

Biosimilar monoclonal antibodies: the next frontier. A summary report from a symposium held at EAHP 2012

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During the annual European Association of Hospital Pharmacists meeting in Milan, Italy, in March 2012, 600 pharmacists attended the European Generic medicines Association (EGA) symposium entitled 'Biosimilar monoclonal antibodies: the next frontier'. The symposium highlighted the established safety and efficacy profile of biosimilars, the stringent regulations surrounding their European manufacture and approval, and their cost-effectiveness compared with their reference products. It also noted the imminent introduction of biosimilar monoclonal antibodies (mAbs). This symposium was co-sponsored by Hospira, Sandoz and Teva.

Chairing the symposium, Professor Dr Theodor Dingerma¹, from Goethe University, Frankfurt am Main, Germany, said that a highly controlled, consistent manufacturing process is intrinsically important in order to ensure the efficacy and safety of both biologicals and biosimilars. He noted that the future of biosimilars now lies with mAbs.

Dr Jan Müller-Berghaus, Head of the Monoclonal and Polyclonal Antibodies Section at the Paul Ehrlich Institute, Germany, a co-opted member of the Committee for Medicinal Products for Human Use (CHMP) and member of the European Medicines Agency (EMA) Scientific Advice Working Party, outlined the history behind, and contents of, the draft EMA 'Guideline on biosimilar mAbs'. He explained some of the challenges of preparing this draft, including:

- General considerations on equivalence versus non-inferiority

- Exploring the best way to compare mAb biosimilars with their reference product in terms of efficacy and safety
- The need to allow for different mAb expression systems
- Issues around selection of the most appropriate reference product
- Extrapolation of clinical efficacy and safety data to other indications of the reference mAb
- The challenge for clinical trial authorisations in Europe for biosimilar mAbs.

Dr Müller-Berghaus concluded, "Once finalised and made available in 2012, the EMA guidance on mAb biosimilars will have been through a stringent and highly regulated approval process to ensure the quality, equivalence and clinical safety/efficacy of mAbs to their reference products".

Dr Jörg Windisch, Chair of the Head of Global EGA European Biopharmaceuticals Group and Head of Global Technical Development, Sandoz Biopharmaceuticals, went on to discuss 'How similar is similar? Meeting EMA standards for biosimilar mAbs'. Dr Windisch explained that mAbs can be thoroughly characterised using state-of-the-art analytical science that assesses their biological and physicochemical characteristics. This means that biosimilars can be systematically engineered to match the reference product in a complex, detailed and highly controlled process that continuously assesses the quality, consistency and stability of the biosimilar mAb (figure 1). Dr Windisch described this four-step, long, complex and costly process of biosimilar development (figure 2).

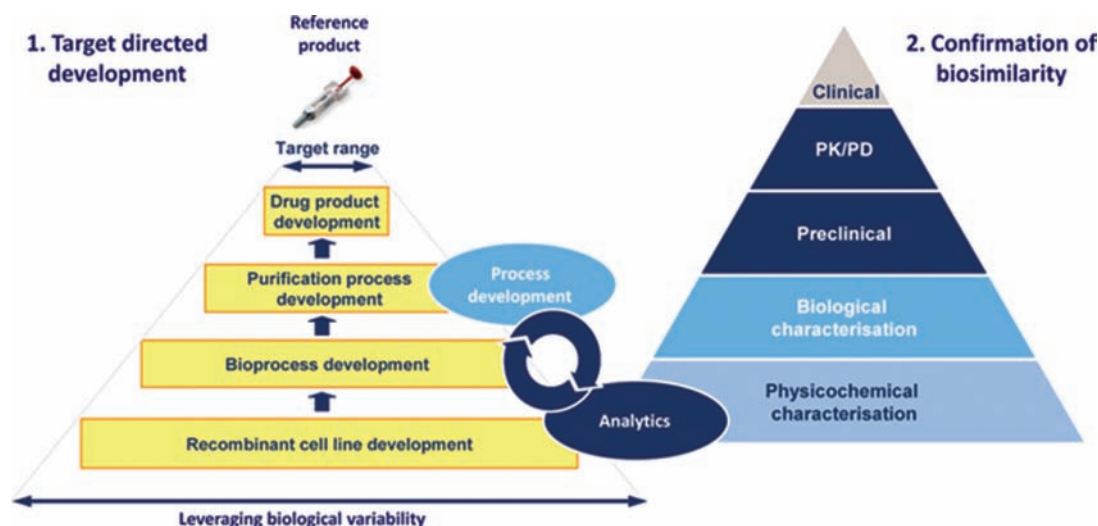


Figure 1. Biosimilars must be systematically engineered to match the reference product. Citation: Sandoz, data on file.

