PORTUGAL



IIGILANCE

REIMBURSEMENT



OTC not

reimbursed

Pharmaceutical

companies

Task: define OTC pricing

Criteria: Decree-Law n.º

134/2005, 16th August

Wholesaler

margins are

VAT (6%)

and Pharmacy

not regulated

Task: decision on market authorisation

Criteria: Quality, safety, efficacy (Directive 2004/27/EC)

National Medicines Agency (INFARMED)

Task: decision on prescription and dispensing conditions

Criteria - Decree-Law No. 176/2006, 30th August; Directive n.º 2004/27/CE,

European Medicines Agency (EMA) or National Medicines Agency (INFARMED)

INFARMED is also in charge of pharmacovigilance

Applied only to Public hospitals

POM (except restrict) + OTC

Pharmaceutical companies

Task: Establish the price of medicines for use in hospitals Criteria: No regulatov

Task: Public Procurement Criteria: European Directives 2004/17/CE and 2004/18/CE Price is an important decision factor

ACSS

Task: Evaluate the added value of new HOM and restrict POM Setting a maximum annual budget for NHS Hospitals Criteria: Decreee-Law 195/2006, 3rd October

Statutory Pricing

HOM and restrict POM

INFARMED

Tendering

Free Pricing

framework

Hospital purchasing body (individual hospital or group of hospitals)

Task: Price negotiations or tendering of medicines

Criteria: Depending on the product;

Price must be lower or equal to the one established by Infarmed or ACSS (public procurement).

Negotiations

No legal framework regarding pricing

In general: Hospital price = ex-factory price + VAT (6%) (Margins are not relevant, unless products are bought from wholesaler or community pharmacy)

Ministry of Health through ACSS and Regional Health Administrations

Task: Financing hospital level of activity, including use of medicines, through Diagnosis-related Groups (DRG).

HIV treatment

Special financing of medicines to HIV treatment.

Criteria: Medicines and medical procedures to HIV patients are subsidized according to the predicted the number of new HIV patients

Medicines for specific conditions and dispensed in hospitals to out-Criteria: medicines reimbursed at 100% for hospital only dispensing

Chronic Kidney disease (comprehensive price) Lysossomal diseases;

National Hospital Formulary

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee

Task: Decision on use of medicines in the hospital

Criteria: Order n.º 1083/2004

Pharmaceutical formulary (Addendum) per hospital

POM (except HOM and restrict POM) + **OTC** reimbursed

Directorate-General of Economic Activities (DGAE)

Task: Retail price of medicines; annual review of prices; exceptional revision of prices and reduction of prices (in exceptional cases)

Criteria: Decree-Law n.º 65/2007, 14th March; External Price Referencing (medium prices SP, FR, IT, GR)

Statutory Pricing

Free Pricing

GENERICS

- •Internal Reference Pricing •<=35% medicine reference
- •If price <10€, the difference applied is 20%

PARALLEL TRADE

<5% PRP of the 'considered medicines and essential similar medicines

Public Retail Price (PRP) = ex-factory price + Wholesaler margins (8%)+ Pharmacy margins (20%) + Special Tax earmarketed for INFARMED+

VAT (6%) PRP = EX-FAC. X1,48

Ministry of Health or INFARMED (in case of generics)

Task: reimbursement of medicines; Withdrawal; reassessement; exclusion and

Criteria: Annex I of Decree-Law n.º 48-A/2010, 13th May

General Scheme

4 levels reimbursement A(95%); B (69%); C (37%); D (15%)

> **Product Specific** Based on therapeutic classification

Specific Scheme

Population Group Specific extra

reimbursement (15%)for pensioners

Disease Specific Defined pathologies e.g. HIV, Alzheimer disease; 100% reimbursed.

Generics From the 5th generic reimbursed, price <5% of the PRP whose generic application is valid, regardless its decision

Internal Pricing Referencing

Reference price - highest PRP of all marketed generics in each Homogeneous Group: <5% of the lowest generic price, with at least 5% of

Compounds Medicines

at 50% of its price

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