Sweden

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS

CHANGES IN PRICING

- The retail margin for pharmaceuticals was changed April 1st 2016. The increase in margin for more expensive pharmaceuticals (> SEK 6 000) was financed by lowering the margin for all packages with SEK 0.75 (€ ~0.08). Now pharmacies receive maximum SEK 1046.25 (€ ~112) per pack for products with a purchasing price between SEK 6 000 to 50 000 (€ ~ 644 to 5 371), compared to SEK 167 (€ ~18) before the change.

- The Supreme Administrative Court has clarified that TLV does not have the legal right to prohibit pharmaceutical companies and County Councils from negotiating discounts on *out-patient* pharmaceuticals included in the national reimbursement scheme (Dec. 2015).

CHANGES IN REIMBURSEMENT

- Pharmaceuticals and consumable products included in the reimbursement scheme are, since January 1st 2016, free for the patient and without co-payment for children under the age of 18 years.

- Young adults will receive free contraceptives, included in the reimbursement scheme, without any co-payment, from January 1st 2017.

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

Systematic review of the market

- The government has commissioned TLV to analyse the development of the market for biological products with competition from biosimilar products.
- This includes analysing ways to stimulate a stronger price competition, and also includes analysing the framework and uptake of biosimilar products in other countries, with particular focus on the Nordic countries.
- The purpose of review is to create an understanding of how other countries have generated effective price competition for biologicals and biosimilars.
- The report is expected to be finalised in the summer of 2016.

Pricing and tendering procedures differ depending on out-patient or in-patient use

- Price and reimbursement for the **out-patient sector pharmaceuticals**, dispensed at pharmacies, is managed by TLV. Prices and reimbursement of biologicals and biosimilars used in out-patient care are subject to the same regular appraisal value based price proceeding as synthetic pharmaceuticals. A biosimilar product must be priced at the same level or lower than the originator. A decision on price and reimbursement of biologicals and biosimilars may be linked to price/risk sharing agreement between the County Councils and the pharmaceutical company.

- The County Councils tender **pharmaceuticals used in the in-patient sector.** Some of the 21 County Councils have joint procurement.
- There is no national guideline or recommendation to switch from original to biosimilar. Some County Councils have instructed their physicians to switch patient to a more cost effective treatment. For example, the uptake of the biosimilars to infliximab (Remsima/Inflectra) varies significantly between the regions, from 0 to 90 per cent in March 2016.

Substitution

- Biologicals and biosimilars are not substitutable on a pharmacy level in Sweden.