PORTUGAL

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS

CHANGES IN PRICING

- **Annual price review**: non-generics and all hospital medicines except generics (01/2016)
- **External reference pricing**: Spain, France and Slovakia (changed from Slovenia) are the reference countries in 2016 (11/2015)
- **Pricing System for non-reimbursed and non-reimbursable prescription medicines** (Planned)

CHANGES IN REIMBURSEMENT

- **No changes**

OTHER CHANGES

- Implementation of ***SiNATS - National System for Health Technology Assessment*** **(07/2015),** which will include a new **Committee for Health Technology Assessment (HTA) (04/2016)**
- Regulation on the **price definition of medical devices** (Planned)
- **A Commitment to Sustainability and Development of the National Health Service**, for the 3-year period 2016-2018, was signed (02/2016) between Ministry of Health and different stakeholders, with the aim to ensure predictability of the expenditure as well as to give some stability to third parties.

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

Price setting – Follow the rules and criteria set for non-generics (international reference pricing), based on the average ex-factory price observed in the 3 reference countries in the outpatient sector.

Reimbursement – outpatient sector –Takes the reimbursement scheme applicable to the biological medicine of reference, by establishing a management entry agreement (MEA), with the adaptations regarding the market share and prices of both medicines. The retail price of biosimilar **cannot exceed 80%** of the retail price of the biological medicine of reference (price linkage).

Reimbursement – inpatient sector – For establishing MEA with biosimilars, the assessment previously made for the biological medicine of reference can be used for decision-making, as long as the maximum value of acquisition **is not higher than 80%** of the ex-factory price set for the biological medicine of reference (price linkage).

In Portugal, it's in place a **reference price system, but it doesn't apply to biosimilars**. Homogenous groups are established whenever there's a generic on the market.

Centralised Public procurement **tender also for INN with biosimilars**.

Biosimilar substitution is not allowed in community pharmacies (outpatient sector). By the time being, there are no legal regulations in relation to this automatic substitution.

The decision to treat with a biosimilar or innovator biological medicine should be made by a qualified health care professional.

According to the **guidelines published by the *National Pharmacy and Therapeutic Committee*** (04/2016):

- In selecting between alternative therapies involving biological medicines, it is recommended to opt, whenever possible, for active substances which have biosimilars;
- For naïve patients, it is recommended that, in cases where there are biosimilars, it should be provided the biological medicine most accessible, in all indications for which it is approved;
- In terms of pharmacovigilance it is very important to keep trace of biological medicine involved in a potential adverse reaction. Switching between biological biosimilar medicines must comply with a minimum of time that safeguards traceability for pharmacovigilance purpose. This period can be set in the Medicines National Formulary for different medicines, and when omitted, it should not be less than 6 months;
- Switching between different brands of the same biological medicine should be coordinated with the clinical services involved, respecting the precautionary principle and in accordance with the therapeutic indications for each situation.