

# COUNTRY POSTER PRESENTATION- PORTUGAL

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**SÓNIA CALDEIRA**

INFARMED,IP

PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES  
IN THE IN- AND OUT-PATIENT SECTOR

4TH PPRI CONFERENCE

VIENNA, AUSTRIA

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# HEALTH SYSTEM STRUCTURE

The Portuguese health system currently consists of three coexisting and overlapping systems:

- ✓ The universal National Health Service (NHS)- funded mainly by taxation
- ✓ Special public and private subsystems for some professional sectors
- ✓ Voluntary private health insurance

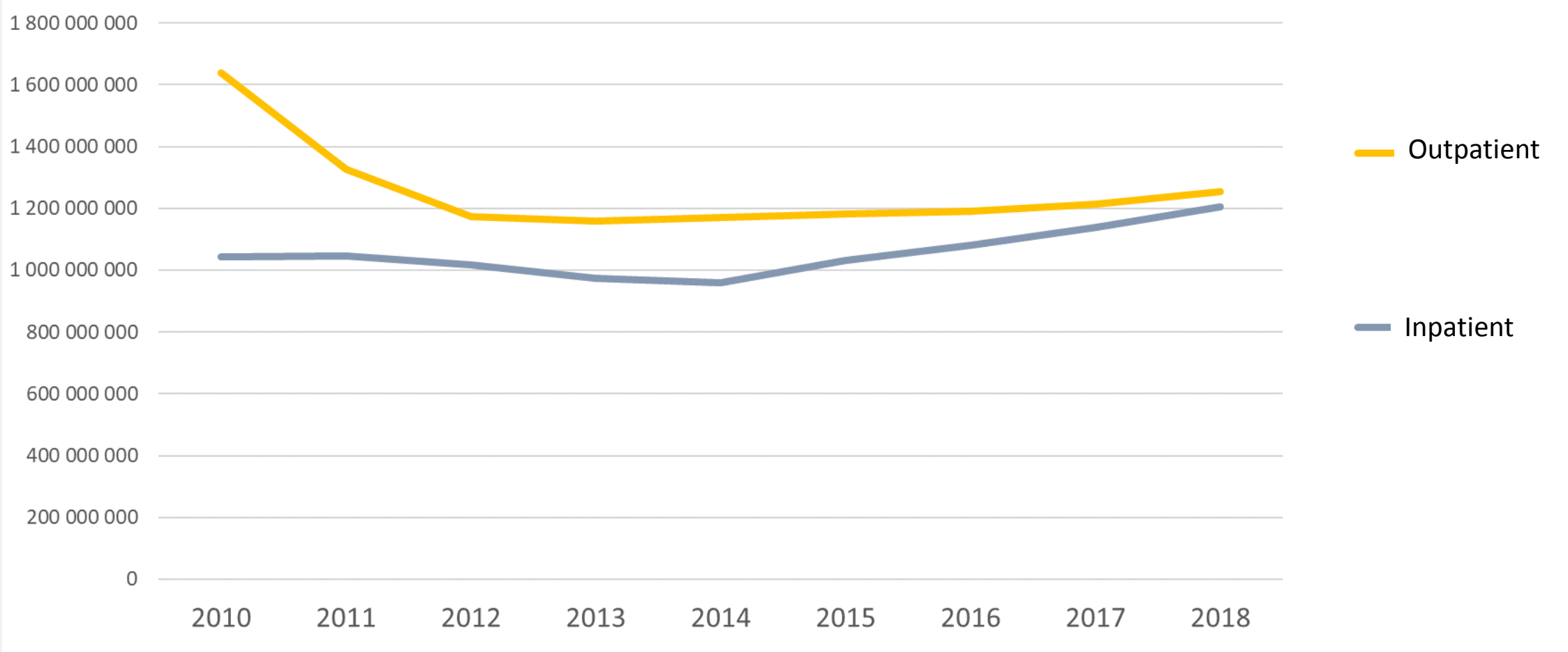
# PORTUGUESE PHARMACEUTICAL SECTOR (2018)

- Inhabitants = 10,3Million 1 NHS accessible to all
- NHS expenditure with medicines  $\cong$  2 462 M€
  - (hospitals  $\cong$ 1 207M€ ; pharmacies  $\cong$  1 255€)
- Patient co-payment with reimbursed medicines  $\cong$ 711 Million euros
- Main therapeutic groups Insulins&antidiabetics $\cong$ 291M€; Oncology  $\cong$ 342M€
- 48% Generic market share (in volume- n.º of units);
- 40 new medicines/new indications approved for public financing

