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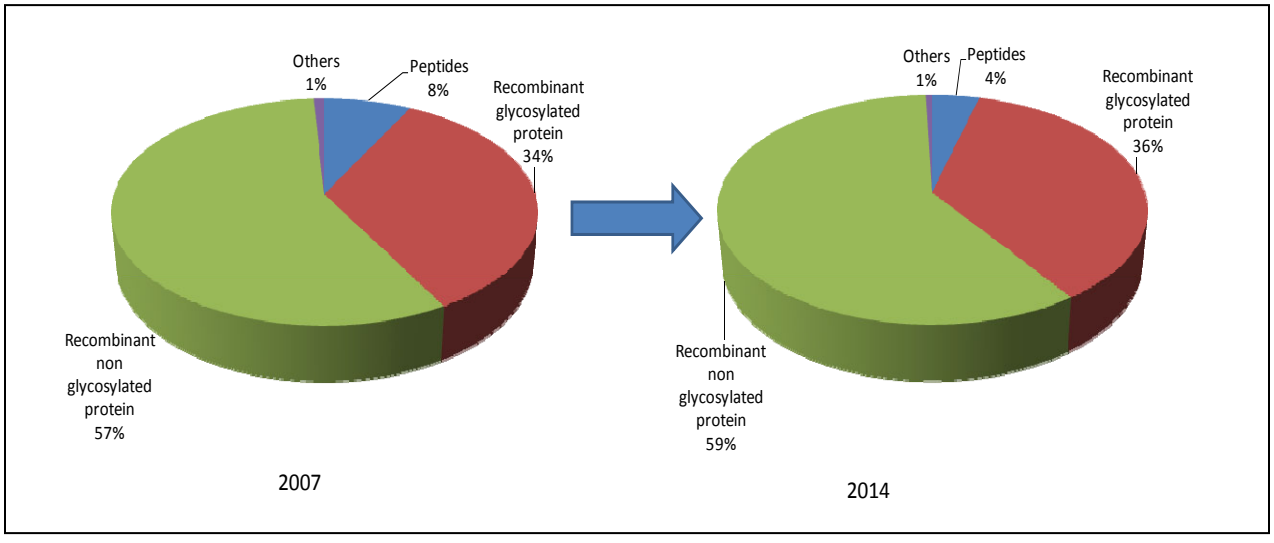
1. BIOSIMILAR PRODUCTS

The objective of this chapter is to provide a detailed analysis of the biosimilar product submarkets, their drivers, inhibitors, opportunities, major players, and the latest developments. The biosimilar products market is categorized into the submarkets for peptides, recombinant glycosylated proteins, recombinant non-glycosylated proteins, and other products such as vaccines, toxins, and steroids. The global market for biosimilar products was worth $xxxx million in 2007 and is expected to reach $xxxxx million in 2014 at a CAGR of xxx% from 2009 to 2014. Recombinant non-glycosylated proteins products form the most popular submarket, as this biosimilar can be synthesized easily and has a range of varied applications.

FIGURE 1

BIOSIMILAR PRODUCT MARKET TREND



Source: MarketsandMarkets

The figure above illustrates the trends in the biosimilar products market from 2007 to 2014. Recombinant glycosylated and non-glycosylated protein products are expected to have increased market shares, as these segments include the top five biosimilar products, and also because of the increasing applications of these two biosimilars in the treatment of wide range

of hematological diseases and growth-hormone related deficiencies. The biosimilar recombinant non-glycosylated proteins market is expected to be the dominating biosimilar products submarket in 2014, with an increase in share from xxx% in 2007 to xxx% in 2014.

1.1 RECOMBINANT NON-GLYCOSYLATED PROTEIN

The market for recombinant non-glycosylated proteins includes blockbuster biopharmaceuticals such as insulin, Somatropin, G-CSF, and interferon. Most of the reference products of this segment have successfully reached a turnover of more than $xxx billion; and the biosimilar of these drugs are also expected to soon reach blockbuster status due to their lower costs. Recombinant non-glycosylated proteins are expected to hold xxxxx% of the total biosimilar market revenues by 2014, mainly because of their massive therapeutic use, high user-acceptance, and easy synthesis.

