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COMPARISON OF BIOSIMILARS REGISTRATION WITH FEW COUNTRIES REGULATORY AUTHORITIES

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Abstract:

A drug master file (DMF) is a confidential, detailed document submitted by Active Pharmaceutical Ingredient (API) manufacturers to the U.S. Food and Drug Administration (FDA). A DMF contains the chemistry, manufacturing, and controls of a drug component. A drug master file is filed when two or more firms work in partnership on developing or manufacturing a drug product. The DMF filing allows a firm to protect its intellectual property from its partner while complying with regulatory requirements for disclosure of processing details. The DMF contains factual and complete information on a drug product's chemistry, manufacture, stability, purity, impurity profile, packaging, and the cGMP status of any human drug product. The pharmaceutical industry is one of the most regulated industries; no drug would be marketed without the teams of medical researchers and other specialists who worked to make sure it receives regulatory authority's approval. There is no legal or regulatory requirement to file a DMF. This study gives the information on regulatory requirements of Drug Master Files by Food and Drug Administration (USA), European Medicines Agency (Europe), Ministry of Health Labor and Welfare (Japan), Central Drug and Standard Control Organization (India) and WHO and their comparison.

Keywords: *DMF, intellectual property, regulatory authority, FDA, WHO.*

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INTRODUCTION:

"Biologics", considered one of the fastest growing sectors of the pharmaceutical industry, have introduced many new treatments that have revolutionized the treatment of rheumatoid arthritis, cancers, psoriatic arthritis, and ankylosing spondylitis and holds promise to expand treatment options for patients with systemic lupus erythematosus or other systemic autoimmune diseases, life-threatening, rare illnesses and have huge market potential.

The first generation of biopharmaceutical products manufactured using recombinant technologies was launched in the 1980s, and they are now on the verge of patent expiration. As a result, research based and generic pharmaceutical companies alike are pursuing the opportunity to develop generic" subsubstitutes for iginaorl biologics, referred to as biosimilars due to the global market demand of 3.6$ billion by 2016 with a Compound nnual Growth Rate (CAGR) of 7.7%.

Biosimilars are defined as biologic products that are highly similar to reference products, not withstanding minor differences in clinically in active components, with no clinically meaningful differences between the biological product and the reference product in terms of safety profile, purity, and potency.

- Biosimilars are defined as biological medicinal products which are:
- Similar in terms of quality, safety and efficacy to an already licensed, well-established reference medicinal product
- Marketed by an independent applicant following expiry of patent and regulatory data/ market exclusivity periods of the reference product, and
- Authorized for marketing through a procedure based on the proof ofsimilarity to the reference product.

BIOSIMILARS- AN EMERGING MARKET

Twelve compounds of biological products with global sales of more than US$67 billion will be exposed to biosimilar competition by 2012, with Enbrel (etanercept) whose US patent has been extended until 2028, scoring global sales of US$7.3 billion by December 2011.

However, despite estimates that the market will reach approximately US$3,987 million by 2017, the biosimilars industry is not for the faint hearted. Considerable investment is required to manufacture and get a biosimilar to market, and with such complex molecule's failure can occur at any stage of the development.

DEVELOPMENT OF BIOSIMILAR:

We refer to "similars" and not "equivalents" since, while the copy of a chemical drug is quite simple, making an identical copy of a biologic drug is nearly impossible. In fact, even knowing the DNA coding sequence, it is very difficult to replicate its precise end structure that would include posttranslational modification (eg. glycosylation and methylation) and the manufacturing process. Development Stages of Biosimilars: There are four stages in the development of a biosimilar: 1) Product development and comparative analysis; 2) Process development, scale up and validation; 3)Clinical trials; 4) Regulatory (EMEA, WHO and FDA) review and approval.

Advantages of Biosimilars:

- There is large market needs and growing affordability for biosimilars in global and domestic market.
- Development and production of biosimilars are boosted by existing manufacturing
- In the recent scenario, there is increasing demand for biological drugs.
- Due to competitive pricing advantages biosimilars are available at affordable prices on global market and they are typically sold at the discount up to 85 %.
- Due to no investment in phase I-II of clinical trials, biosimilars are available at cheaper prices than the reference products, so that it has low market risk.

Disadvantages of Biosimilars

- The development and manufacturing process of biosimilars is more complex than of molecule of drugs.
- Manufacture of biosimilars requires growing and harvesting of the product from living cells which is very costly & time consuming process.
- The development of biosimilars is lengthy process & can take many months to produce.
- As compared to chemical drugs, Biologics are often dozens to thousands of times larger, so that development process is very critical.

