

THE PORTUGUESE PHARMACEUTICAL SYSTEM: STRUCTURE AND CHALLENGES

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AGENDA

1. Healthcare System
 2. Pharmaceutical System
 3. Pricing
 4. Reimbursement
 5. Challenges and opportunities
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HEALTHCARE SYSTEM

THE HEALTHCARE SYSTEM

PORTUGAL: KEY FACTS



- 10.6 million inhabitant residents¹
- In 2024, Portugal's GDP per capita in purchasing power standards stood at 82% of the EU27 average (up from 81% in 2023)²
- The 2009–2012 economic crisis led to a Memorandum of Understanding with international institutions.
- Ageing population, worsened by migration of young workers.³
- Health inequalities persist, linked to gender and geography.³

Sources:

1- INE; 2- preliminary estimate EUROSTAT; 3- Health Systems in Transitions

PORTUGUESE HEALTHCARE SYSTEM

BRIEF OVERVIEW



National Health Service

Universal, general and mostly free of charge.

Funded through general taxation – primary funding source



Health Sub-systems

Complementary systems for specific professional groups.

Funded by employee and employer contributions



Private Insurance

Funded by copayments and direct payments

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PHARMACEUTICAL SYSTEM

ABOUT INFARMED

HEALTH TECHNOLOGIES' LIFE CYCLE

R&D	<ul style="list-style-type: none">• Clinical trials• Regulatory and scientific advice
Marketing Authorization	<ul style="list-style-type: none">• Proof of quality, safety and efficacy• MA renewals and amendments
Manufacturing	<ul style="list-style-type: none">• Inspections and Licensing
Reimbursement	<ul style="list-style-type: none">• Relative effectiveness• Cost-effectiveness• Negotiation
Distribution and prescription	<ul style="list-style-type: none">• Pharmacovigilance• Information to healthcare professionals and patients
Monitoring	<ul style="list-style-type: none">• Measures to control expenditure and utilization• RWE/RWD

PHARMACEUTICAL SECTOR

FIGURES IN 2024

- NHS expenditure with medicines \cong 3 958,6 M€
hospitals \cong 2 274,8M€ (+16,1%) ; pharmacies \cong 1 683,8 M€ (+5,6%)
- Patient co-payment with reimbursed medicines \cong 920,4 M€ (+7,1%)
- Main therapeutic groups (highest NHS expenditure):
 - Outpatient: Antidiabetics \cong 417,4 M€;
 - Inpatient: Oncology \cong 747,6 M€
- 91 applications of new medicines/new indications were approved for public financing in 2024

M€- million euros

Source: <https://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/monitorizacao-mercado/relatorios>

MARKET SHARE IN VOLUME (OUTPATIENT)

Generics

52.2%

As % of the Total Market

70.8%

As % of the Homogeneous Groups

Portugal has implemented many strategies to promote generic adoption
Pharmacists may substitute generics unless explicitly prohibited by prescribers

