

## BELGIUM

### Recent and planned developments in pharmaceutical policies 2018

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

#### CHANGES IN PRICING

- 01.2019:** Reform economic margin of the pharmacist (outpatient sector)
- 04.2019:** The measure 'price reduction after 15 years of reimbursement' is modulated, depending on the total of sales of the molecule ("volume cliff measure"). This also applies for the "patent cliff" and "biocliff" (advanced application of the price reduction after 15 years on cluster opening).
- 04.2019:** 'ceiling prices measure' also applies for products used in hospitals

#### CHANGES IN REIMBURSEMENT

- 05.2018:** Quinolones are reimbursed in chapter IV (restriction regarding the reimbursed indications) instead of chapter I.
- 01.2019:** Hospitals that deliver products that are included in the reference price system, or products with a reimbursed biosimilar, or contrast agents, only get 85% of their costs reimbursed (as from 01/01/2018, this was 90%).
- 2019:** review anti-HIV, diabetes, haemophilia (reimbursement conditions and/or reimbursement level)

#### OTHER CHANGES

- 01.2019: Introduction of 'cheap prescription' in hospitals
- 01.2020: Mandatory e-prescription for medicines for ambulatory patients (with exceptions)

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

##### Research and Development

- Belgian Patent Box also known as Innovation Income Deduction is a tax relief scheme for innovative companies in Belgium. Corporation tax on profits from a company's own innovations are reduced by up to 85%.

##### Market access prior to marketing authorisation

Financial intervention for promising therapies for severe/fatal diseases with no reimbursed alternative treatment → often orphan drugs

- *Unmet Medical Need list* : yearly updated list with high UMN indications
- *Early Temporary Authorisation (ETA)*: a framework for Compassionate Use / Medical Need Programm (RD 25/04/2014)
- *Early Temporary Reimbursement (ETR)*: a Belgian Early Access Scheme (RD 12/05/2014)

##### Taxes

- Exemption of taxes (ca. 10%) for orphan drugs → instead: Orphan tax depending on revenue (0% to 5%)

##### Assessment of orphans

- No special HTA and appraisal procedure for orphan drugs, however no obligation to submit cost-effectiveness model

##### Funding / Reimbursement

- *Special Solidarity Fund*: additional safety net to cover high cost rare diseases excluded from the universal insurance system; complementary to the compulsory health insurance coverage; several criteria have to be met in order to be eligible for reimbursement
- *College of Medical Doctors for Orphan Drugs (CMDOD)*: individual reimbursement advices are taken on a case by case basis