

## PORTUGAL

### Recent and planned developments in pharmaceutical policies 2018

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

##### CHANGES IN PRICING

- **Annual price review:** for non-generics in in-patient and out-patient sector and for generic medicines with price above the reference medicine (01/2018 and planned for 01/2019)**External reference pricing:** In 2018, reference countries remained the same as in 2017: Spain, France and Italy, with a maximum price reduction of 10% for outpatient sector (01/2018). Reference countries for 2019 might include Spain, France, Italy and Slovenia: maximum price reduction of 10% for outpatient sector for medicines with prices <= 10,00€ (still under appreciation)
- **Discounts:** In evaluation the possibility of a price discount in the new oral anticoagulants, in addition to the NHS maximum expenditure already established by managed entry agreement
- **Price changes:** Introduction of a price reduction on fixed associations (planned)

##### CHANGES IN REIMBURSEMENT

- **Changes/modifications of reimbursement lists:** Exceptional reimbursement scheme for some medicines and food supplements for children with respiratory, neurological and/or gastrointestinal sequelae due do extreme preterm birth (03/2018)
- **Changes/modifications in the reference price system:** Reference price corresponds to the average of the 5 lowest prices within the homogeneous group (same as before), but cannot exceed the price of the highest generic (implemented in October 2017 and still in place).

##### OTHERS CHANGES

- **Hospital's outpatient e-prescription:** Establishes the legal regime for electronic prescription of medicines to outpatients within the ambulatory hospital setting of the NHS (03/2018)



- **Educational campaigns**

In order to promote health literacy, INFARMED, I.P. developed an institutional campaign aimed at promoting citizens' confidence in the products regulated by this national authority (Medicines, Medical Devices and Cosmetics). The campaign **#PodeConfiar** (you can trust) was addressed to all citizens, with a special emphasis on young people. A microsite (<http://podeconfiar.infarmed.pt>), launched simultaneously, functioned as a repository of audiovisual resources of the campaign. (08/2018)

A partnership campaign between Infarmed and the Directorate-General of Health about antibiotics is being launched on November 2018 with the (#NovembroMesdoAntibiotico and #KeepAntibioticsWorking).

- **Horizon scanning:** INFARMED is initiating a national project to map the expected new medicines to come under evaluation for reimbursement within the next two years. In this initial phase, the aim is to better allocate resources and accelerate the market entry of new health technologies (04/2018).
- **Dispensing:** A pilot to make anti-HIV medication in community pharmacies is ongoing. The availability of anti-HIV medication in community pharmacies nation-wide is under evaluation. Nowadays, these medicines can only be dispensing in hospitals' outpatient pharmacies.
- **Biosimilars:** As in previous years, hospitals contractualization includes medicines indicators, including one for biosimilars. In 2018, the infliximab, etanercept and rituximab had sœbiosimilars cial incentives.

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

##### Integrated National Strategy for Rare Diseases (2015-2020)

An interministerial, intersectoral and interinstitutional cooperation aiming to establish strategies for supporting diagnosis, therapy, rehabilitation and social inclusion, including the access to special education for rare disease patients, duly adapted to the exceptional nature of these diseases.

##### Availability

Unauthorised medicines may be available via compassionate use programme for individual patientes, that are reimbursed in full.

If an authorised (orphan) medicine is not commercialised in Portugal but is marketed in another Member State the treating hospital can request special authorisation explaining the reasons for the request to INFARMED via specific forms. If the use is approved, the hospital acquires the medicine directly from the manufacturers and no co-payment is required of the patient.

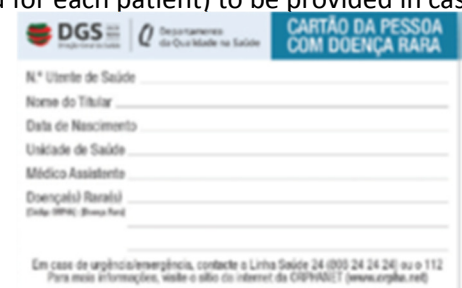
In 2017, Portugal had available 62 orphan medicines in the universe of 80 with MA.

##### Rare Diseases Card

Since 2014, a personal card is being distributed to patients with rare diseases. It includes relevant information such as, the name and the "orphan code" of the disease; the name and contact of the Reference Centre and it has on its back-side specific health recommendations (totally addressed for each patient) to be provided in case of emergency. The main objectives of this card are:

- To ensure access to relevant information, to doctors and nurses on clinical data and recommendations regarding emergencies and urgencies acts
- To improve the integrated management of the disease to avoid delay, error and harmful procedures
- To guarantee the correct referral to Reference Centers
- To improve continuity of care, between all the levels of care

The information on the card is also being used as the base of simple epidemiological registry.



##### Funding and Pricing

There are no special arrangements for setting pricing and reimbursement for OMP.

The funding of OMP treatment in the Portuguese NHS system depends on the utilization setting, it can be community outpatient (subject to copayment) or hospitals' outpatient or inpatient (fully financed by the NHS hospital's budget). Funding of reference hospitals for certain diseases has a mojoration when compared to non-specialised hospitals, whose funding is based on diagnosis-related group price. Lysosomal Methabolic diseased have a special funding mechanism with a payment per treated patient.

While the reimbursement assessment of orphan drugs is ongoing, they can be used at NHS hospitals through special authorization procedure (named patient basis). In this case, and during the legal timeframe for this assessment, medicines are given to patients under Early Access Program (provided free of charge to the hospital). The reimbursement of OMP may also be linked to conditions such as the obligation to enrol in a registry: this is for instance the case of lysosomal disorders. The treatment of these patients needs to be approved and monitored by the National Coordination Centre of these diseases.