, coagulation factors and bio-oncology drugs — in 11 European countries

FOR MORE INFORMATION:
Biosimilars in Europe is scheduled for release in July 2007.
For more information, please contact:

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DAFSA, a Global Insight company, focuses on primary market research in France and Europe. With 20 consultants leveraging years of expertise in verticals such as pharmaceuticals, financial services, and telecommunications, we are able to provide a wide range of customized research, as well as multi-client industry reports, for the French and European markets.

DAFSAs Health Department has been providing expert analysis on pharmaceutical industry and health policies for more than 10 years. Our previous European surveys, Successfully Developing Pharmaceuticals for European Markets and Pharmaceutical Parallel Trade in Europe, are unique in their comprehensive coverage and focus on cross-country comparative analysis. DAFSA’s other health and pharmaceuticals products and services include:

Multi-Client Studies and Market Research
Focusing on the French and European markets, DAFSA applies a tailor-made methodology adapted to the deliverables of each project, using marketing tools such as B2B interviews, consumer and B2B surveys (phone, face to face, or Internet based), panels, and “mystery shopping.”

Pharm on Line (POL - France) and POLInternational
Pharm on Line France and POLInternational are regularly updated, comprehensive, searchable drug databases that identify all pharmaceuticals marketed in France, Germany, Italy, Spain, the United Kingdom, and the United States. These databases provide information on pharmaceutical price levels and reimbursement status. Since 1993, we have categorized more than 60,000 entries in POL - France.

Drug Prescription and Retailing Behaviours
Using specialised marketing tools developed for the health and pharmaceutical industry, and leveraging the in-depth expertise of our Paris-based consultants, we provide detailed operational information and analysis of the French and European markets.

DAFSA is a member of SYNTec ‘Etudes Marketing et Opinion,’ which guarantees the respect of professional deontological rules, particularly the international code of practice CCI-ESOMAR.

THE POWER OF PERSPECTIVE

ABOUT GLOBAL INSIGHT: Global Insight, Inc. provides the most comprehensive economic coverage of countries, regions, and industries available from any source. The company has over 3,800 clients in industry, finance, and government around the world, with 23 offices in 13 countries, covering North and South America, Europe, Africa, the Middle East, and Asia.

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The recent authorisation of the first two biosimilars could precipitate the launch of numerous other generic drugs. As patents expire and new biosimilars are developed, the success of their adoption will largely depend on how each country implements pricing and reimbursement strategies. How will the relevant authorities manage biosimilar launches? How will health professionals react to these products?

DAFSA, a leading provider of primary market research for the pharmaceutical industry, is conducting extensive research to answer these questions. We will look at the regulatory framework for biosimilars in 11 European countries and identify key drivers and challenges related to the prescribing, purchasing, and dispensing of these drugs.

Our special study, *Biosimilars in Europe*, will address questions surrounding these launches, including:

- What will be the main criteria used by authorities to fix the price of biosimilars? Will they follow the average or minimum price differential between on- and off-patent drugs in the country? Will the higher production costs of the products be taken into account?
- Will biosimilars be listed as generics or as innovative biological products? Will the latter be included in a reference price system?
- Will substitution by pharmacists or dispensing doctors be allowed?
- Will the prescription guidelines vary between biosimilars and the original biological products? Will the prescription of biosimilars be restricted to certain medical specialties or to hospital use only at first as a result of immunogenicity risks?
- How will opinion leaders react towards the launch of biosimilars?
- What are the prescribing habits forecasted by physicians and medical advisory boards of patients associations?
- What are the purchasing and dispensing habits forecasted by pharmacists in hospitals and retail pharmacies?
- What are the concerns of healthcare professionals regarding biosimilars?
- What information do they need, and what is the best way to give it to them?

**STUDY OBJECTIVES INCLUDE:**

- Detailing the regulatory framework for biosimilars in each country, as well as at the European level
- Identifying the drivers and problems related to the prescribing, purchasing, and dispensing of biosimilars forecasted by healthcare professionals for each category of drug
- Assessing the potential development of biosimilars in these and future drug classes (e.g., LMW Heparins)

**METHODOLOGY**

Using a combination of primary and secondary research, the report will include in-depth analysis of the European legal and regulatory framework for biosimilars and an overview of the present situation and market trends in 11 countries. We will also evaluate the launch of Omnitrope®, the first biosimilar authorised in Europe, and highlight its challenges and achievements.

**Primary research**

A qualitative approach including in-depth interviews

- 30-35 interviews of professional organisations of physicians, family doctors, learned societies, and medical advisory boards in patients associations
- 20-25 interviews of pharmacists (in hospitals and retail pharmacies)
- 15-20 interviews of stakeholders (evaluation and pricing authorities, representatives of the research-based pharmaceutical and generics industry)

**Secondary research**

Legal and regulatory framework and market trends

- Extensive analysis of the legal and regulatory framework
- Extensive analysis of the market trends for biological products and generics
- Detailed country profiles of the current and forecasted environment for biosimilars in terms of pricing, reimbursement, substitution, prescription, and dispensing

**A focus on the marketing of Omnitrope® in Germany**

- Primary and secondary research options will include a focus on the particular situation in Germany, where Omnitrope®, the first biosimilar authorised in Europe, is marketed
- Interviews will encompass the issue of advantages and/or difficulties experienced by healthcare professionals regarding Omnitrope®

**DRUG COVERAGE**

- Growth hormone
- Somatostatin and analogues
- EPO
- Insulin
- Infertility drugs
- G-CSF
- Interferons
- Coagulation factors
- Bio-oncology drugs

**COUNTRY COVERAGE**

- Belgium
- Denmark
- France
- Germany
- Italy
- Netherlands
- Poland
- Romania
- Spain
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