What's Next for BIOSIMILARS?

Biologics, whose active substance is derived from a living organism, have enabled healthcare to make significant therapeutic advances across a whole raft of therapy areas since their introduction in the 1970s. However, these medicines come at a price, reflecting the complexities involved in developing and manufacturing products derived from living cells. Annual treatment costs in the United States can range from $25,000 to $200,000.

Biosimilar medicines, the follow-on "generics" to biologics which have come off-patent, present a significant opportunity to introduce cutting-edge therapies to the treatment landscape for many diseases, while also addressing the cost-effectiveness demands now being made on global healthcare systems. Europe remains well ahead of the United States both in mapping out a viable approval pathway for biosimilars, which in the latter country remains mired in regulatory and legal uncertainty, and in delivering actual approvals.

A Slow Start

Until recently, the European Medicines Agency had granted marketing authorization to a total of 14 biosimilars based on three reference molecules: filgrastim, somatropin, and epoetin. Yet the impact of these products has to date been somewhat muted, with a combined volume share of around 11% of the accessible biologics market in the EU member states (plus Norway and Switzerland) during the 12 months to June 2011, according to IMS data. Cost savings have been relatively modest too, with patchy uptake and reported discounts of 10% to 30% on reference brands — a far cry from the 80% to 90% margins seen in the more aggressively competitive market for mainstream generics.

Are Things About to Change?

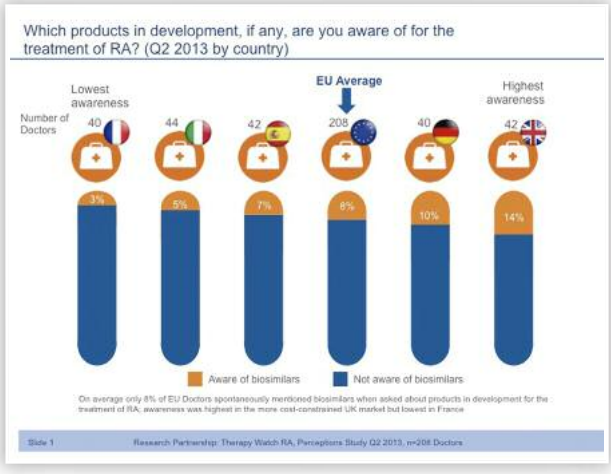
We may be about to witness a sea-change. The European Commission's approval in late 2013 of Hospira's Inflectra (infliximab), for the treatment of inflammatory conditions including rheumatoid arthritis, Crohn's disease, and psoriasis, was the first ever biosimilar approval in Europe for a monoclonal antibody (mAb) — larger, more complex molecules than the biosimilars previously cleared by the EMA.

All Eyes on the EU

Companies that stand to make substantial inroads with mAbs and other biosimilars in the similarly cost-sensitive U.S. market once a workable approval pathway is in place will be watching very carefully the progress of Inflectra. That said, with a more fragmented system of healthcare coverage, there will not be the same pressure from government in the United States to use biosimilars. Moreover, high prices and revenues in the United States mean biologics originators will be better equipped to defend patents for as long as possible. First, though, if there is to be sufficient uptake and buy-in from key stakeholders — KOLs, physicians, payers, and patients, there are some challenges which biosimilars need to overcome.

Low Awareness

According to recent findings from Therapy Watch, Research Partnership's syndicated study of patient data submitted by a panel of specialist physicians across Europe, awareness of biosimilars is currently very low. Only 8% of rheumatologists questioned spontaneously mentioned biosimilars as products in development for RA, with Remsima/Inflectra the only biosimilar mentioned specifically by name.



Dr Anne Hacène, who is a physician on the panel, said "I'm a bit suspicious of them overall. I think that there is currently little information out there to defend their use, whereas there is a lot out there to encourage us to be wary about them. We hear about them, but we have never received a presentation about them and we haven't had anyone come to talk to us about them in an official capacity."

