

## Biosimilars Educational Series

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# The case for biosimilars—a payer's perspective

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Biosimilars have the potential for making savings in healthcare costs and in resource allocation, if competition is permitted at the level of treatment induction.

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The last decade or so has seen the introduction of many truly innovative biological pharmaceuticals that have had a profound impact on the treatment of many diseases. This is a welcome development. The future of these biologically produced pharmaceuticals looks bright, with almost 300 monoclonal antibodies alone having international nonproprietary name status, 70 of which also have trade names.

Unfortunately, the companies that have brought these drugs to market have uniformly chosen to sell them at very high prices. This presents healthcare financing systems with a dilemma, for the reasons outlined below.

Biological pharmaceuticals are produced using living cells genetically modified to produce a particular substance. This is a hugely complex process that is only partly controllable. In addition, a variety of different cell types can be used to produce each substance. Together with other manufacturing complexities, biosimilar pharmaceuticals are never completely identical to their reference products. The main consequence, from a payer's perspective, is that regulatory agencies are unlikely to allow pharmacies to substitute these drugs for the originals.

In Sweden, where generic drug alternatives are available, there is mandatory substitution at the pharmacy level. This means that the pharmacy will substitute a branded product with the cheapest generic drug available within a predetermined substitution group, unless the prescribing physician has indicated a medical reason for not doing so. This has led to a very competitive environment within the generics sector, resulting in substantial price decreases and savings for the healthcare system. By and large, all stakeholders find this arrangement acceptable,

since it allows the introduction of new and innovative products at the early end of the product lifecycle. It rests, however, on one fundamental and generally accepted assumption: that generics are perfect substitutes for each other – as well as for the original drug, e.g. 10 mg simvastatin from one source is the same as 10 mg simvastatin from another, regardless of supplier.

Thus, substitutability becomes a central issue if one hopes to induce the same type of competitive dynamics for biological drugs as already exists for generics, even though it is reasonable not to expect the same magnitude of price decreases due to the more complex nature of manufacturing. Biosimilars that have been approved by the European Medicines Agency are approved pharmaceuticals in their own right, having passed a number of rigorous safety criteria and following the same pharmacovigilance rules as originator products, and having demonstrated comparable quality and clinical activity to the reference product.

Introducing a more macroeconomic perspective, the current eurozone crisis and general economic conditions clearly signal that politicians responsible for allocating resources have little room for increases in public expenditure. Indeed, many countries are experiencing decreases in public spending. Thus, barring a major redistribution of resources within the healthcare sector, it is highly unlikely that there will be a major budget increase for pharmaceuticals anywhere within the EU in the short- to mid-term. Payers and industry alike must face up to a largely static pharmaceutical budget (shrinking dramatically in some cases) for the foreseeable future.

Also at stake is the issue of equity. Biological pharmaceuticals are almost always priced at levels that lead to high treatment costs.

If a very small number of patients consume large amounts of the resources allocated to pharmaceuticals, this may be perceived as unfair, which in turn is politically sensitive. If the high cost of treatment with biological pharmaceuticals for small groups of patients overwhelms the ability to pay for other treatments for larger patient groups public opinion could become quite negative.

From a payer's perspective, the case in favour of biosimilars is a strong one. There is a clear incentive to foster a competitive climate for biosimilars, including through allowing substitution at treatment initiation. The potential price reductions can then create room for new products or expanded patient populations or both, given the budgetary constraint. This will certainly be encouraged in Sweden and other countries in Europe and beyond. Although manufacturers of originator products may be opposed to the introduction of biosimilars if profit margins fall, this development should nevertheless be embraced by industry as a whole in order to make room financially for the launch of new and innovative products.

## For patients

The increasing popularity of biopharmaceuticals as treatments for a variety of conditions, including chronic illnesses is placing pressure on healthcare systems to make these available to patients. Their high costs, however, are encouraging healthcare providers to look to cheaper similar versions of the same biopharmaceuticals, or biosimilars, as lower cost alternatives. For approval in Europe, biosimilars must compare well in safety and efficacy compared to their reference products. Once on the market, competition between products can lead to a reduction in price for both biosimilars and branded products, which in turn will make them more accessible to the patients that need them [1].

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## Reference

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