Expensive medicine to be replaced: Massive annual savings for the regions.

Today, the Danish Medicines Council gave its final go-ahead to replace the costly drug Humira with much cheaper, new medicine. Amgros, the Danish Regions' procurement organisation, expects that replacing Humira alone will save the regions around DKK 335 million every year.

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The Danish regions can anticipate annual savings of around DKK 335 million from the beginning of 2019. This was the conclusion after today's meeting in the Danish Medicines Council, where the Council made a final recommendation to allow Humira to be replaced by less expensive pharmaceuticals.

Humira contains the substance adalimumab and is currently used for patients with skin diseases, arthritis and chronic intestinal diseases.

The bill for Humira alone was around DKK 387 million for the past 12 months. However, in August 2018 - a few months before the expiry of the Humira patent - the Medicines Council recommended that new and cheaper drugs with *adalimumab*, so-called biosimilars, be started up at Danish hospitals when the Humira patent expired.

Since then, Amgros, the regions' procurement organisation, has organised and completed a tendering procedure resulting in the price of pharmaceuticals with adalimumab reaching an all-time low.

"We're very pleased to have achieved this result. We ensure more cost-effective health solutions and this ultimately benefits a lot of Danish patients," said Steen Werner Hansen, who shares the chairmanship of the Danish Medicines Council with Jørgen Schøler Kristensen. Steen Werner Hansen is also the deputy director of Herlev and Gentofte Hospital.

According to Amgros, the new drugs replacing Humira will cost the regions around DKK 52 million annually - a saving of DKK 335 million every year.

Safe switch to new medicine

The prospect of considerable savings on pharmaceutical costs is based on an assessment by the Danish Medicines Council in August 2018 that patients currently being treated with Humira can switch to the new so-called biosimilars.

A biosimilar is a new version of an existing biological pharmaceutical. Patients can safely switch to the biosimilar, according to Jørgen Schøler Kristensen. He explained that the matter has been carefully reviewed by a specialist committee at the Danish Medicines Council consisting of both physicians and patients.

Like the Danish Medicines Council, the specialist committee has come to the conclusion that it is safe to start using the new, less expensive pharmaceuticals.

"The task of the Medicines Council is to assess which medicine is best for the patients and help to ensure that we spend money in the best possible way. In our assessment, the biosimilars are good and safe, and a switch may free up a lot of money that can be well-spent elsewhere in the healthcare sector to help Danish patients," said Jørgen Schøler Kristensen, adding that the switch from one type of medicine to another should of course be based on good dialogue between the hospital and the patient, and the number of switches between pharmaceuticals should be kept to a minimum. The Danish Medicines Council also emphasised this in its assessment of adalimumab.

“Furthermore, specific individual patient considerations may sometimes prevent a switch," explained Jørgen Schøler Kristensen, medical director at Aarhus University Hospital.

Total savings: DKK 420 million

In fact, the regions can anticipate even larger savings after Amgros' tendering procedure, as the tender not only included Humira, but also a number of other drugs with overall costs for society of DKK 1.6 billion annually. In addition to discounts on biosimilars with adalimumab, Amgros also achieved considerable price reductions on a number of other drugs.

Amgros thus expects total annual savings for the regions of around DKK 420 million.

According to Flemming Sonne, CEO at Amgros, the reason for achieving savings of this scale is that several new players have been waiting in the wings, and that the original suppliers have fought back.

"We've managed to achieve savings of this scale because we've had a unique competitive environment with no less than four new biosimilars entering the market after the patent expiry. The fierce competition in this market of almost DKK 1.6 billion means that all suppliers have offered far lower prices than we had imagined," said Flemming Sonne.

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FACTS:

Humira

For more than a decade, Humira has had the largest annual turnover of all pharmaceuticals in Denmark. The turnover of Humira amounted to around DKK 400 million in Denmark in 2017. The Humira patent expired in mid-October 2018. Humira is currently used for patients with skin diseases, arthritis and chronic intestinal diseases.

Biological pharmaceuticals

A biological pharmaceutical differs from other types of pharmaceuticals by being produced from biological material (from humans, animals or plants) or through genetic engineering. By far the majority of biological pharmaceuticals in use today are produced through genetic engineering, using cells from a mammal, yeast cells or bacteria to produce the drug molecule. A biological pharmaceutical often has a far more complex molecule structure than a synthetically (chemical, non-biological) manufactured pharmaceutical.

Biosimilars

A biosimilar is a new version of an existing biological pharmaceutical (reference drug) that must have been approved (in the EU) for no less than 10 years. Biosimilars may have certain minor molecular differences compared with the original version of the pharmaceutical, but these differences may not impact the effect and safety (side effects) of the biosimilar compared with the original biological pharmaceutical.

The Danish Medicines Council has previously recommended switching to biosimilars for treatment of arthritis and several types of cancer, for example breast cancer.

The Danish Medicines Council

The Danish Medicines Council is an independent council that prepares recommendations and guidelines on pharmaceuticals for the five regions. The council was established on 1 January 2017 to ensure rapid and uniform use of new as well as existing pharmaceuticals across hospitals and regions; to impose stricter requirements for documentation that new and existing medicines benefit patients; and to provide a stronger foundation for Amgros' price negotiations and tendering procedures.

Amgros

Amgros is the common procurement organisation of the regions and is responsible for organising and carrying out tendering procedures and for procurement, primarily of medicines, for public hospitals in Denmark.

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