DENMARK

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

PHARMACEUTICALS

Changes in pricing

- Signing of a price cap agreement with effect from 1 April 2016 which entails a 10 pct. reduction on list prices of medicines in the secondary health care sector over the next 3 years.
- Ongoing negotiations with the pharmaceutical industry concerning a price cap agreement on list prices of medicines in the primary health care sector (spring/summer 2016).

Changes in reimbursement

- With effect from 1 January 2016 a fixed annual user charge ceiling was introduced of expenditure on reimbursed medicines. That means that patients automatically will be granted 100 pct. reimbursement when their expenditure on reimbursed medicines is higher than the user charge ceiling which is 3,880 DKK (~ 520 €) annually (2016 figures).

Other changes related to medicines

- The Danish Regions have decided to establish a 'Medicines Council' which assess i.a. new medicines by categorizing it in terms of added value compared to standard treatment (the method is similar to the one being used by the German Institute for Quality and Efficiency in Health Care, IQWIG).
- All parties of the national parliament of Denmark have agreed upon 7 principles for prioritising medicines.
- Ongoing analysis on how to better manage rising medicines expenditure (i.a. reducing waste, optimizing logistics and procurement and forming the basis of creating access to better and more extensive data on use and consumption of medicines).

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

The tender process together with guidelines (RADS) in Denmark will be the solution for a quick introduction of biosimlars.

For infliximab and etanercept, both products have been included in guidelines for rheumatology, gastroenterology and dermatology since 2011.

A working group of doctors, pharmacists and pharmacologists from the clinical setting, RADS and Amgros has been planning the introduction of biosimilars within these areas since 2013.

The plan has been to prepare the guidelines (together with the doctors), timelines for the tender process and education material for doctors, nurses, pharmacists, and patients.

And when the documentation from the EMA approval was available, there have been discussions with the doctors, and based upon these discussions, the doctors decided when to switch patients.

For both products, there has been a statement that unless the patients have problems, it will be possible to switch the patient from the original products to the biosimilar products.

The introduction of infliximab went much quicker than expected. In month 2, infliximab had a MS of 90%. The introduction of Benepali will begin 1st May, 2016.