TABLE 1

GLOBAL BIOSIMILAR NON-GLYCOSYLATED PROTEIN MARKET, BY PRODUCTS 2007 – 2014 ($THOUSANDS)

Product	2007	2008	2009	2014	CAGR % 2009 – 2014
Interferons	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Human Growth Hormone (Somatropin)	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Granulocyte-CSF	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Insulin	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Interleukin-2	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Lepirudin	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Interleukin-11	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Anakinra	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Total	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx

NA* means market was not commercialized and CAGR is calculated from the year of commercialization to 2014 if the market came into existence after 2009, else it is calculated from 2009 to 2014

Source: MarketsandMarkets

The global market for recombinant non-glycosylated protein products was worth $xxxxx million in 2008 and is expected to reach $xxxx billion by 2014, at a CAGR of xxx% from 2009 to 2014. Interferon is major drug category in this segment; and is expected to generate $xxx billion in 2014.

1.1.1 DRIVERS

The global market growth of recombinant non-glycosylated proteins is fuelled by three main attributes of the product. These are the facts that recombinant non-glycosylated proteins can:

- Address a vast range of therapeutic categories, including treatment for cancer, diabetes, autoimmune diseases, and growth-related deficiencies.
- Command high user-acceptance because of their higher efficacy and safety value.
- Involve an easier and more cost-effective synthesis and manufacturing process in comparison to glycosylated proteins.

TABLE 2

GLOBAL BIOSIMILAR RECOMBINANT NON-GLYCOSYLATED PROTEIN MARKET, BY GEOGRAPHY 2007 – 2014 ($THOUSANDS)

Region	2007	2008	2009	2014	CAGR% 2009 – 2014
America	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Europe	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Asia	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Row	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Total	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx

Source: MarketsandMarkets

The American market for non-glycosylated protein worth $xxxx million in 2008 and is expected to reach $xxx billion by 2014 at a CAGR of xxxx% from 2009 to 2014.

TABLE 3

MAJOR PLAYERS AND THEIR RESPECTIVE DEVELOPMENTS

Product	Company	Description
Insulin	Sembiosys Genetics Inc	In June 2009, Sembiosis Genetic Inc. completed its Phase I/II study of its biosimilar human insulin. The company is to announce the result at the American Diabetes Association's 69th Scientific Sessions in New Orleans.
	SciGen	In April 2008, SciGen has acquired the rights to market and distribute Generex's Oral-lyn, an oral insulin spray product, in Hong Kong, Indonesia, South Korea, Malaysia, the Philippines, Singapore, Thailand, and Vietnam. SciGen will also be responsible for obtaining product approval. Oral-lyn is in Phase III trials in U.S.; and has already been approved in India.
	Biocon	In January 2008, Biocon announced that it is to globally launch four biosimilar drugs in the next two years. Worth $xxx billion each, the drugs are G-CSF, Reteplase, Streptokinase and insulin drug Glargine. Biocon is currently holding discussions for strategic marketing and distribution tie-ups with several companies.
Interferon Alfa	LG Life Sciences	In May 2009, LG life Sciences is developing, a sustained-release formulation of recombinant interferon Alfa 2a, for the potential treatment of hepatitis C virus (HCV) infection. The agent uses LG's BIOHYDRIX sustained-release delivery technology. Phase II evaluation of LBSI5535 is under way in South Korea. This program is available for worldwide licensing.

Product	Company	Description
	BioSante	In November 2008, the National Institutes of Health awarded BioSante a $xxxxx Small Business Innovation Research (SBIR) grant to develop an inhaled interferon Alfa (IFN-Alfa) formulation for the safe and effective treatment of hepatitis B and C virus infections. BioSante will develop the agent using its proprietary calcium phosphate nanoparticulate (CaP) technology (BioAir), designed for the efficient delivery of large molecules.
Interferon Beta	Biogen Idec.	In July 2009, Biogen Idec's PEGylated interferon beta-1a (BIIB017) received Fast Track FDA approval for the treatment of relapsing multiple sclerosis (RMS). Biogen Idec is currently recruiting RMS patients in a global Phase III study for evaluating the efficacy and safety of bi-weekly and monthly injections of PEGylated interferon beta-1a.
	Modigene Inc.	In August 2008, the Israeli government awarded grant of $xxx million to Modigene Inc., to support the development of its longer-acting biosimilar version of Interferon Beta.
	Merck Serono	In September 2007, Merck Serono received EMEA approval for a new formulation of Rebif, a recombinant interferon beta-1a, for the treatment of relapsing-remitting multiple sclerosis. The new formulation provides better injection tolerability and an improved immunogenicity profile.
G-CSF	Apotex Inc & Intas Biopharmaceuticals Ltd	In January 2009, Apotex Inc and Intas biopharmaceuticals Ltd extended their business agreement to develop a biosimilar version of pegfilgrastim, a recombinant pegylated G-CSF, used in neutropenia treatment. Intas has already begun manufacturing and marketing the protein in India; and is now eyeing the peg G-CSF market in U.S. and Europe.

