

## MACEDONIA

### Recent and planned developments in pharmaceutical policies 2018

#### Special topic: national incentives and derogatory procedures for orphan medicines

##### CHANGES IN PRICING

- price reviews – change from twice a year to annual (implemented in October 2017), still according to the old methodology:
  - revision of methodology just initiated – co-operation with the World Bank
- AIM – simplification of the procedure – eg. lower number of reference countries (currently 12) in EPR ; harmonization with reimbursement policies

##### CHANGES IN REIMBURSEMENT

- Law on Health Insurance - ongoing revision, draft in parliamentary procedure, expected acceptance any time. Major changes in:
  - ✓ MoH responsible for Methodology for Positive List and the Committee nomination, instead of the Government
  - ✓ One Committee for Positive List of 9 members, instead of 14 Committees of 17 members each
  - ✓ Bigger influence of the HIF and MoH (4/9 members instead of 2/17 members)
  - ✓ Pharmacist included in the Committee
  - ✓ Longer period for obtaining the medical expert opinion (30 days instead of 15)
- AIM – “opening” of the Positive List (closed for 9 years)
- changes/modifications of reimbursement rates and reference price system methodology – process initiated, in accordance with reimbursement list changes and pricing changes

##### OTHERS CHANGES

###### Planned changes:

- connection of the HIF system with the National Electronic Medical Database (so called “Moj termin”) – real time surveillance
- re-distribution of budget caps at pharmacy level – more equitable distribution among pharmacies
- changes in disbursement fee for reimbursed drugs in out-patient sector (pharmacies) – from regressive to fixed

#### SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

**Marketing authorization:** Regular procedure, with possibility for “conditional authorization” if availability is threatened; can be available on the basis of compassionate use

**Financing:** Government budget through the MoH Special Program – since 2009, with constant increase in budget; availability regardless of insurance status of the patient  
 Financed in part of the excise tax of alcohol  
 Not part of the Social Health Insurance and the Positive List

**Registry:** National Registry developed, available electronically since august 2018

**Decision:** National Committee for Rare Diseases, elected by the MoH

**Therapy and disbursement:** in-patient; Reference Centers (Center of Expertise) authorized by the MoH

**Pricing:** No special procedure, however MoH undertakes centralized tenders as a mechanism to lower prices

**Availability:** Improving; however, threatened by the parallel import procedures (lack of quality assurance) and public procurement procedures (price is the only criteria, and procedure takes very long time); Patient organizations very active in improving the availability