Biosimilars

66,7%



Follitropin

23,7%



Insulin glargine

53,2%



Enoxaparin

42,8%

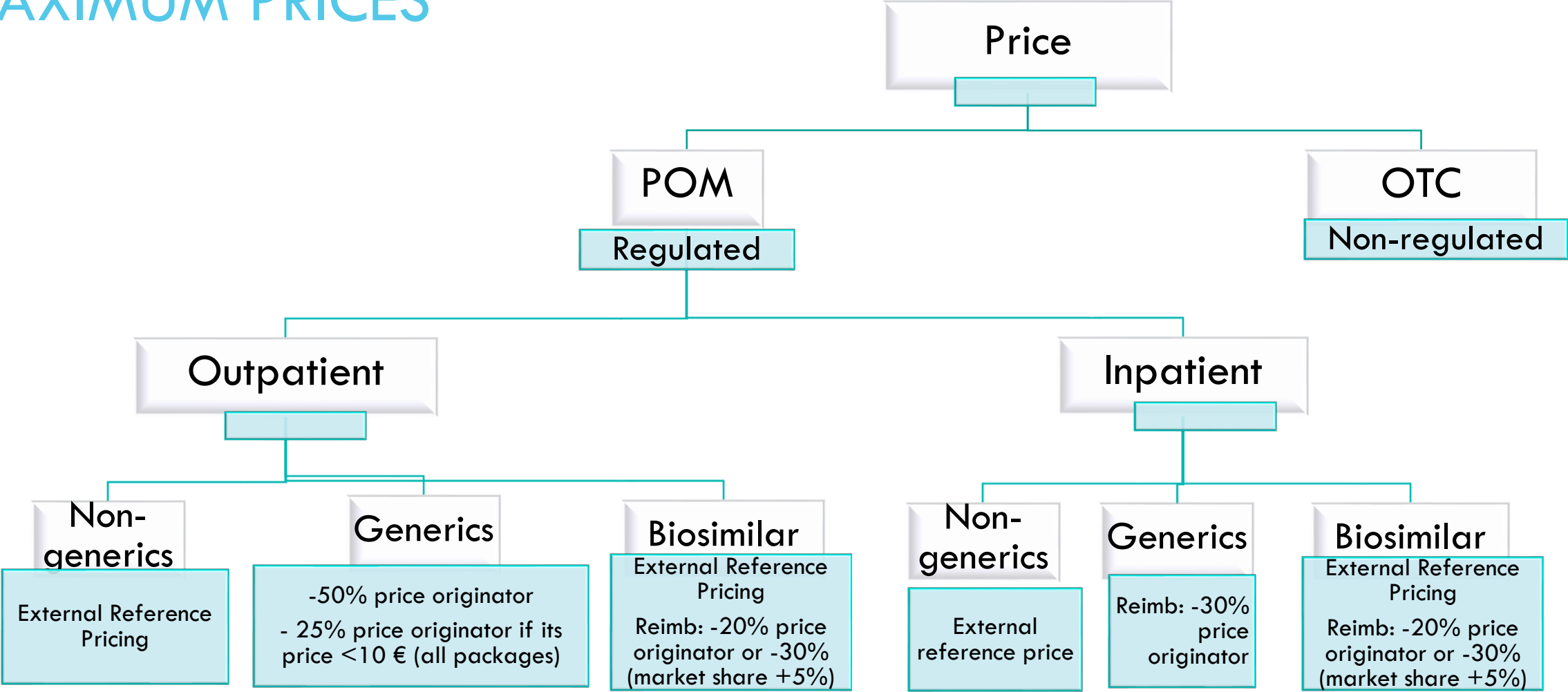


Teriparatide

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PRICING

MAXIMUM PRICES



NON-GENERICs – PRICE STRUCTURE

Outpatient

Maximum Retail Price (PVP) =

ex-factory price (PVA)*

+ Wholesale margin

+ Pharmacy margin

+ Sales Tax (0.4%)

+ VAT rate (6%)

Inpatient

Maximum acquisition price (PVH) =

ex-factory price (PVA) #

+ Sales Tax (0.4%)

+ VAT rate (6%)

Distribution Remuneration-

6 price tiers (fixed + variable components)

