

Competing sustainably in biosimilars – more than just a numbers game [1]

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As the global biosimilar market gets ready to expand rapidly, one question I often get asked is what it will take to succeed in the long term.

The subject came up again at last week's Biosimilars Media Day in Schafftenau, where we gave a group of European journalists the chance to discuss in detail where the market is going, the potential positive impact on patient access, and what Sandoz is doing to make it happen.

From our perspective, the answer boils down to four numbers: 3, 5, 8 and 6. **Three** is the number of biosimilars we already market worldwide, **five** is the number of new medicines we intend to launch by 2020, and **eight** is the number of additional products (conservative estimate) already coming through our next-stage pipeline.

As for **six**, that's how many core capabilities we think it takes to compete sustainably in this market: top-class analytics, technical and device development expertise, clinical development skills, regulatory / policy experience, manufacturing expertise, and commercialization know-how.

The common thread to all four numbers is that they represent various aspects of our sustained, long-term commitment to this business. One example is our state-of-the-art manufacturing facilities in Kundl and Schafftenau, where we are investing more than USD 1 billion over the period 2010-2020. We believe that, without this level of commitment, it will not be possible to ensure continued patient access to biosimilars -- and healthcare systems will not be able to benefit from the potential savings.

With table stakes that high, it's hardly surprising that several companies are thinking seriously about whether they have what it takes to succeed. As expected, we are seeing the emergence of a handful of key competitors, all of whom are partnering externally to acquire the necessary mix of commercial and generic capabilities, financial resources, clinical expertise and manufacturing networks.

Of course, the potential prize is huge – while forecasts vary considerably, our “best-guess” estimate is that the global biosimilar market will grow from approximately USD 1 bn last year to nearly USD 15 bn by 2020. The growth will be driven by the opening up of the massive US market as well as key products losing patent protection, particularly in the field of immunology.

Biosimilars are already having a major impact on healthcare systems. Sandoz products alone now account for more than 250 million “patient days” of safe* clinical experience and market acceptance is growing all the time – the total market share of biosimilar filgrastim products is now over 50%.

But we won't be satisfied until we see a dramatic increase in one critical number: of patients with access to the medicines they need, when they need them. For example, it is estimated that only 5% of patients with

moderate-to-severe psoriasis currently receive a biologic. This is a heartbreaking statistic – and it doesn't even account for the extent to which patients' families and friends also suffer the knock-on effects of lack of access to critical medicines.

At Sandoz, this is the change we are committed to driving. Everything else is just a numbers game.

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