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Biosimilars by approval – Biogenerics in practice?

With an increasing number of biosimilar products entering the market, a discussion on the sustainability of these products is urgent. In Norway, the uptake of monoclonal biosimilars (infliximab, etanercept and rituximab) has been quite rapid owing to the large discounts given in comparison with the originators. Discounts have been up to 70%. So far it has been more or less a one way ticket from originator drugs to biosimilars. Biosimilar infliximab has a market share of more than 95%, indicating that almost all patients have been switched from the originator to the biosimilar. In fact, this represents a possible transition from one monopoly to another monopoly. In Europe there are now (January 22nd 2018) three approved infliximab biosimilars, three etanercept biosimilars, three adalimumab biosimilars (marketing will not take place before October 2018) and six rituximab biosimilars. The unanswered question is whether the second, third or later biosimilar entrants will have commercial success. In Norway, the first infliximab biosimilar gained total market dominance in two years. However, in the national tender for 2018 (in force from February 1st 2018), another biosimilar gave the best price – with a very large discount. Economically, all hospitals should switch their patients from the "old" biosimilar to the "new" one. Some physicians in Norway have expressed doubts about switching between biosimilars with the same originator as reference. However, if this way of switching does not take place, the market forces will not be able to secure further price cuts. In October 2017, the Norwegian Medicines Agency issued a statement effectively saying the following:

1. Switching from originator to biosimilar is safe.
2. Switching from biosimilar to originator is safe.
3. Switching between biosimilars with the same reference originator is safe.

Biography

Steinar Madsen is medical director at the Norwegian Medicines Agency. He has been working with the safe and cost-effective use of medicines for more than 20 years. He has been working with generics since 2000 and biosimilars since 2006. In 2001, generic substitution at pharmacy level was introduced in Norway. Dr. Madsen is a specialist in internal medicines and cardiology and works part time as a consultant in cardiology.

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