

GREECE

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING

- Two price bulletins with general price revisions
- Four price lists with new pharmaceutical products per year
- Pricing policy:
 - Coutry basket : 27 European countries
 - Reference products with no generics in the market: average of the three lowest prices in EE
 - Reference products with generics in the market: 50% of their price at the time their first generic entered the market, without falling lower than the lowest price in EE
 - Generics: 65% of the reference product
- The MoH is considering changes as far as pricing policy is concerned. The new legislation is expected to be completed till the end of the year

CHANGES IN REIMBURSEMENT

- New legislation in place for the introduction of Health Technology Assessment for pharmaceuticals and reformation of the Negotiation Committee for Pharmaceuticals (Law 4512/2018-Official Gazette 5A/17.01.2018):
 - Establishment for HTA Committee for Pharmaceuticals (articles 247-253) to be used as a transitory step up to the establishment of the HTA Organization
 - Negotiation Committee (articles 254-256) mainly refers to the establishment of the Negotiation Committee in the Ministry of Health giving the authority to negotiate agreements for both the reimbursement fund (EOPYY) and public hospitals.
 - All new active substances have to be evaluated by the HTA Committee and be referred to the Negotiation Committee for the estimation of the budget impact.
 - However it exist in parallel that a new active substances will only be included in the List of Reimbursable Medicinal Products if they are reimbursed in two thirds (2/3) of the EU Member States in which they are marketed, provided that the Members States in which they are marketed are at least nine (9), and at least half of the Member States in which the medicine is reimbursed are included in the following list of Members States applying Health Technology Assessment mechanisms in respect of medicinal products for human use: Austria, Belgium, Great Britain, France, Spain, Netherlands, Portugal, Sweden and Finland.
- On 19.2.2018 (Official Gazette 416/ B') a new positive list has been issued including new active substances (17 new high cost drugs) and revision of prices. Since then, other three positive reimbursement lists were published (current list: 17 August of 2018).

OTHERS CHANGES

- New electronic system for supporting prior authorization procedure for pharmaceuticals (01/08/2018)
- A rebate rate of 0.8% was established to EOPYY on the retail price of prescription drugs after the expiry of the protection period for the year 2018 (law 4549/2018)
- New therapeutic protocols for: dyslipidemia, hypertension, osteoporosis, acute infections (acute bronchitis, community pneumonia) have been uploaded in the e-prescription system. Therapeutic protocols for PCSK-9 inhibitors and coronary heart disease will be uploaded in the e-prescription system.
- New web application for Marketing Authorization Holders/local distributors providing access to reimbursement data.

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

Availability

All orphan drugs are available to patients (out-patients and in-patients).

Pricing

An orphan drug is included in the price bulletin if it is marketed in 2 EU countries.

Note: Marketing Authorisation Holders of orphan drugs are excluded from rebate payments.