SWEDEN

Recent and planned changes in pharmaceutical pricing and reimbursement and overview of the medical devices system

PHARMACEUTICALS

Changes in pricing

- The government and LIF – the research-based pharmaceutical industry – have agreed on a 7.5 percent price reduction on pharmaceuticals authorised 15 years ago or earlier. The price cut applies to the pharmacies' purchasing price and was implemented in January 2014. Total saving amounts to € 40 million in the first year.
- Price reductions on pharmaceuticals once they reach 15 years of authorisation will continue annually.

Changes in reimbursement

- A pharmacist can to a greater extent dispense a pharmaceutical within the reimbursement scheme even if the prescribed pharmaceutical no longer is reimbursed.
- Situations when a pharmacist can make an exception from dispensing the product of the month are further clarified. To be implemented on the 1st of January 2015.

Other changes related to medicines

- Pharmaceutical companies are obligated to inform TLV each month if their product is available in a sufficient volume to supply the Swedish market to be considered available within the substitution system. The new process will be implemented on the 1st of July 2014.
- Pharmaceutical companies and pharmacies risk sanctions if they do not fulfil their commitment to supply/dispense the product of the month in sufficient volumes if they earlier on informed TLV that the product is available in sufficient volumes. Implemented: 1st of July 2014.
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- Pharmacists are obliged to inform their patients at what pharmacy they can find their medicine, from the 1st of July, if the pharmacy does not have it in stock.
- An information campaign on generic substitution was launched during 2013 in collaboration with the Swedish Medical Products Agency (MPA). The campaign is aimed at providing thorough information regarding generic substitution to prescribers, pharmacists and patient, as well as to strengthen and support the patient-prescriber and patient-pharmacists dialogue regarding substitution. The patient leaflet will be translated to other languages than Swedish later this year.

MED. DEVICES

Pricing and reimbursement system of medical devices

The Swedish market for medical devices is estimated to a sales value of 2 billion € per year.

TLV conducts health economic evaluations of medical technology since 2012. The aim is to analyse available documentation including quality assessment and possible uncertainties, as well as a consequence analysis. The TLV evaluation does not result in a decision or a recommendation.

- **Competent authority**: MPA is responsible for safety, CE-approval and approving clinical trials.
- **Price regulation**: "Medical items" like colostomy bags and injection needles are priced similarly to pharmaceuticals, i.e. on a national level. For the majority of medical devices the price is agreed on a regional level between individual County council and the manufacturers.
- **Reimbursement**: "Medical items", are included in the reimbursement scheme while medical devices are not generally reimbursed.
- **Price:** There is no overview of prices of medical devices as a whole, although prices for reimbursed "medical items" are published in the same public database as medicines.