Satellite symposium report

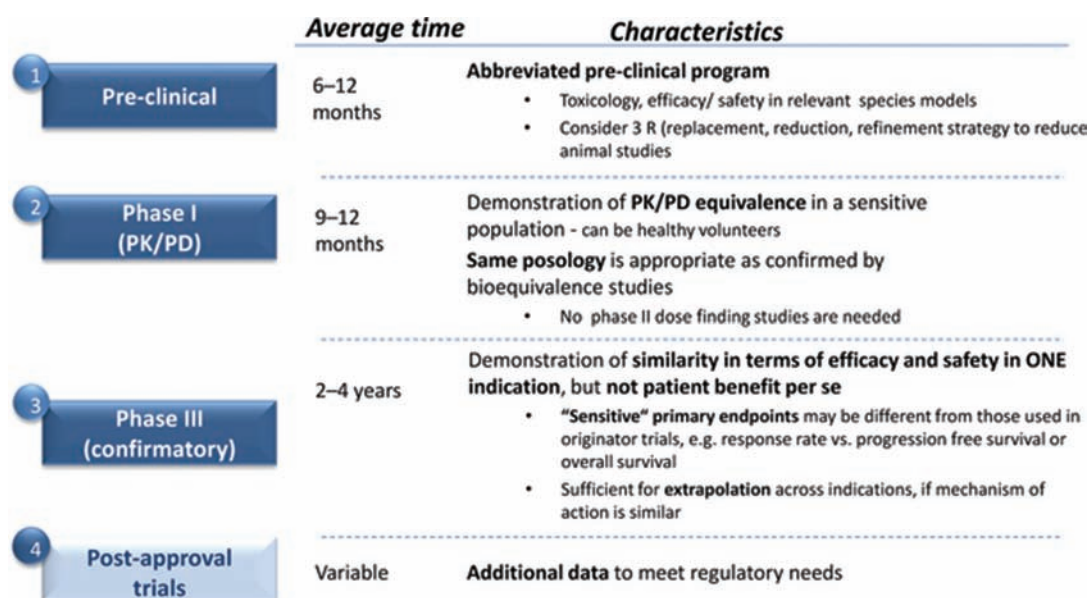


Figure 2. Pre-clinical and Clinical Development of a biosimilar is a 4-step process. Citation: Sandoz, data on file