Product	Company	Description
	BioGeneriX AG and Novo Nordisk	In September 2008, Neose Technologies sold its assets to development partners BioGeneriX AG (Germany) and Novo Nordisk (Denmark) for $xxxx million. The sale of these assets is the first step in the liquidation of Neose, which seems to have fallen prey to the high development costs and regulatory uncertainty associated with biosimilar development. Neose focused on the development of follow-on products of GlycoPEG-GCSF for chemotherapy-induced neutropaenia, and GlycoPEGylated hemostasis compounds Factor VIIa, Factor VIII and Factor IX target.
	Teva Pharmaceuticals Industries Ltd	As part of its biosimilar expansion strategy Teva Pharmaceulicals signed a $xxx million deal in January 2008 to acquire CoGenesys Inc., a company that has developed five biosimilars, the most advanced of which is G-CSF conjugate.
	Teva Pharmaceuticals Industries Ltd	In September 2008, Teva received marketing authorization for the first European G-CSF biosimilar under the brand name TevaGrastim. Teva will progressively market the product throughout Europe in 2009.
	Abraxis BioScience, Inc. and Biocon	In August 2007, Abraxis and Biocon formed a license agreement under which Abraxis acquired the right to market Biocon's G-CSF in North America and Europe. Biocon will receive an upfront license fee and royalties from Abraxis following regulatory approvals. Biocon has also received regulatory approval from the Drug Controller General of India for the use of G-CCF in the treatment of neutropenia. The company will launch the product in India through its Oncotherapeutics division.

Product	Company	Description
	Sandoz	Sandoz received European approval for its third biosimilar, G-CSF (Filgrastim), in February 2009.
	SciGen	In June 2008, SciGen announced that it will tap the Swiss capital market to raise funds for the development of G-CSF and other biosimilars in its pipeline; and to finance the launch of its third-generation Hepatitis B vaccine within the next three years.

Source: MarketsandMarkets

1.1.2 INSULIN

Insulin is a naturally-occurring small protein hormone secreted by the pancreas to regulate carbohydrate metabolism. External insulin is essential for the survival of patients with type 1 diabetes mellitus. Because of the high development costs of insulin, only a few biosimilar producers have as yet ventured into the insulin market; which thus has plenty of room for new players with quality products. The global biosimilar insulin market was worth $xxxx million in 2008 and is expected to reach $xxxx billion in 2014 at a CAGR of xxxx% from 2009 to 2014.

TABLE 4

GLOBAL BIOSIMILAR RECOMBINANT INSULIN MARKET, BY GEOGRAPHY 2007 – 2014 ($THOUSANDS)

Region	2007	2008	2009	2014	CAGR% 2009 – 2014
America	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Europe	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Asia	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Row	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx
Total	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx

Source: MarketsandMarkets

The American biosimilar insulin market was at $xxx million in 2008, and with an estimated $xxxx million in 2014, the region is expected to be the largest insulin market in the future. The American insulin market has a very high CAGR of xxxxx% from 2009 to 2014 mainly because of the increasing demand from the large population of diabetic patients in the U.S.

1.1.2.1 Drivers & Opportunities

1.1.2.1.1 Increasing demand from huge patient-base

Patients with Type 1 diabetes mellitus depend on external insulin for their survival as the body can no longer produce the hormone. Type 2 diabetes patients usually are insulin-resistant, and may eventually fail to respond to any effort to stabilize insulin levels. Diabetes is the fifth-largest cause for human death; and an estimated 220 million people globally suffered from diabetes in 2008. The increasing demand from this huge patient-base is thus driving the global market for biosimilar insulin.

1.1.2.1.2 Improvements in drug delivery method

Subcutaneous injections currently form the only mode of insulin delivery for diabetes patients. This often presents issues such as infections and uncontrolled blood glucose levels, due to which patients find it difficult to continue the medication (and thus to maintain their blood sugar levels) for longer period. However, various non-invasive drug delivery methods such as oral insulin and transdermal delivery are already in the research stage. The tremendous benefits that these alternate insulin delivery methods can offer patients is expected to significantly boost the market growth for biosimilar insulin.