INTERVIEW

Amgen's move into the biosimilars market

Biotech giant Amgen now has a biosimilars programme that includes nine different molecules. A representative from Amgen has spoken to GaBI about the company's venture into biosimilars. Topics included how to encourage the use of biosimilars and how a Japanese example of biosimilars uptake can help Europe in increasing use of biosimilars.

Keywords: Biosimilar, naming, uptake

Amgen's views on how to encourage the use of biosimilars in Europe differ from some [1]. In an interview on 10 October 2014, Mr Geoff Eich, Executive Director of External Affairs for Amgen Biosimilars, spoke to GaBI about Amgen's approach for biosimilars, which is more like a branded biologicals model than a traditional generics approach.

Encourage do not force use of biosimilars

Biosimilars are a good strategic fit for Amgen and it is leveraging its existing biologicals experience and capabilities to build upon a current, successful biologicals development programme. However, it believes that physicians and patients alike should have a choice in prescribing and using biosimilars. This is perhaps in contrast to the European Generic medicines Association (EGA), which believes that governments should introduce pricing and reimbursement policies to force the use of biosimilars [2]. Generics and biosimilars can play a major role in reducing healthcare expenses [3], however, lack of penetration is seen as a lost opportunity and a barrier to future savings [4].

Instead, Amgen believes in 'a more sustainable method' of controlling healthcare budgets. This can be achieved by offering physicians and patients the choice of which originator biological or biosimilar they want to use. Amgen considers that physicians and patients can be encouraged to use biosimilars by making the supporting data available in the product information, and that high quality data and the responsibility of manufacturers will support the use of biosimilars. Amgen wants 'to give assurance and accountability' with the use of their biosimilars. Therefore, patients will 'get the value of the lower cost of biosimilars, as well as the accountability'.

Biosimilars use not just based on cost

Use of biosimilars 'cannot just be a benefit to the government; it has to be a benefit to the patient. In Europe, cost is covered, but in many other countries it is not covered.' Amgen believes that it is important to maintain high quality standards and manufacturers' accountability in order to make sure physicians and patients have the confidence needed to prescribe and use these medicines. Such standards should not be a trade-off for cost – Amgen believes you can have both.

The Japanese example

Despite the fact that uptake of biosimilars in Europe is slowly increasing, they still account for a relatively small segment of the European Union (EU) pharmaceutical market [5]. There are currently six classes (ESA – erythropoiesis-stimulating agent, G-CSF – granulocyte colony-stimulating factor, HGH – human growth hormone, FSH – follicle stimulating hormone, insulin, TNF – tumour necrosis factor) with at least one biosimilar, as most biologicals are still patent protected. In fact, even in Germany, which has one of the highest uptakes of biosimilars, they have only reached around 50% by volume [6]. The best biosimilar success story is outside of Europe.

Japan Chemical Research Pharmaceuticals' (JCR) biosimilar recombinant human erythropoietin kappa (JR-013) was approved for renal anaemia in kidney dialysis patients and premature infants in Japan in 2010 [7], under the Japanese Adopted Name (JAN) of 'Epoetin kappa (genetical recombination) [epoetin alfa biosimilar 1]' with the brand name: Epoetin alfa BS Inj 750/1500/3000 'JCR'. By the first quarter of 2014, the biosimilar had achieved a market share of 74% compared to the reference product [Kyowa Hakko Kirin's Espo (epoetin alfa)].

JCR's biosimilar has achieved this success despite the fact that Japan has a lower generics uptake than in Europe or the US (26% in Japan versus 82% in Germany and 91% in the US [8]), therefore, one would not expect a high uptake of a biosimilar. Biosimilars also have distinguishable international non-proprietary names (INNs) in the country (the JAN system which does not follow INN) which signifies that the medicinal product is a biosimilar in the first place; an issue that has been suggested would affect the uptake of biosimilars [9].

The reason, according to Amgen, that JCR has such a high market share 'is that the physician and patient are choosing the biosimilar and they do that by choice, not by force'. This example indicates 'that the whole argument of naming is not as important to uptake as people say' [10].

The question is what is JCR doing differently and how has it achieved such high uptake for its biosimilar? The answer is that they have worked hard to make sure the clinicians understand how the biological is being developed. They have also emphasized quality. JCR is known as a high quality company, with a good/trustworthy name and their erythropoietin kappa is of high quality. JCR has also carried out a very successful promotional strategy to increase use of the biosimilar and has maintained this over time. Amgen thinks that, in a similar way to JCR, they 'can make the biosimilar programme more successful in Europe and globally'.

Competitive advantage

The development of biosimilars is nothing short of a challenge and Amgen knows that it is going to take extensive scientific skills to be successful in this market. With more than 30 years of biologicals experience, and a long track record of successfully supplying high quality biologicals to patients around the world, the company is confident in its competitive advantage and ability to deliver on its biosimilars portfolio.

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It is scientifically difficult to create biosimilars and Amgen believes that manufacturing nuances will set biosimilars apart and pave the way for the company to become a leader in the field. In short, Amgen believes that manufacturing matters. However, generics giants like Mylan and Sandoz have said that it is risky to play up differences because of physician and patient concerns about the safety of biosimilars.

Amgen agrees that instilling confidence in stakeholders will perhaps be the number one challenge to overcome. Physicians and patients may wonder if there is compromise in the quality of the product in order to achieve cost savings. Amgen is committed to patient safety and it believes that education of these key stakeholders will be important for instilling physician and patient confidence, and ultimately for the success of biosimilars.

The fact is, biosimilars are made in living cells and therefore no two biosimilars will be the same and no biosimilar will be the same as the reference product. Mr Scott Foraker, Amgen's Vice President and General Manager of biosimilars, points to this when he says 'biosimilars are not all the same and each will represent a distinct therapeutic choice'. However, he believes that, 'in each challenge, we have unique and significant competitive advantages'.

Mr Geoffrey Eich, Executive Director of External Affairs for Amgen Biosimilars, believes that it is within those fine nuances that Amgen is planning to break away from the pack. 'That is where we are going to see the value of experience, the value of quality, and frankly different strategies and philosophies on how to bring them to market,' Mr Eich said.

Mr Foraker has also praised the US Food and Drug Administration's 'thoughtful and deliberate' approach toward biosimilars. Adding that regulators 'want to be cautious, because they understand the sensitivity and complexity in developing biologic[al]s, and that makes perfect sense.'

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