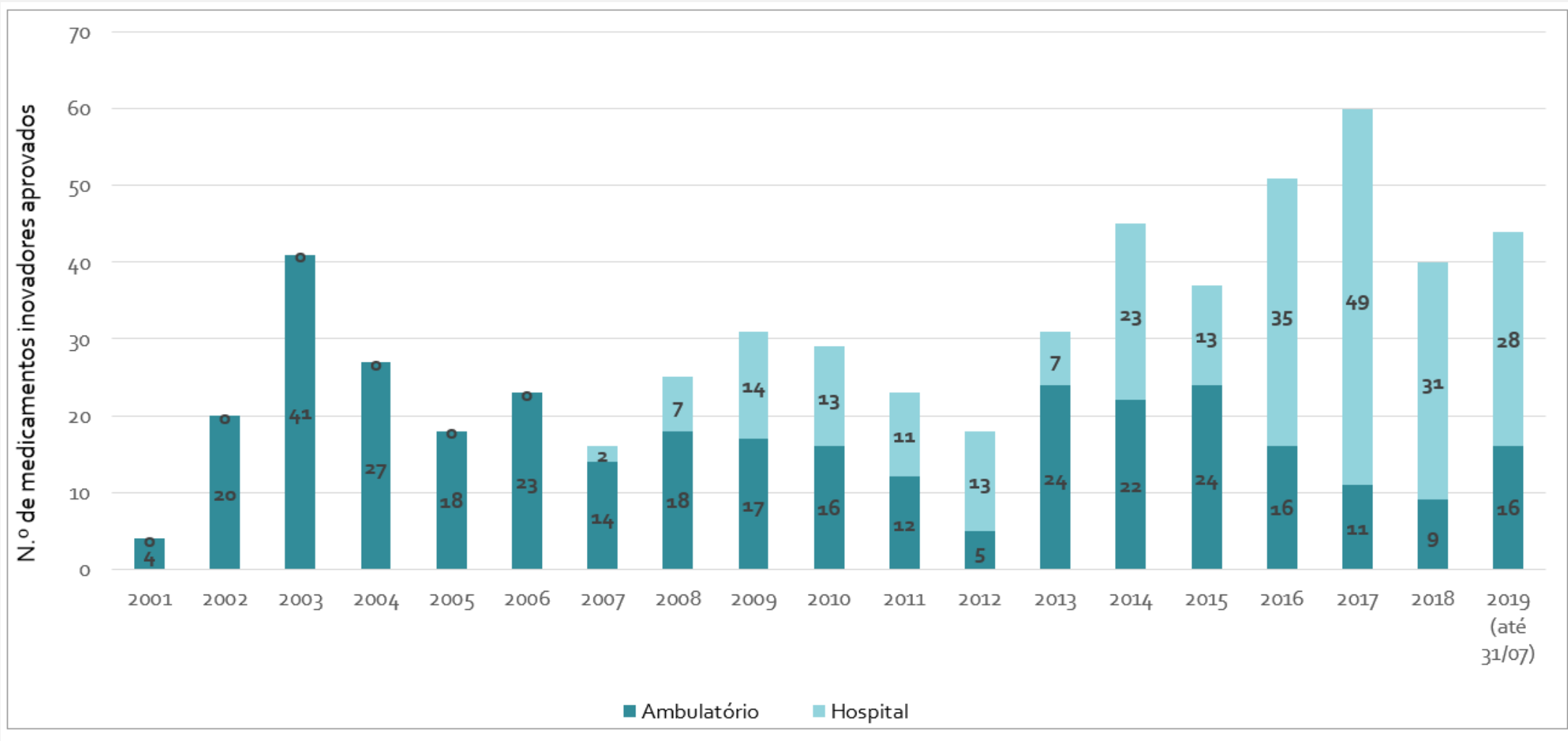


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# NHS EXPENDITURE WITH MEDICINES