Confidence in Safety/Efficacy

The challenge with biosimilars is that, like the originator biologics, they are complex to make and need to be manufactured under very controlled, high-tech conditions. This has raised concerns about quality. Dr Hacène comments, "Currently we don't have enough

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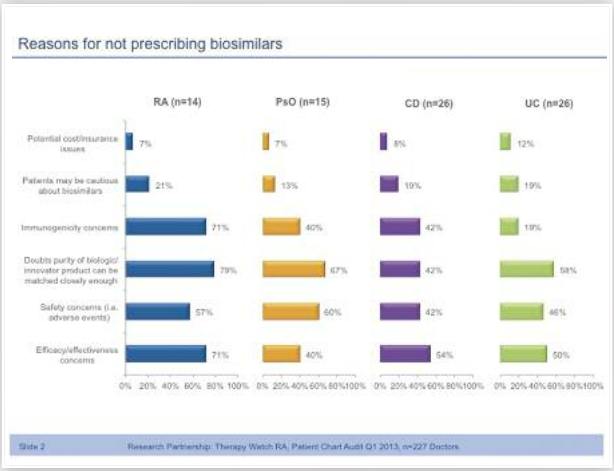
trial data or hindsight on these drugs to demonstrate equivalent efficacy and similar levels of side-effects. If they were backed up by trustworthy, large-scale clinical studies, we could probably think about this differently."

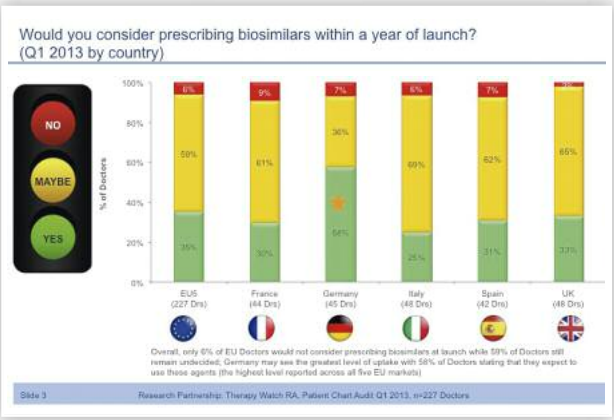
The Therapy Watch data tell a similar story. Those physicians across the EU5 who said they would not consider prescribing biosimilars within a year of launch mostly cited concerns about purity versus the originator product, immunogenicity, and efficacy/effectiveness.



Likelihood to Prescribe

According to the data, only 35% said they would definitely consider prescribing biosimilars for RA within one year of launch. The most positive response, not surprisingly, came from Germany, which is regarded as the most biosimilar-friendly market in Europe. Here, 58% of physicians said they would consider prescribing biosimilars within a year of launch.

However, while physicians will certainly play an important role in future uptake of biosimilars, they are likely to look to local or national guidelines for support. According to a major UK payer, it won't be clinician-driven at all. And it appears physicians agree. According to Therapy Watch data, two-thirds believe that their use of biosimilars will be dictated by local or national guidelines.



Price

Of course, pricing will be a major factor. Cost savings from available biosimilars in Europe have so far been relatively modest, with reported discounts of 10% to 30% on originator brands. But it seems budget holders will be looking for "quite a considerable differential." According to the UK payer, "We would be looking at a difference of around 30%; I think anything less than that would be deemed as disappointing."

At the same time, though, the biosimilars industry will need to bear in mind the possibility that originators may lower their own prices to drive uptake by physicians, leading possibly to unsustainable price erosions.

Manufacturers will need to deliver a value story that is about more than just price. Finding early adopters to act as key opinion leaders (KOLs) for these products will be critical. KOLs will want reassurance over practical issues such as supply-chain logistics, particularly if biosimilars are manufactured abroad. Manufacturers will also have to compete against value-added services offered for some biologics, such as healthcare at home.

Sales and Marketing Efforts

Marketing platforms at all levels must drive home the message that biosimilars are a very different proposition from commodity generics.

It is a sentiment felt by the UK payer, "Some companies have done a really bad job of launching their biosimilars, he comments. "They have treated them as generic molecules — just thrown them at the market with a good price, expecting uptake — which hasn't happened. They need to treat them as any other branded product, with the full sales and marketing weight behind them, as if they are launching a new chemical entity."

In Conclusion

There is little doubt that biosimilar medicines present a significant opportunity to embrace cutting-edge therapies while addressing the cost-effectiveness demands on healthcare systems across Europe — and perhaps none more so than in a chronic condition associated with rapidly ageing populations, such as rheumatoid arthritis.

All the same, achieving widespread acceptance and uptake of biosimilars in Europe is by no means a done deal. Companies entering the market will need to ensure they have in-depth customer insights to offer a real value proposition that makes a meaningful difference to patients, healthcare professionals and increasingly hard-pressed healthcare systems. They will need to educate physicians in order to raise awareness and build confidence. A properly thought-out market access strategy must also take full account of payers, who may prove to be the real engine for uptake of biosimilars. Most importantly, manufacturers must convey the message that biosimilars are a very different proposition from commodity generics. PV