Submission from

the MAH/ representative

Medicines (In&Out

patient)

Medical Devices,

Other technologies

PORTUGAL

PPRI

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INFARMED - National Authority of Medicines and Health Products, I.P.

Population *: 10,4M GDP per capita*: 20.217 € NHS (tax funded system):

Health expenditure *: 10,6% GDP NHS pharma expenditure #:

NHS Ambulatory care: 1 593,8 M€

NHS Hospital care: 1 959,2 M€

www.ine.pt / www.pordata.pt (2022)

www.infarmed.pt (2023)

Pharmaceutical pricing and reimbursement policies

Infarmed

Assessment

(at HTA dep + HTA Committee for new INN & new therapeutic indications)

a) Relative Effectiveness (Added Therapeutic Value)

b) Cost-Effectiveness (Economic Value)

c) Other dimensions (including affordability)

Contract negotiation

- Price
- b) Financing/reimbursement
- c) Control and cost limitation
- Risk sharing / Additional monitoring of use

Decision

Ministry of Health (MoH)

Reports and recommendations for use

Reassessment

OUT - PATIENT

IN-PATIENT: Applied only to Public hospitals

OTC non

reimbursed

Pharmaceutical

companies

Establish OTC price

Free Pricing

POM (prescription only medicines)

National medicines agency (Infarmed)

Retail price of medicines & Annual price revision

using External Price Referencing (average prices ES, FR, IT, SI); exceptional revision of prices (to rise the prices)

Statutory Pricing

GENERICS

≤ 50% originator's price (or 25% if originator ≤10€)

PARALLEL **IMPORT**

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

reimbursable POM ility of price increase up to 10% per year (max.

Public Retail Price (PRP) = ex-factory price + Regressive Wholesaler & Pharmacy margins (fixed and %) by price ranges + Infarmed Special Tax + VAT (6%)

NOTIFIED PRICES

Non reimbursed/ 2.5€)

> Wholesale and pharmacy margins are not regulated VAT (6%)

POM + OTC to be purchased by public hospitals

National medicines agency (Infarmed)

Maximum price for hospital purchase & Annual price revision using External Price

Centralised public procurement for some medicines and public Referencing (lowest price ES, FR, IT, SI) procurement for other medicines

Shared Services of Ministry

of Health (SPMS)

Statutory Pricing

Tendering

Hospital purchasing body

(public individual hospital or group of hospitals)

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

GENERICS

≤70% originator

BIOSIMII ARS

≤ 80% originator's price ≤70% if biosimilar is ≥5% market share Private hospitals Free pricing

Ministry of Health or INFARMED (currently power delegation on generics, biosimilars and reimbursement delist)

General Scheme

4 levels reimbursement : A (90%); B (69%); C (37%); D (15%)

Product Specific

Based on therapeutic classification

Generics

ABURSEMENT/ FINANCING

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

Biosimilars

≤ 80% originator's price ≤70% if biosimilar has 5% market share

Reference price – average of 5 lowest PRP at the market (including non-generics) in each Homogeneous Group (HG); not higher than the most expensive generic in each HG

Internal Reference Pricing

Reimbursement

<5% of the lowest generic price, with at least 5% of market share, in each HG

Specific Scheme

Population

Group Specific extra reimbursement (5% (A) or 15%) for pensioners

Disease Specific Upgrade level of

reimbursement (up to 100%) for defined pathologies e.g. HIV, Alzheimer disease

Financing at 100% for hospital only medicines (in public hospitals)

Negative HTA restriction of

use in public hospitals

Positive HTA USE IN HOSPITALS

> National Formulary

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic Committee

Adoption of medicines in the hospital

Economic advantage from HTA

If equivalent to comparator: Price ≤90%

Ministry of Health through ACSS (Central Administration of the Health System)

Reimbursement of medicines to Community Pharmacies based on reimbursed dispensed medicines

Specific Scheme

Some medicines to Specific diseases, although are used at out patient level are dispensed at hospital pharmacies without charges for patients

Financing hospital level of activity, including use of medicines, through Diagnosis-related Groups (DRG). Hospitals are funded prospectively through contracting of services (contracting programs) between ACSS and hospitals, which includes:

ACSS ADMINISTRAÇÃO CENTRAL DO SISTEMA DE SAÚDE, IP

Medicines for specific conditions and dispensed in hospitals to out-patient with no co-payment

Criteria: medicines reimbursed at 100% for hospital only dispensing

Comprehensive price (e.g. chronic kidney disease, lysosomal disease, HIV)



Legislation: Decree-Law n.º 97/2015, 14 June; Ordinance n.º 195-C/2015, 30h June; Ordinance n.º 195-A/2015, 30h June; Ordinance n.º 195-D/2015, 30h June; Ordinance n.º 195-D/ European Directives 2004/17/CE and 2004/18/CE; Ministerial Dispatch n.º 1083/2004