# ACCESS TO INNOVATION



More therapeutic options available, essentially at hospital level

# PHARMACEUTICAL SYSTEM

**SiNATS**

**National Health Technology Assessment System**

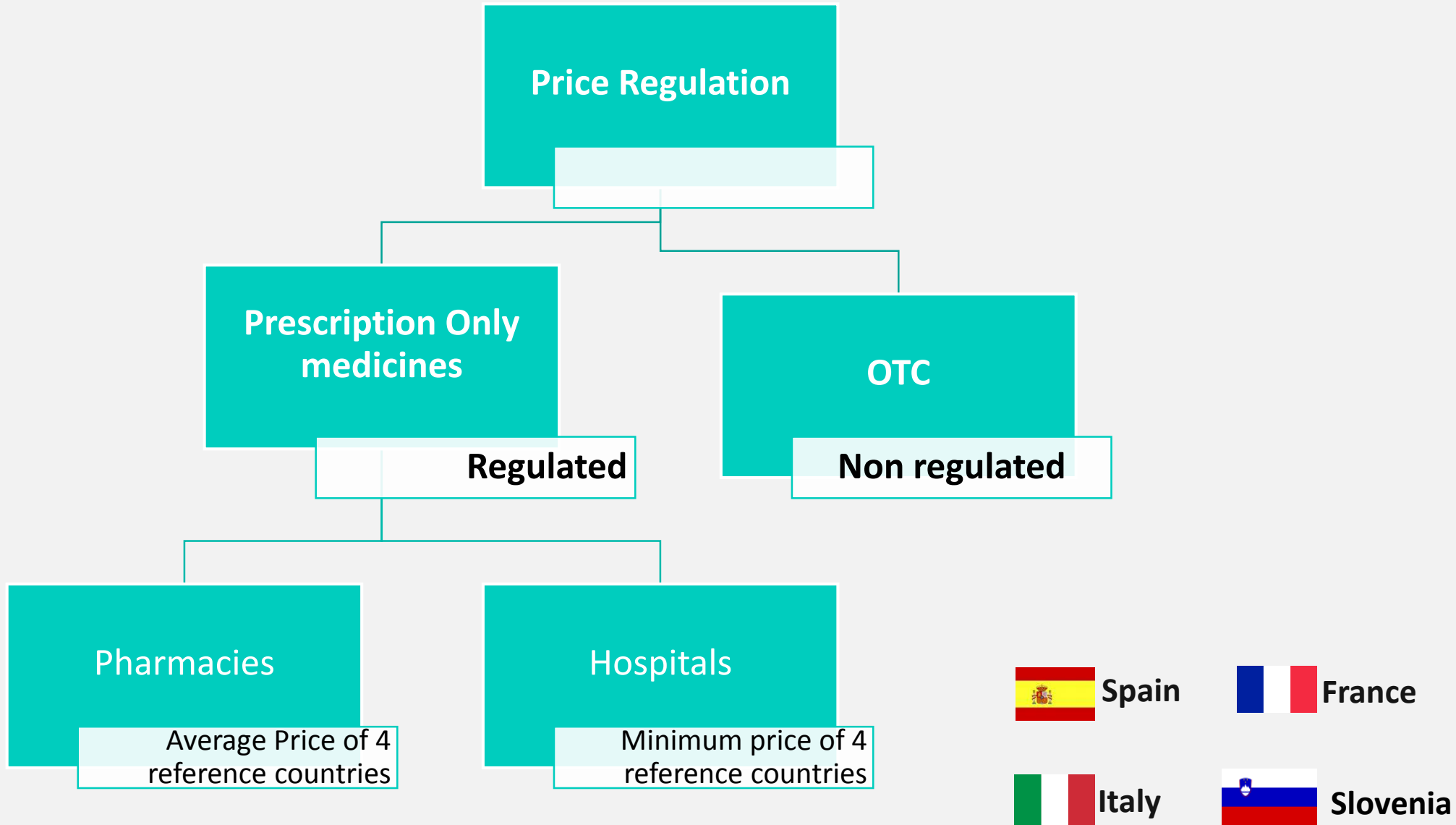
**Pricing System**

**Reimbursement system**

**Procurement and  
National Formulary**

# Pricing System

# PRICING SYSTEM





# PRICING SYSTEM

- Outpatient Setting

- Non-Generic Medicines
- Generic Medicines



- Inpatient Setting

- Non-Generic Medicines
- Generic Medicines



The Portuguese medicine legislation has specific rules for each setting and for each type of medicine

