Sweden

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

2019-06-01 111 products (different substance and form) will have their prices cut by 7.5 percent in accordance with the 15-year rule, where prices are cut on substances whose patent expires but do not yet face generic competition. Substances to have their prices cut include risperidone and atazanavir. (Decided by TLV)

CHANGES IN REIMBURSEMENT

2019-01-01 The high-cost threshold has been raised from SEK 2250 to SEK 2300 per year and patient. (Decided in parliament)

OTHERS CHANGES

2019-04-15 A new electronic communication platform, KLAS, is launched by the Swedish e-Health Agency for prescribers to submit motivations for the licencing of medicines without market authorisation in Sweden. KLAS provides an automatic and secure electronic platform for the communication of sensitive patient information.

2019-02-09 Implementation of the security system of the European Medicines Verification Organisation (EMVO) according to the EU-FMD (Falsified Medicines Directive). The system is run by e-Verifikation i Sverige, e-VIS, a non-commercial association of pharmaceutical trade associations.

SPECIAL TOPIC: patient-based reimbursement decisions

OUT-PATIENT

There is no practice in Sweden of reimbursing individual patients for medicines that have market authorisation but are not on the reimbursement list.

When there is no authorised medicine available, a doctor may prescribe a medicine that is authorised in another country (but not by EMA). In this case, the doctor/hospital must submit a motivation to the Swedish e-Health Agency stating why a specific patient should be treated with the non-authorised medicine. The motivation is then sent to the pharmacy, which makes an application to the Swedish Medical Products Agency for a patient specific approval. A medicine licenced by the Swedish Medicine Board will as a rule be automatically reimbursed, unless otherwise stated by TLV.

If a licenced medicine receives market authorisation from the Swedish Medicine Board or EMA, the medicine may no longer be prescribed on license to patients. The company that markets the medicine then has the option of applying for subsidised status to TLV. To ensure that patients on the medicine will not be without subsidised medicines while TLV is processing the application, TLV may grant a temporary reimbursement. This means that the medicine is reimbursed during the time the application is processed to patients that previously received the medicine on license.

Some medicines are only reimbursed with restriction and only certain patient groups get reimbursement for these medicines. In some cases, the population that are eligible for reimbursement can become very narrow. This is the case with Aimovig, which may be prescribed only to patients that have previously tried but rejected two other migraine prophylactics. The medicine is also only reimbursed when prescribed by specialised doctors.

IN-PATIENT

The Council on New Therapies (NT-rådet) is the body that gives recommendations to the healthcare regions on which new therapies to include for in-patient treatments. In case of severe diseases with very high-cost therapies, the Council on New Therapies may form an ad hoc treatment council that may admit patients to the treatment on an individual basis. This was the case with Spinraza.