





SWEDEN

Recent and planned developments in pharmaceutical policies 2014 Policies related to high cost medicines

DEVELOPMENTS	 Changes in pricing and reimbursement The government has commissioned TLV to develop the value based pricing framework for branded medicines not subject to generic competition. One reason is the high – and inflexible – prices Sweden pays for patented drugs. Dynamic pricing, early and equitable access to effective medicines as well as a more cost effective use during the products entire life cycle are priorities. It is supported by (1) a new form of collaboration between TLV, county councils and manufacturer, and (2) price adjustments when new data arrive on effectiveness in real-life or when competing drugs are marketed, etcetera. The government and LIF – the research-based pharmaceutical industry – have agreed on a price reduction of 7.5 percent on medicines, with little or no generic competition, authorised 15 years ago or earlier. Total saving amounts to approx. € 40 million in 2014. Price reductions will continue two times per year once the medicines reach 15 years of authorisation. The extra retail margin for substitutable pharmaceuticals provided by at least two MAH will increase to SEK 11.50 from January 1st 2015. Generics without competition will no longer receive the extra retail margin. The change is cost/income neutral for the stakeholders. Other changes Generic market: Pharmaceutical companies are obligated to inform TLV each month which products that will be available in a sufficient volume to supply the Swedish market with the product of the month. Pharmaceutical companies and pharmacies risks sanctions if they do not fulfil their commitment to deliver/dispense the product of the month (since July 1st 2014). Pharmacists are obliged to inform patients at what pharmacy they can find their medicine if the pharmacy does not have it in stock (starting 1st of July 2014). The patient leaflet A safe substitution at the pharmacy is now translated into 8 other languages than Swedish: Arabic, Bosnian
	and patient-pharmacist dialogue regarding substitution.
S P	High cost medicines
E C I	 Special pricing policies: A new form of collaboration between representatives from the county councils and TLV has been utilized to develop a national recommendation and a plan for introduction of a new medicine. The first pilot was Olysio, a Hepatitis C drug, where the pharmaceutical company and the county councils have signed a risk and cost sharing agreement.
A L	 Special reimbursement/funding policies: A one-time remuneration to the county councils is under consideration due to the expected cost increase for Hepatitis C medicines.
T O P I C	 High cost medicines at the interface of out-patient and in-patient sectors: Medicines in the in- and out-patient are reimbursed and mainly funded by the county councils. Medical treatments for infectious disease and for persons without perception of their own state of illness are funded on a national level.