# PRICING SYSTEM – NON GENERICS

## System based on:

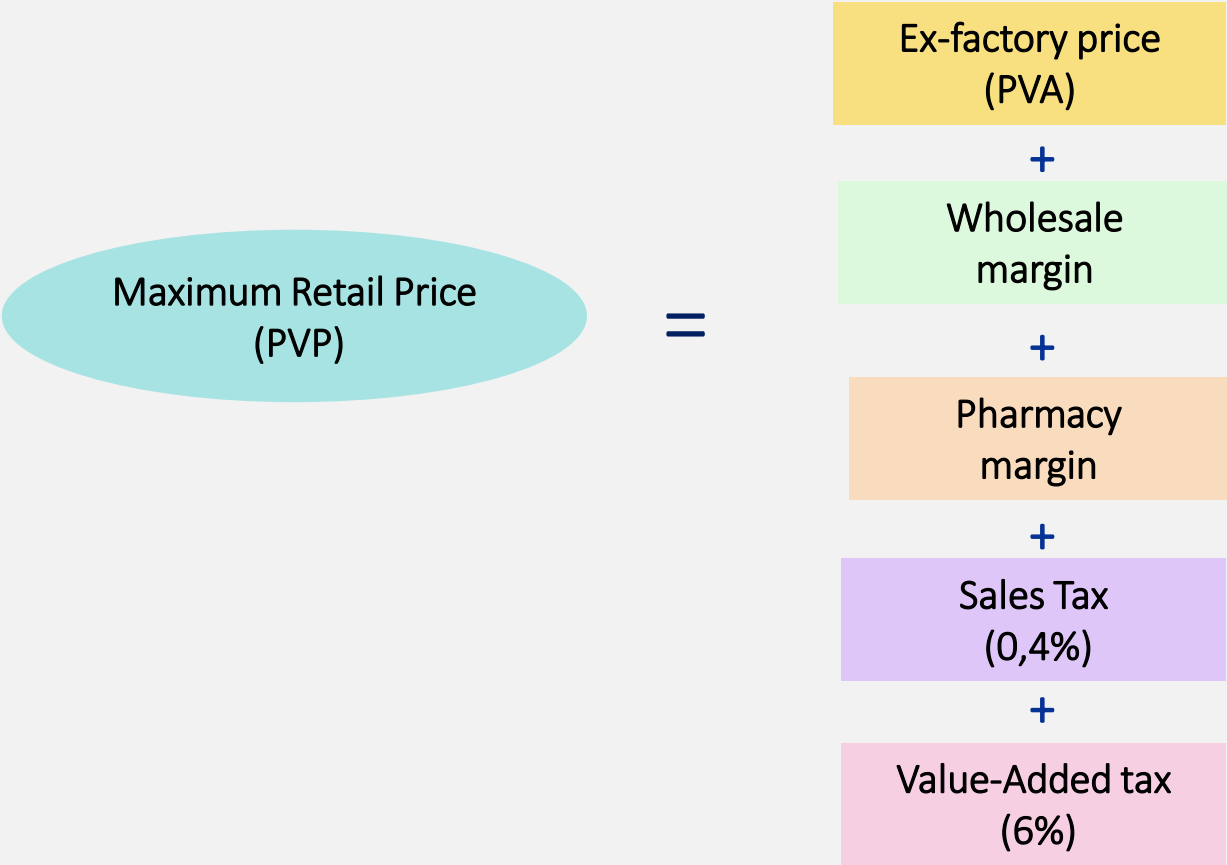
- Maximum prices
- External reference pricing (is done by comparing the medicines price between countries for the same medicine or similar medicine)

## Reference countries:

- In Portugal: Spain, France, Italy and Slovenia
- The selected countries are used as reference for the approval of new prices as well as for the annual price revision