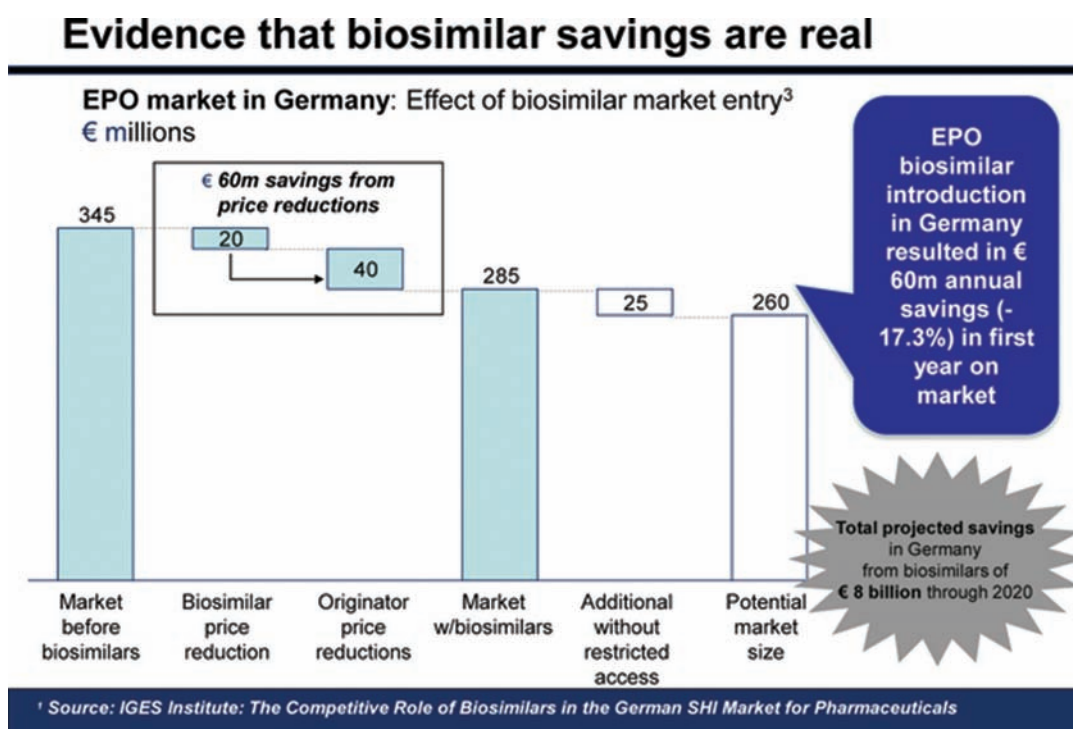


Figure 3. Evidence that biosimilars savings are real. Citation: The Competitive Role of Biosimilars in the German SHI Market for Pharmaceuticals. IGES Institute GmbH, data on file at Sandoz, January 2009.

In conclusion, Dr Windisch said that, with several biosimilar mAbs in advanced stages of clinical development (eg, rituximab and infliximab), it can be assumed that safe and effective biosimilar mAbs will become available to healthcare providers and patients in the near future. This will introduce enhanced affordability and access to these common and increasingly used products.

The final speaker, Dr Paul Cornes, Consultant Oncologist, Bristol Haematology and Oncology Centre, UK, discussed 'Why use biosimilar monoclonals? A clinical and health economic perspective'. With mAb therapies being used with such great effect for so many common conditions, for example, several common

cancers, their future use is set to increase significantly. Focusing on cancers, he noted that these are costly conditions with a significant impact on healthcare economies. However, novel cancer treatments are also costly, and so growth in expenditure needs to be controlled in order to sustain healthcare development.¹ With this in mind, increasing emphasis must be given to formal budget impact/cost-effectiveness approval, for example, by the National Institute for Health and Clinical Excellence (NICE) in the UK.

With biological therapies being a key driver of increased cancer costs,² substantial savings could be made by substituting biologicals for biosimilars, as has been shown with epoetins in Germany³ (figure 3) and with filgrastims across the G5 group of countries

in Europe.⁴ Dr Cornes said that the increased affordability of biosimilars over their reference products also offers the opportunity to treat more patients with the same resources.

Dr Cornes emphasised that hospital pharmacists are central to achieving improved patient care and outcomes.⁵ With further cost constraints and increasing numbers of generic and biosimilar medicines becoming available, for example, the biosimilar mAbs, hospital pharmacists will be increasingly called upon to make well-informed recommendations and decisions on drug choices in hospitals.

Dr Cornes concluded by stressing that “Biosimilars are not generics”. Many everyday common household items are ‘similar’ to other products and are readily accepted as doing the same job, for example, laptops and MRI scanners; such should be the case with biosimilars.

Symposium keypad voting confirms hospital pharmacists are convinced by the evidence for biosimilars.

By the end of the symposium, the keypad voting indicated that the hospital pharmacists who had heard the evidence and discussions concerning biosimilars felt better informed. They also felt more convinced by the evidence supporting the efficacy and safety of biosimilars/biosimilar mAbs when compared with their reference product. Furthermore, they were more confident in using biosimilars in general and biosimilar mAbs in particular, once they are available. By the end of the symposium:

- 96% of attendees would be more likely to use biosimilar products in their hospital
- 86% ‘had some confidence’ or were ‘very confident’ with the robustness of the regulatory requirements for licensing biosimilars in Europe versus 64% at the start of the meeting

- 92% of attendees were ‘convinced to start use, in some patients’ or ‘very convinced and would actively support’ the initiation of the process for introducing a biosimilar mAb in their hospital, once available
- 32% of attendees said they felt better informed and 68% felt more confident in the future role for biosimilar mAbs.

The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.

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Competing interests None.

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