

November 27, 2008

Biosimilar medicines can create financial “headroom” for German healthcare system

- *New study shows German statutory health insurance funds could save EUR 8.1 billion by 2020 through the use of biosimilars*
- *Germany risks “missing out” on the medical and financial benefits of a key development in modern medicine*
- *Only well-established generics companies can overcome considerable barriers to entry in the emerging market for biosimilars*

Berlin, November 27, 2008 – Sandoz today unveiled the results of a new study, which shows that the German statutory health insurance (SHI) system could save EUR 8.1 billion by 2020 through the use of biosimilar medicines.

The study, “The role of biosimilars in competition in the German SHI market”, was commissioned by Sandoz and conducted by the Berlin-based IGES institute. It also addressed the issue of the political and legal framework conditions necessary to encourage the use of this new generation of biopharmaceutical medicines. Biosimilars are marketed following the expiry of reference product patents on the basis that they have demonstrated comparable quality, safety and efficacy.

IGES director Professor Bertram Häussler told a media conference in Berlin today that the share of highly complex, expensive biopharmaceuticals in the overall German pharmaceutical market was likely to increase from 13 percent today to 21 percent in 2020. In the year 2020 alone, he estimated that the SHI funds would pay out a total of about EUR 10 billion for biopharmaceutical reference products. The use of biosimilars could save the funds more than EUR eight billion over the next 12 years – but only if they were given a “fair market chance”.

Mr. Häussler said: “There are a number of potential barriers to market entry that could prove to be real stumbling-blocks to free and fair competition. The SHI funds must recognize that it is in their own vital interests to ensure that barriers of this kind do not get erected.”

The IGES study identifies three particular barriers to market entry, which could prevent genuine competition between the producers of biopharmaceutical reference products and of biosimilars:

- Incumbents, who have already recovered their development costs, drop prices below the level at which it is possible for biosimilar producers to cover their investment costs
- Incumbents sign exclusive “rebate contracts” with health insurers prior to patent expiry
- Introduction of a reference price system, with direct comparisons of reference product and biosimilar products, reduces the economic incentive to develop biosimilars

Hannes Teissl, Head Global Biopharmaceutical Business Unit, said: “Our politicians today have the power to pave the way for biosimilars to become successfully established on the market. However, we see a real risk that Germany will miss out on this ‘fast-track’ option for realistic, long-term savings. The necessary framework conditions for long-term biosimilar success have not yet been established.”

Mr. Teissl added that biosimilars were fundamentally different from conventional generic medicines, with typical development timelines of seven to 10 years and development costs in the range of USD 70 to 100 million. Only a handful of strong, well-established generics companies would have the resources and long-term commitment to make this sort of substantial financial investment. He said it was “short-sighted and paradoxical” that precisely those companies in Germany who were able and ready to do so were subjected to ever-increasing cost pressures.

Sandoz has established itself as the pioneer of the new market for biosimilars. In a precedent-setting decision in 2006, it was the first company to obtain EU approval for a biosimilar medicine, human growth hormone Omnitrope[®]. Binocrit[®] / Epoetin alfa Hexal[®], the first complex (glycoprotein) biosimilar, was approved and launched in the EU in 2007. Sandoz also has an unrivalled biosimilar pipeline, with two dozen projects at various stages of development.

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About Sandoz

Sandoz, a Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. Sandoz has a portfolio of more than 950 compounds and sells its products in more than 130 countries. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances and anti-infectives. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and Eon Labs (US). In 2007, Sandoz employed around 23,000 people worldwide and posted sales of USD 7.2 billion.

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For further information

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