# PRICING APPROVAL – OUTPATIENT SETTING

## PVP calculation formula



# PRICING APPROVAL – OUTPATIENT SETTING

## Maximums marketing margins

1º - PVA up to €5,00

Wholesale - 2,24 % over PVA + 0,25€  
Pharmacy - 5,58 % over PVA + 0,63€

2º - PVA between €5,01 and €7,00

Wholesale - 2,17 % over PVA + 0,52€  
Pharmacy - 5,51 % over PVA + 1,31€

3º - PVA between €7,01 and €10

Wholesale - 2,12 % over PVA + 0,71€  
Pharmacy - 5,36 % over PVA + 1,79€

4º - PVA between €10,01 and €20,00

Wholesale - 2,00 % over PVA + 1,12€  
Pharmacy - 5,05 % over PVA + 2,80€

5º - PVA between €20,01 and €50,00

Wholesale - 1,84 % over PVA + 2,20€  
Pharmacy - 4,49 % over PVA + 5,32€

6º - PVA above €50,00

Wholesale - 1,18 % over PVA + 3,68€  
Pharmacy - 2,66 % over PVA + 8,28€

# PRICING APPROVAL – OUTPATIENT SETTING

## Generic – Pricing Rules

- If the PVA of all packages of the reference's medicine are below €10, the generic price has to be 25% lower than the PVA of the reference's medicine, with the same dosage and equal pharmaceutical form,
- or
- If the PVA of one package of the reference medicine is above €10: the price has to be 50% lower than the PVA of the reference's medicine, with the same dosage and equal pharmaceutical form

# PRICING APPROVAL – OUTPATIENT SETTING

## Notified Prices

- The MAH can apply for changing their drugs prices, from the Maximum Prices System to Notified Price System, with increases up to 10% and limited to 2,5€ in amount, annually.
- The communication is made by the MAH, through an electronic platform, during the first 10 days of each month, to be effective at the first day of the next month
- This procedures are automatically, with no intervention of INFARMED, I.P. needed

## Paralell Import

- The parallel importer communicates to INFARMED the price of the pharmaceutical, which is **at least 5% lower to the price of the considered pharmaceutical** and of the identical or essential similar pharmaceuticals with a market authorisation in Portugal.

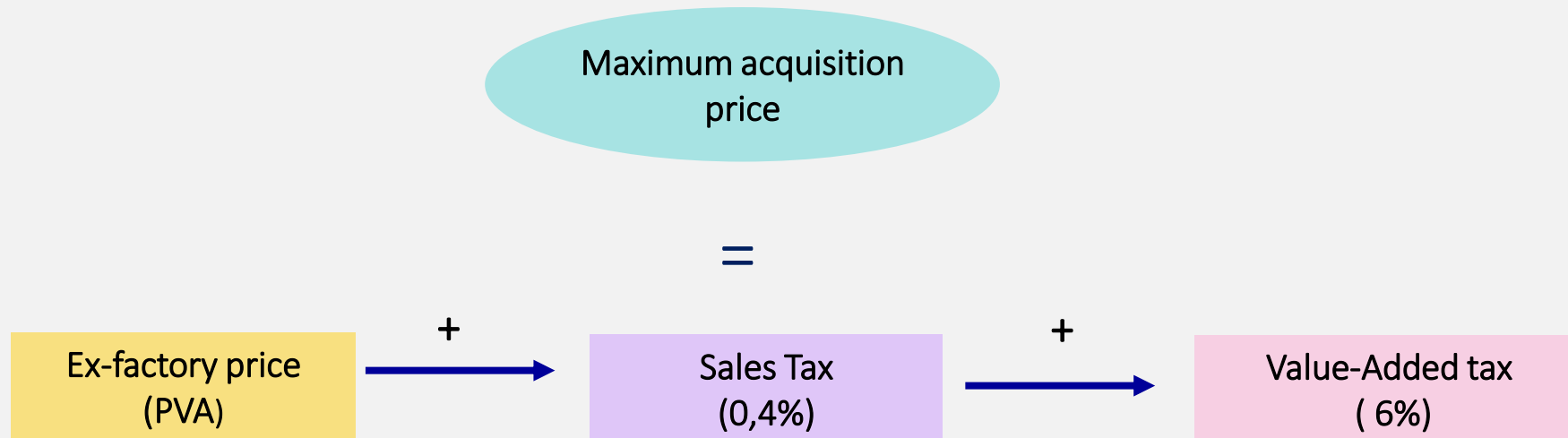
# PRICING – INPATIENT SETTING



- The price of medicines corresponds to a **maximum price** for the acquisition by the NHS
- This price is established through the prior assessment to the acquisition by hospitals (NHS) or result from the annual price revision
- The PVA of non generic medicines is the **minimum PVA** practice in the reference's countries