* **Average price** of the 4 reference countries

Lowest price of the 4 reference countries



Spain



France

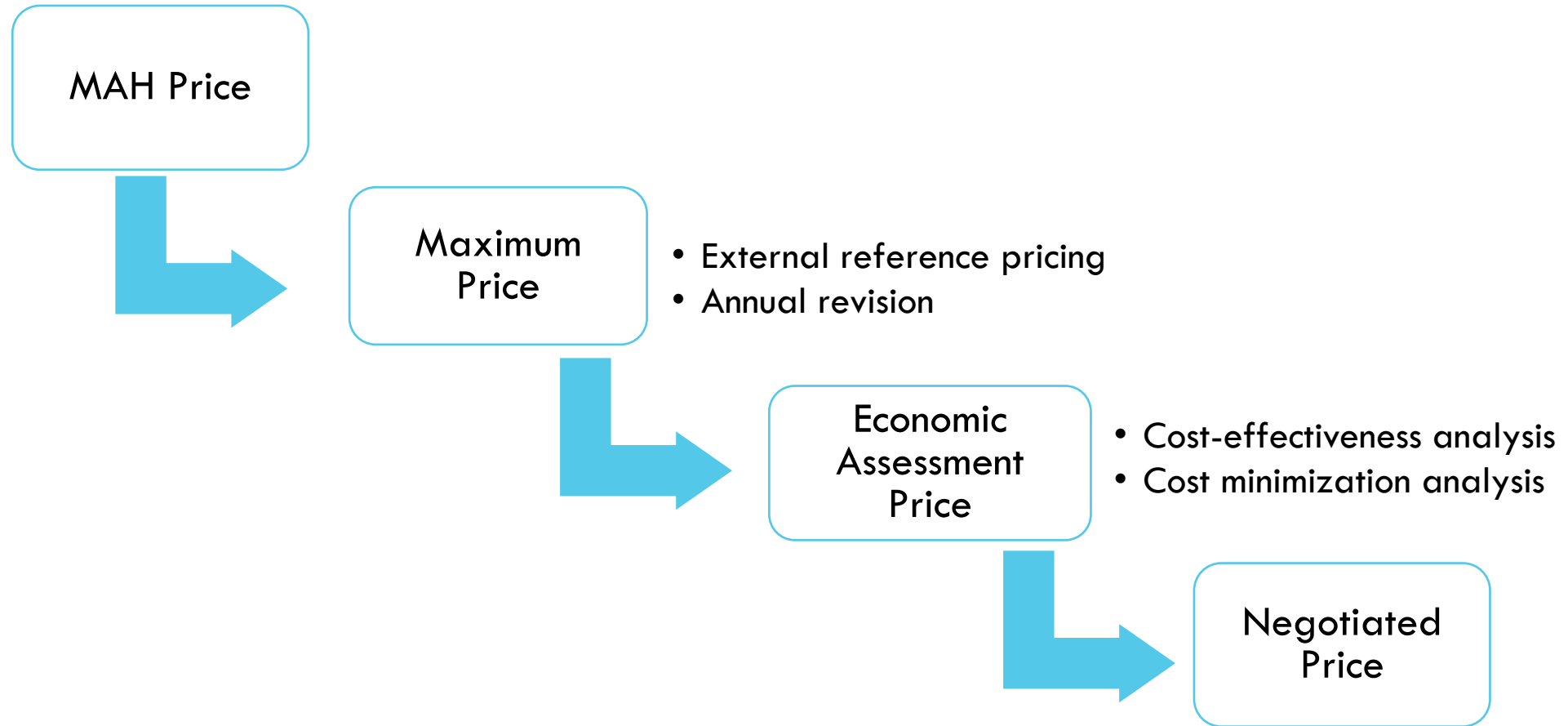


Italy

