

SLOVENIA

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

Regular semi-annual price reviews (external price referencing for all medicines that are financed from public funds - 4380) – ongoing.

The Ministry of Health has published an amendment to the Rules on the Pricing of Medicinal Products for Human use due to changes in wholesale margins in France – Feb 2019

CHANGES IN REIMBURSEMENT

Depends on new Health Care and Health Insurance Act, which is still under consideration, all below listed changes are possible

- changes/modifications of reimbursement lists
- changes/modifications of reimbursement rates
- changes/modifications of co-payment
- changes/modifications in the reference price system (methodology)
- reimbursement reviews
- changes in the assessment/appraisal of products to be included in the reimbursement system
- other changes/modifications of the reimbursement system

OTHERS CHANGES

Implementation of the security system of the European Medicines Verification Organisation (EMVO) according to the EU-FMD (Falsified Medicines Directive). Concerned are Prescription-Only-Medicines – Feb 2019

New Health Care and Health Insurance Act is under consideration (planned changes and implementation dates not known yet)

- changes in generic policies (change from indicative to mandatory generic substitution and INN prescribing)
- volume control, prescription monitoring, prescription budgets, measures to improve prescribing performance
- measures to improve medicines management at the interface of out-patient and in-patient sectors
- educational and information activities

e-submission of an application for reimbursement is in preparation

SPECIAL TOPIC: patient-based reimbursement decisions

OUT-PATIENT

Reimbursement of medicines that are not authorized or not included in the reimbursement list (non reimbursable medicines and medicines not applied for inclusion in the reimbursement list):

Medicines that are not authorized and not included in the reimbursement list are only allowed to be prescribed and covered by the health insurance fund in justified cases: when the treatment with such a medicine is necessary for compelling therapeutic reasons, and no alternative (reimbursed) medicine is available.

(Source: Health Care and Health Insurance Act)

The individual applications per patient have to be approved by a head of the medicinal department at health insurance fund. The applications have to include:

- Diagnosis
- Anamnesis, results of medical findings, pre-treatment data
- The prescribed medicines
- The justification

The head of the medicinal department at health insurance fund may only approve the application in case the justification is available and the principles of appropriateness and economic efficiency of the prescription are considered.

In case the medicine has no marketing authorisation in Slovenia, the individual application may be approved if an authorised medicines is not available or has been unsuccessful.

IN-PATIENT

For medicines not included in the hospital formularies (each hospital has its own hospital formulary) the prescribing physician has to submit a justification and together with the hospital pharmacy the decision is taken. If the medicine is very expensive an additional approval of the medical director of the hospital is needed.