Q&A SESSION WITH STEINAR MADSEN

STEINAR MADSEN, Medical Director, **Norwegian Medicines Agency**

Dr. Steinar Madsen is Medical Director at the Norwegian Medicines Agency. He has been working with generic substitution since it was introduced in Norway in 2001. He is member and previously chairman of the committee for generic substitution at the Agency. Dr. Madsen is also engaged in the drug information service, with a special interest in the safe use of drugs. He graduated from the University of Oslo in 1981, is a specialist in internal medicine and cardiology and works part time as a consultant in cardiology.

What are the main challenges inhibiting the adoption of biosimilar products in Europe at the moment, and what do you think is the key to moving towards greater approval and uptake of biosimilars?

The main challenge is physician-initiated switching. Unless you have this switching, the uptake of monoclonals will be very slow, even in the face of substantial discounts.

That is why the originator industry is working hard to dissuade switching. In Europe we see uptake of biosimilar Infliximab from almost nothing (UK) to almost 100% (DK).

What do you think are likely to be the most exciting developments for the biosimilars industry over the next couple of years?

The expected approval of biosimilar Etanercept in Europe in 2016 is very exciting. Also, it now seems that the first biosimilar will be coming onto the American market within a few weeks. This is a real breakthrough, considering all the legal efforts from the originator company to stop this.

You are presenting at this year's Congress on the future of biosimilars and what we can learn from Infliximab – why is this a particularly exciting subject right now?

I think that the biosimilar Infliximab is more or less an acid test of the whole biosimilar idea. With discounts ranging from 45 to 70% in Europe combined with the proven safety record of European biosimilars for almost 10 years now, there are no medical reasons for a low uptake. It is the result of ten years of danger-mongering from the originator industry that still holds its grip over physicians. I believe that uptake of biosimilars is a management task and cannot be left to individual doctors.

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