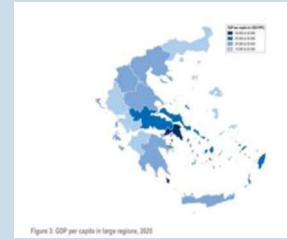


# GREECE

E.O.P.Y.Y.  
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POPULATION: 10,314,404 (worldometer), HEALTH INSURANCE SYSTEM HEALTH EXPENDITURE: 10,88 BILLIONS  
EOPY PHARMACEUTICAL EXPENDITURE : 4,6 BILLIONS

## PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES

### PRICING OF MEDICINES

National Organization for Medicines (EOF) Pricing Department regulates the the pricing of medicines (POM, P, OTC).

#### PRICING RULES

| Drug                         | Market Pricing/Policy   |
|------------------------------|---|
| On patent                    | Pricing based on Average of the 2 different lowest prices in the Eurozone                         |
| Off patent                   |   |
| Hybrids                      |   |
| Bio -similar                 |   |
| Well established medical use |   |
| Fixed combinations           |   |
| Generics                     | 65% of the Off patent price   |
| Domestically produced        | Based on a cost list and not a higher price than individual products of the same active substance |

Repricing 1 time per year \* (new active substances every 90 days and generics every 30 days)

The Daily Treatment Cost (DTC) which is protected against repricing is €0.20 in Retail Price (about €6/month)

Vaccines, blood products and non-reimbursable drugs are priced once

Drop prices up to 7% each year are allowed

Orphans are priced at 2 lower eurozone prices

The price of drug combinations is lower than the individual components

#### REBATES

Pharmaceutical Companies are required to offer mandatory rebates every three months based on their total sales to the National Organisation for the Provision of Health Services (EOPY) -a 9 percent discount on factory price + an additional 2-21 percent depending on the type of product and the volume of spending- and to cover the amount in excess of the budget for the EOPY and hospitals. Pharmaceutical

#### CLAWBACK

At the end of each semester, the clawback is calculated as the difference between the budget limit and the final expenditure, i.e., the gross spending minus • patient copayments, • mandatory rebate ranging from 14% as an entry level up to 30% according to sales volume, • voluntary discounts provided by the companies

The RRF program for health introduced a co-responsibility clause, whereby if the clawback exceeds a certain level, then a contribution by the state would be enacted

The Medicines Department of National Health Service Provision Organization (E.O.P.Y.Y.) operates a horizon scanning system for drugs  
Aim: developing a framework for the identification of drugs that will have the highest impact on the health system

### COVERAGE/REIMBURSEMENT

EOPY  
IS THE MAIN  
HEALTHCARE PAYER  
IN GREECE

Purchasing health services funded by public resources based on the National Social Security Fund (EFKA) contributions and state budget

#### OUT-PATIENTS

PHARMACEUTICAL EXPENDITURE = REIMBURSEMENT PRICE-CITIZENS CO-PAYMENT

The reference price of each therapeutic category is defined as the lowest unit cost of daily treatment between the weighted average unit cost of daily treatment of all reference drugs (with or without protection status) and the weighted average unit cost of daily treatment of all generic drugs of the respective category and are published in the respective catalogue.

#### CO-PAYMENT

##### STATUTORY PARTICIPATION RATE



In the event that the patient chooses a pharmaceutical preparation with a retail price that coincides with the insurance price, the patient pays the statutory participation rate.

In cases where a drug is chosen with a retail price higher than the reimbursement price, the patient covers, in addition to the statutory contribution, the entire difference between the reimbursement price and the retail price of the drug. The amount that the patient covers in addition to the statutory participation cannot exceed the amount of 20 euros per unit preparation for on-patent medicines or the 3 euros for generics.

In cases where the retail price of the drug is lower than the reimbursement price, the reimbursement price lowers to retail price.

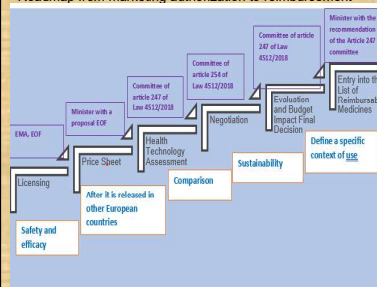
From 2014, for the special cases where a drug is chosen which does not have a generic or a therapeutic category as a whole contains one or more active substances without generic drugs, where a drug with a retail price higher than the reimbursement price is chosen, the patient covers in addition to the prescribed statutory contribution half of the difference between the reimbursement price and the retail price of the medicine. The rest is charged to the pharmaceutical company or marketing authorization holder in the form of a rebate

##### Assisted reproduction-General framework

- Costs of assisted reproduction are reimbursed to patients aged up to 54 years and up to 4 completed attempts
- CRYOPRESERVATION is allowed only to cancer patients and for social reasons

The HIGH COST MEDICINES for chronic serious or rare diseases, which are distributed by EOPY-Pharmacies are free for patients. EOPY started a home-delivery free cost programme of high cost medicines through EOPY-Pharmacies.

#### Roadmap from marketing authorization to reimbursement



#### SPC FILTERS

They are based on data from the marketing authorization, are integrated into the electronic prescription system and do not allow the issuance of a relevant prescription.

-Apply:

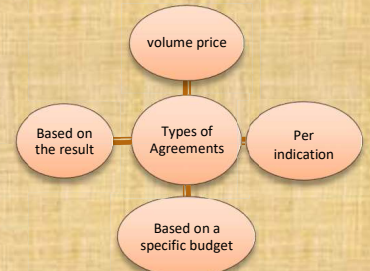
- A) at indication level (ICD-10)
- B) at age level
- C) at the level of quantity

#### HTA COMMITTEE

Introduced in 2018, the HTA framework in Greece is a big step forward towards evidence-based resource allocation decisions, as well as patient access to innovative therapies at affordable prices and in a timely manner. Since its establishment, a significant improvement in the performance of the HTA process has been observed by decreasing the backlog of medicinal products as well as the time of HTA clinical assessment.

HTA focuses specifically on the added value of a health technology compared to other new or existing health technologies.

#### NEGOTIATION COMMITTEE



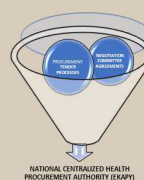
### ELECTRONIC PRE-APPROVAL SYSTEM

- Controlled Entry of New Medicines - Real Data ( RWD)
- Unified request management platform
- Simplification of approval process
- Development of indicators for decision making

- It is created in E.O.P.Y.Y. single Electronic Pre-Approval System (EPS), through which electronic management and examination of requests regarding the necessity of compensation medicines for which the E.O.P.Y.Y. takes a decision.
- Drug Categories
  - High Cost Medicinal Products
  - Off-label
  - Products that have received a price
  - Compassionate use program



### IN PATIENTS



Hospital inpatient care is reimbursed on the basis of KENs (equivalent to international Diagnostic-related Groups - DRGs). For hospital inpatient treatments that are not included in the KEN-list, EOPY reimburses with a daily hospitalization fee which is defined by Ministerial Act. Additionally, the Unified Health Benefits Regulations (EKPY) defines a list of pharmaceuticals, medical products and materials as well as medical acts that are reimbursed extra further to the KEN (or daily hospitalization fee) tariffs.