PORTUGAL

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

- **Annual price review:**
  - for non-generics in in-patient and out-patient sector (02/2019) , maximum price reduction of 5 % for non-generics in outpatient sector (01/2019)
  - for generic medicines only with price above the reference medicine (both sectors) (03/2019);
- **External reference pricing: Change in the number of** Reference countries for 2019 (from 3 to 4), which are Spain, France, Italy and Slovenia (01/2019)

CHANGES IN REIMBURSEMENT

- **National registry for Spinal Muscular Atrophy** aims to manage the access to medicines for the treatment of this disease, following the managed entry agreement signed for Spinraza (03/2019)
- Request by MAH for the **definition of PICO**, for financing purposes, after positive opinion of the CHMP and before reimbursement application is submitted (04/2019)

OTHERS CHANGES

- **Agreement with Pharmaceutical Industry**: agreement for 2019, setting the goals and principles for NHS for increasing access to innovation and the use of generics, while maintaining the sustainability of NHS (04/2019);
- **Patients Involvement in HTA procedures**: have already the opportunity to contribute - "INCLUIR" Project (from 2017, HTA inputs from 2019)
- Set the **pricing system** for medicinal products, preparations and substances based on the **cannabis plant** for medicinal purposes (01/2019)

SPECIAL TOPIC: patient-based reimbursement decisions

I) Exceptional Use Authorization (AUE) - Medicines <u>without a Marketing Authorization</u> (MA) in Portugal

- Medicines with a preliminary evidence of clinical benefit

- Although the medicinal product does not have MA in any country, there is preliminary experimental evidence of clinical benefit.
- AUE may be part of an Early-Access Program.

II) Exceptional Use Authorization (AUE) - <u>post-Marketing Authorization</u>

- Allows exceptional acquisition by NHS hospitals of non-reimbursed medicines.
- Applicable when the medicinal product already has a marketing authorisation, but the pharmacoeconomic assessment for its clinical indication is not yet completed.
- The acquisition is only justified in **exceptional circumstances** arising from the <u>absence of alternative therapy, where the patient is in an immediate life-threatening situation or at risk of developing serious complications</u>.
- AUE is part of an Early-Access Program (post 08/09/2017)

Early-Access Program (PAP)

Regulation setting the terms and participation conditions to be included in an early access to medicines (through exceptional use authorizations).

- For the AUE- post-marketing authorization (II) there is <u>no cost to the NHS</u> within the timelines defined in law (at least 210 days counted from the submission file for reimbursement). If these timelines are exceed, the provision of these medicines may no longer free of charge to the NHS hospital entities.
- At the request from a company, INFARMED may allow an early access program setting out the conditions for access, e.g. by defining the n.º of patients, the exclusion/inclusion criteria within the therapeutic indication requested and the price of the medicines under the PAP.

Procedure (applicable to I and II)

- Applications must be requested from NHS hospitals, after careful evaluation by the Pharmacy and Therapeutic Committee (CFT) on a patient-based decision;
- The request is presented for a specific patient (identified through acronyms) by describing the clinical history and the rationale for the treatment of the patient in question. The submission of requests for specific patient should be done in the module "Authorization for specific patient" of the SIATS Portal;
- INFARMED evaluates the request in a case-by-case basis and grants these special authorizations (5 days for decision or requests additional information);
- Decisions are made one time only for the same patient, in the specific clinical condition