# PRICING – INPATIENT SETTING

## Acquisition price calculation formula





# Reimbursement System

# THE REIMBURSEMENT SYSTEM

## ☐ Hospitals (inpatient setting)

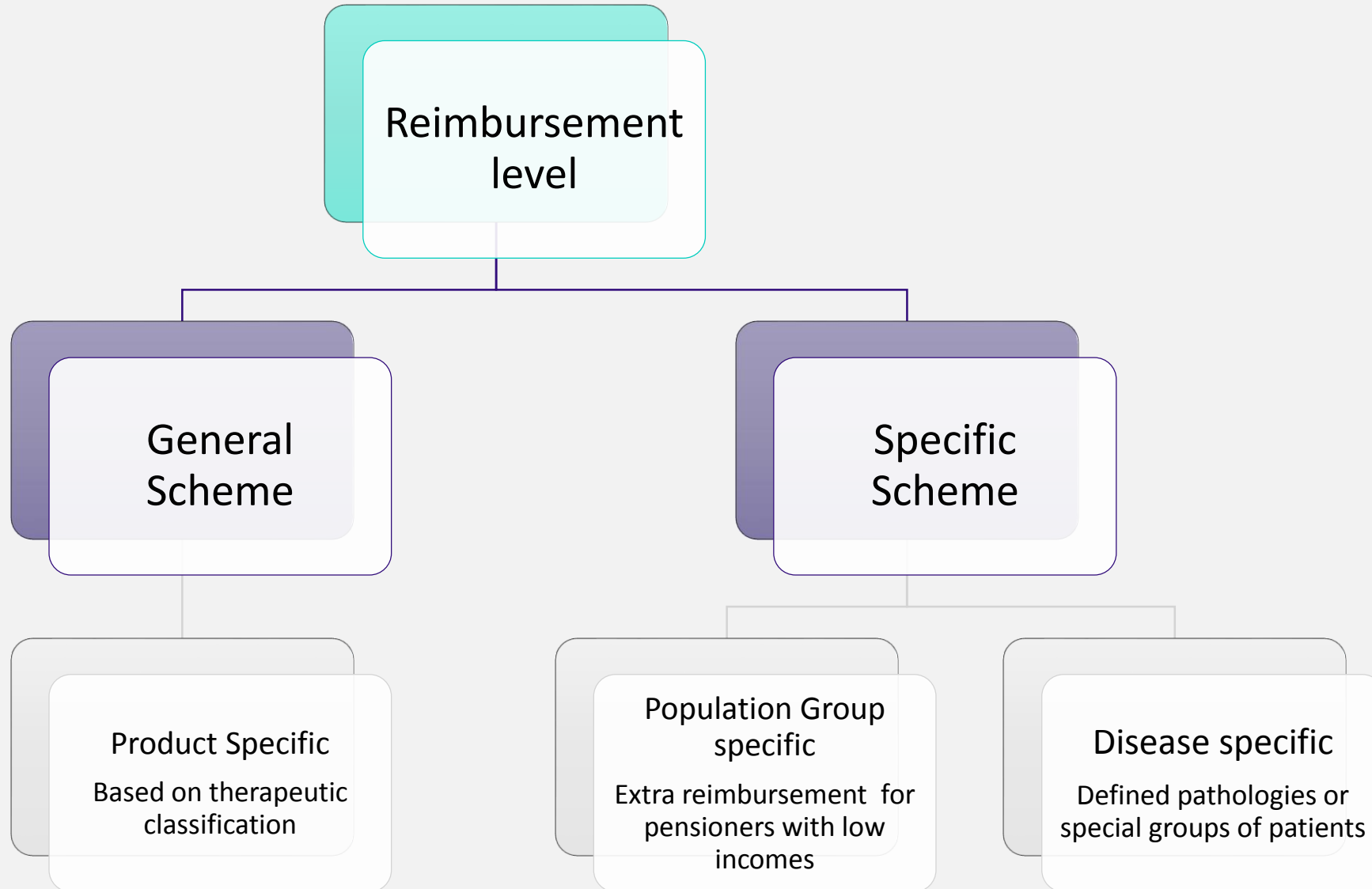
NHS or third payer is responsible for **all** the expenses with inpatient consumed medicines

## ☐ Pharmacies (outpatient setting)

NHS or third payer is responsible for **all or part** of the expenses with consumed medicines

on the purchasing act the consumer does not pay or pay only a part of medicine's price