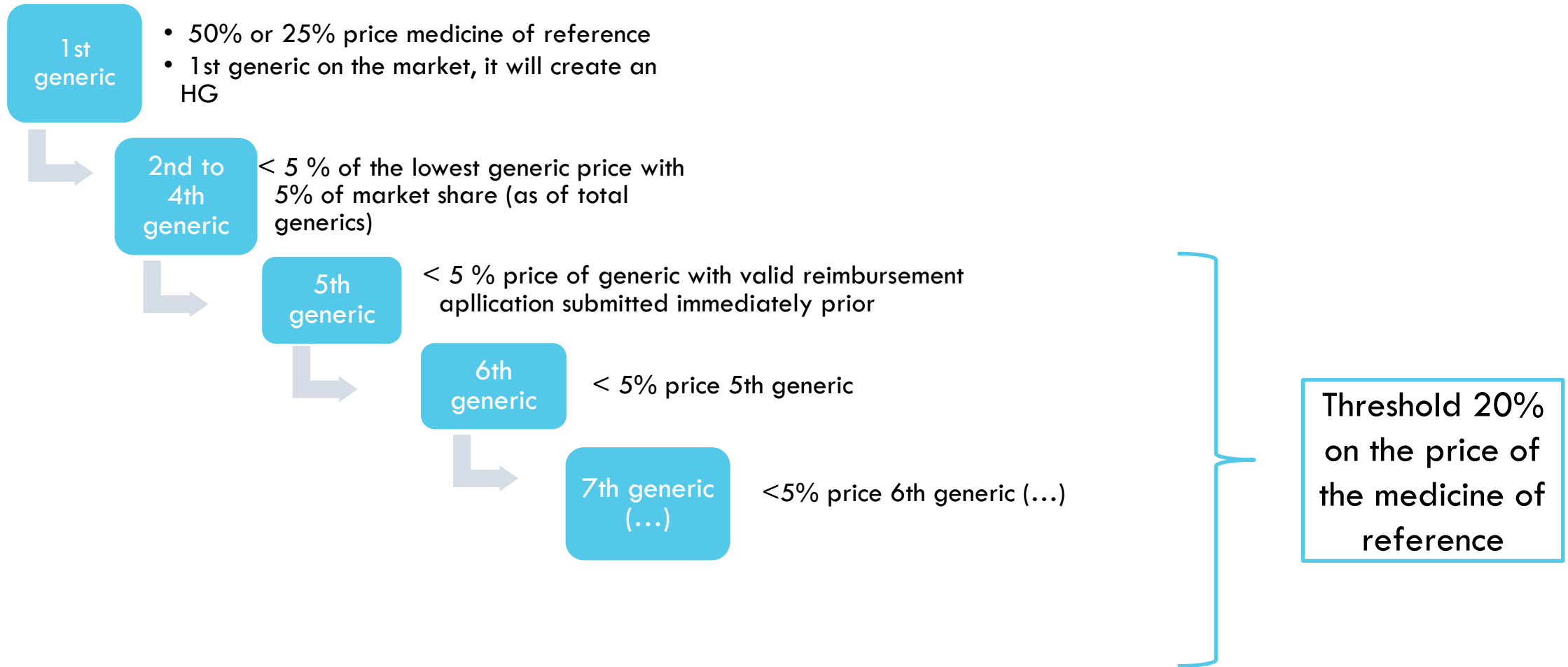


Belgium

PRICE NEGOTIATION



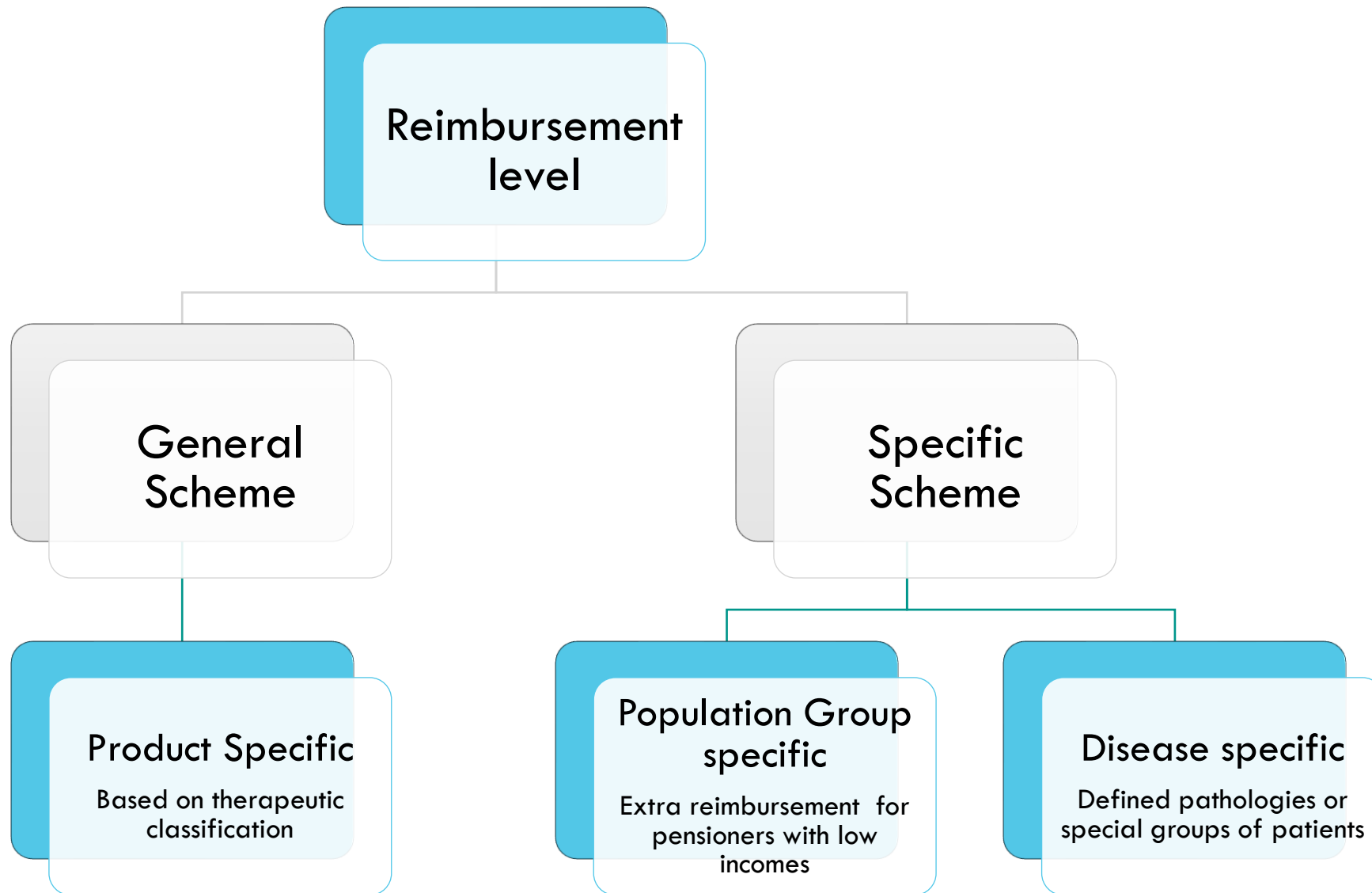
GENERICS – REIMBURSEMENT (OUTPATIENT SETTING)