Regulatory Framework

In Europe, biosimilars are regulated by the European Medicines Agency (EMA).

In India, biosimilars are overseen by the Central Drugs Standard Control Organization (CDSCO).

Both regulatory authorities require extensive data on quality, safety, and efficacy for biosimilar approval.

AIM AND OBJECTIVES:

The above literature was carried out with intention of Biosimilars registration of Various countries regulatory authorities .

So that we were aim to comparision of two countries such as India and European Union biosimilars Registration.

The aim of this study is to analyze and compare the current regulatory guidelines for Biosimilars recommended by the following regulatory / international agencies:

- Food and Drug Administration (USA)
- European Medicines Agency (Europe)
- Health Canada (Canada)
- Therapeutic Goods Administration (Australia)
- Ministry of Health Labour and Welfare (Japan)
- Korean Food and Drug Administration (South Korea)
- Central Drugs Standards Control Organization (India)
- State Food and Drug Administration (China)
- National Pharmaceutical Control Board (Malaysia)

OBJECTIVES:

1. To describe the main regulatory procedures for biosimilars.
2. To compare the quality aspects of biosimilar guidelines in different countries.
3. To compare the efficacy aspects of biosimilar guidelines in different countries.
4. To compare the regulatory aspects of biosimilar guidelines in different countries

INDIA:

CDSCO headed by the Drug Controller General of India (DCGI) is the apex regulatory body under Ministry of Health & Family Welfare (MoHFW), Government of India, which is responsible for the approval of clinical trials as well as new drugs. In the context of Similar Biologics, CDSCO is responsible for clinical trial approval (also grants permission for import of drugs for clinical trial and export of clinical samples for biochemical and immunological analysis) and permission for manufacturing and marketing. Zonal offices of CDSCO are responsible for authorizing import of drugs for examination, test and analysis for research and development.

The Indian guidelines on similar biologics address the pre-marketing and post-marketing regulatory requirement (i.e., “comparability exercise”), and also address the requirements related to manufacturing process and quality control.

EUROPEAN UNION:

The European Union (EU) has pioneered in the development of a regulatory system for biosimilar products. The European Medicines Agency (EMA) began formal consideration of scientific issues presented by biosimilar products at least as early as January 2001, when an ad hoc working group discussed the comparability of medicinal products containing biotechnology-derived proteins as active substances.

Since then, 13 biosimilar products have been approved by EMA under the pathway. Two of them are somatropins, five are epoetins, and six are filgrastims. One of the rejected biosimilar is Alpheon (interferon alfa-2a).It was developed by Bio-Partners GmbH, and designed to become a biosimilar of the reference product Roferon-A for the treatment of adult patients with chronic hepatitis C.

The CHMP guidelines addressing the planning and conduct of biosimilar comparability studies should always be read in conjunction with relevant scientific guidelines and legislative provisions in force in the European Union.

Companies developing biosimilars are invited to contact Regulatory Authorities in the EEA to obtain further advice on their development, whenever there is a need for more detailed information than provided in the guidelines already available.

Summary:

Biologics will become an important part of the future healthcare landscape. Biologics andproperly regulated biosimilars will increasingly become available. The development ofbiosimilars represents a significant opportunity for generic firms interested in entering themarketplaces for biotechnologically produced drugs. Without the necessity of undertakingcostly full-scale R&D activities, they can manufacture and market recombinant proteins.However, success in the biosimilars industry will require significant capital investment andin-house experience. Biosimilars manufacturers have to face higher costs formanufacturing, clinical

development, registration and product marketing compared toclassic generics.

The establishment of a globally harmonized regulatory framework is important. India andArgentina currently apply standard generic drug authorization provisions to biosimilars. Onthe other hand Australia, Bulgaria, Canada, Chile, China, Croatia, European Union, Israel,Japan, Mexico, Serbia, Switzerland, Taiwan, Turkey and Ukraine have already establishedspecial provisions. Egypt, New Zealand, Oman, Panama and Russia do not permit and application for biosimilars.

CONCLUSION:

Based on the above consensus there is a scope for harmonization of guidelines onbiosimilars in the above mentioned areas by which registration of biosimilars in differentcountries can be done in a most efficient and cost effective manner. The name of the gameis harmonization due to increased healthcare costs, R&D expenditure and publicexpectation to safe and effective biological drugs for the myriad of diseases and illnesses.

Unifying the approval pathway globally will abolishthe need for bridging studies, which could make biosimilar development cost effective(since the sponsors will then have a single product development cycle for all geographies)but with the same standards of safety and efficacy.

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