# REIMBURSEMENT LEVEL IN OUTPATIENT SETTING



# REIMBURSEMENT LEVEL IN OUTPATIENT SETTING

## General Scheme

**Product Specific**  
Based on therapeutic classification

### Category A (90%)

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

### Category B (69%)

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

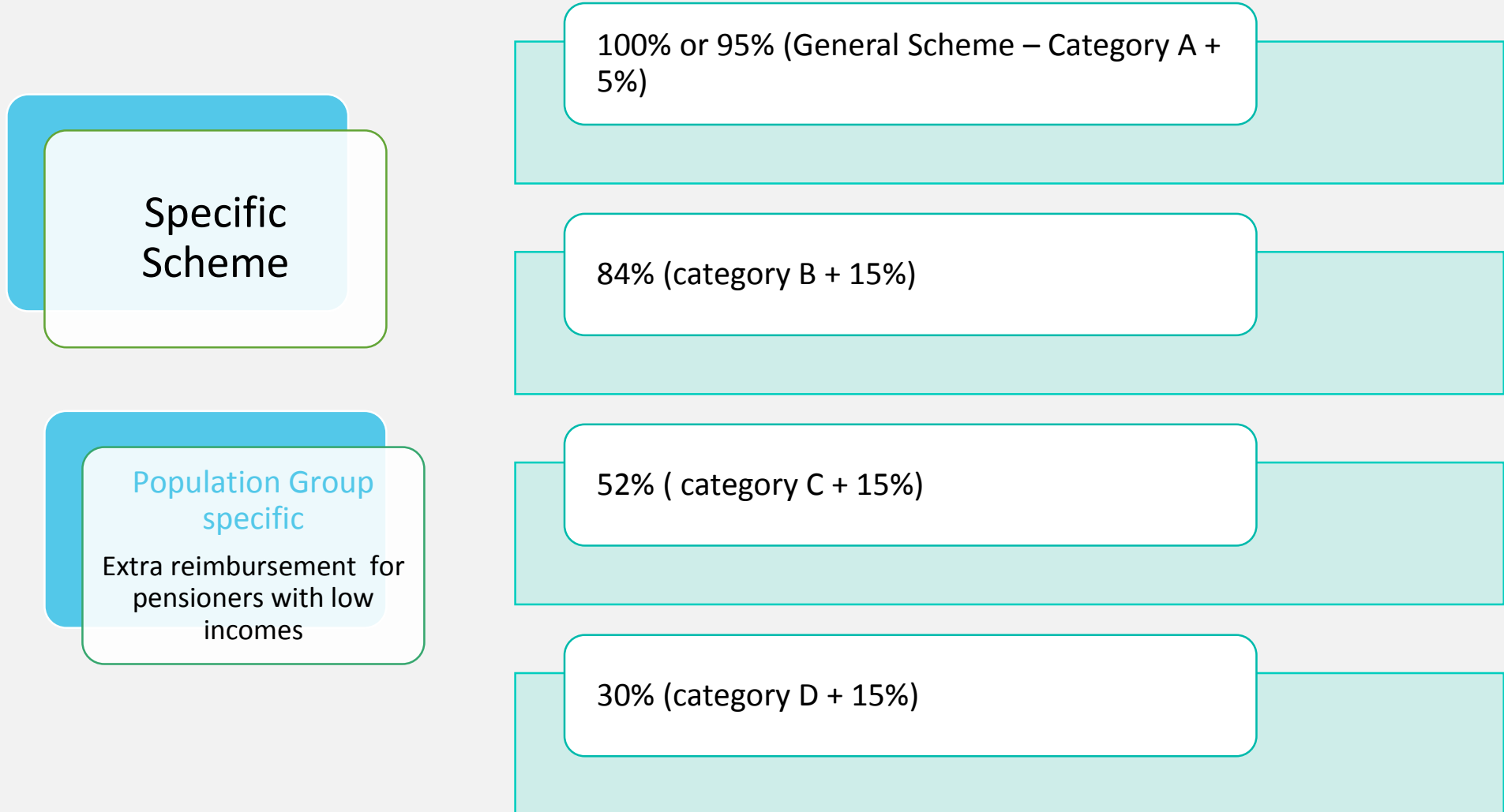
### Category C (37%)

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

### Category D (15%)

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

# REIMBURSEMENT LEVEL IN OUTPATIENT SETTING



# REIMBURSEMENT LEVEL IN OUTPATIENT SETTING

Specific Scheme

Disease specific

Defined pathologies or special groups of patients

Examples:

- Psoriasis – 90%
- Amyloidosis – 100%
- Alzheimer disease – 37%
- Arthritis – 69%