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REIMBURSEMENT

REIMBURSEMENT LEVEL IN OUTPATIENT SETTING



REIMBURSEMENT LEVEL IN OUTPATIENT SETTING

Population Group specific

Extra reimbursement for pensioners with low incomes

Category A (90%) +5%

- Treatment of chronic diseases (90%) or life-saving pharmaceuticals (100%), such as cancer and diabetes

Category B (69%) +15%

- Treatment of serious illnesses, such as anti-asthmatic, cardiovascular medicines

Category C (37%) +15%

- Not priority medicines, with proven therapeutic value (such as anti-infectives, vaccines, immunoglobins, anti-parasitics)

Category D (15%) +15%

- New medicines whose therapeutic value is not yet proven. It is a transitional category

Product specific

Based on therapeutic classification

REIMBURSEMENT LEVEL IN OUTPATIENT SETTING

SPECIFIC SCHEME

Disease specific

Defined pathologies or special groups of patients

E.g. Alzheimer disease:

- Dispensed by the community pharmacy
- Reimbursement rate (general scheme) – 0%
Reimbursement rate (exceptional scheme)- 37%
- Prescription is restricted to neurologists or psychiatrists, with mandatory reference to the legal framework on the prescription

- May involve:
 - **Higher reimbursement rates** in community pharmacies
 - **100% reimbursement** for outpatient medicines dispensed in NHS hospitals
- Include **specific prescribing conditions**:
 - Indication/patient group
 - Prescriber's medical specialty
 - Reference to legal framework on the prescription
- Reimbursement application by **MAH**
- Subject to **Government approval**

INTERNAL REFERENCE PRICING

OUTPATIENT SETTING



Homogeneous Groups (HG)

Medicines clustered by the same active substance, strength, route of administration and pharm. form
At least one generic on the market



Reference Price

Average of 5 cheapest medicines in group (including non-generics in each HG)
Not higher than the most expensive generic in each HG



Quarterly Review

System updated every three months.
New HG can be introduced monthly



Reimbursement

Is applied to reference price instead of the approved price

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CHALLENGES AND OPPORTUNITIES

KEY STRENGTHS

- Robust Regulatory Framework
- Generics Medicines Policy enhanced patient access to more affordable treatments
- Complementary Pricing and Reimbursement Policies that support accessibility while maintaining financial sustainability
- Balancing Patient Access and Sustainability, where the pharmaceutical system presents both challenges and opportunities for continuous improvement

MAIN CHALLENGES

FOR PATIENTS

Access to medicines is

- High accessible, with medicines completely subsidized by the state in public hospitals
- Some barriers in the outpatient sector, requiring knowledge of the generic availability, reference prices, reimbursement tiers and special reimbursement schemes.
- Delays in the access to innovation, due to the lengthy evaluation

MAIN CHALLENGES AND OPPORTUNITIES FOR DECISION-MAKERS

- The P&R system may limit the introduction of new medicines by keeping **prices relatively low** → Review the P&R models to ensure that prices better reflect market reality and encourage innovation
- Complex and time-consuming processes → Streamline evaluation and reimbursement for innovative medicines using IT and resource optimization
- Lack of transparency in hospital pricing (confidential discounts) → Promote greater visibility and consistency across NHS institutions
- Fragmented reimbursement system, focused on medicines rather than patients (support high co-payments that can reach up to 67%) → Need to improve **equity and patient-centred approaches**

THANK YOU

OBRIGADA

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