# INTERNAL REFERENCE PRICING

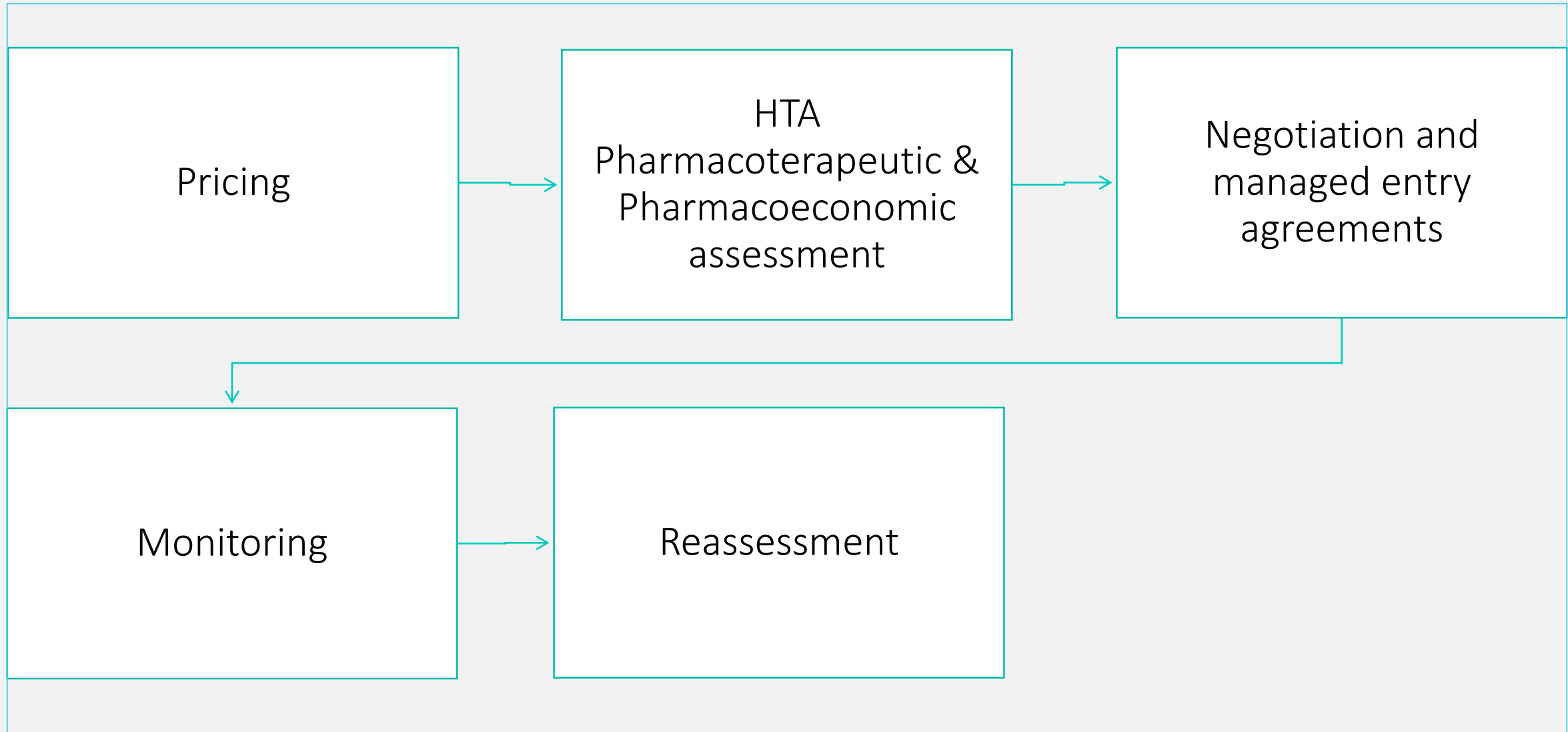
- **Medicines are clustered in homogeneous groups (HG)**(same active substance, strength, route of administration, pharmaceutical form). At least one must be a generic medicinal product.
- **The reimbursement % will be applied to the reference price** instead of the price approved for the medicinal product.

# INTERNAL REFERENCE PRICING

- **Reference price** is the **average price of the 5 cheapest medicinal products**, including non-generics in each HG.
- Not higher than the most expensive generic in each HG
- Reimbursement: lower than 5% of the cheapest generic with at least 5% of market share in each HG
- Reviewed each trimester, but new homogeneous groups can be introduced every month.



# PRICING, HTA AND REIMBURSEMENT



Promote a sustainable and efficient access

# THANK YOU

SONIA.CALDEIRA@INFARMED.PT

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