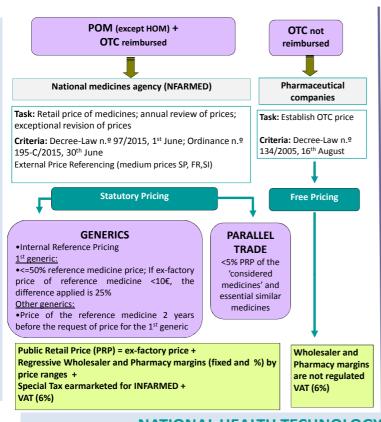


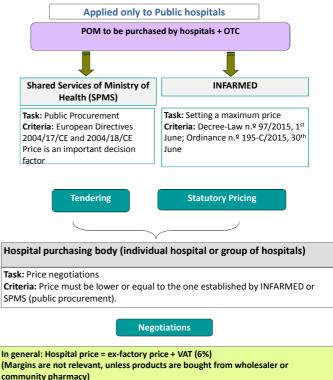




Caldeira, Sónia (sonia, caldeira@ nfarmed.pt); Santos, Cláudia (claudia.santos@infarmed.pt); Furtado, Cláudia (claudia.furtado@infarmed.pt); Ramos, Ricardo (ricardo.ramos@infarmed.pt) INFARMED - National Authority of Medicines and Health Products, I.P. 3rd international PPRI Conference, 12 - 13 October 2015, Vienna

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector







REIMBURSEMENT

NATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEM (SINATS)

-Technology: Medicines + Medical Devices + Other Technologies -Assessment:

- a) Relative Effectiveness (Added Therapeutic Value)
- b) Cost-Effectiveness (Economic Value)
- c) Other dimensions of the technology value (including affordability)

-Decisions:

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

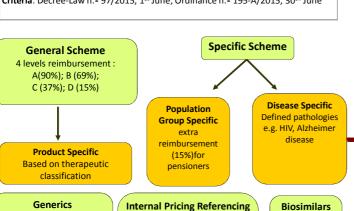
Re-assessment of technologies on the market (ex-post evaluation) – New paradigm -Participation in the European HTA system

0 Figure 1 – SiNATS – A System of Health Technology Assessment to Portugal [1]

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

Task: Reimbursement of medicines; reassessment; exclusion and sunset clause

Criteria: Decree-Law n.º 97/2015, 1st June; Ordinance n.º 195-A/2015, 30th June



Ministry of Health through ACSS (Central Administration of the Health System) and Regional Health Administrations

Task: Financing hospital level of activity, including use of medicines, through Diagnosis-related Groups (DRG). There's a National Formulary with guidelines for the rational use of medicines taking HTA into account and covering both outpatient and inpatient

Special financing of medicines to HIV/ HCV treatment.

Criteria: Medicines and medical procedures to HIV patients are subsidized according to the predicted the number of new HIV patients/ Central financing for HCV treatment Medicines for specific conditions and dispensed in hospitals to out-patient with no co-payment Criteria: medicines reimbursed at 100% for hospital only dispensing Chronic Kidney disease (comprehensive price)

> LISE IN HOSPITALS **National Formulary**

> > in consultation with

Additional financing

Hospital/ Hospital Pharmacy/ Pharmaceutical and Therapeutic

Task: Decision on use of medicines in the hospital Criteria: Ministerial Dispatch n.º 1083/2004

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

Internal Pricing Referencing

Reference price – average of 5 lowest PRP at the market (including nongenerics) in each Homogeneous Group (HG); Reimbursement -<5% of the lowest generic price, with at least 5% of market share, in each

HG

Price <=80% biologic medicine reference price

OUT-

[1] Martins, J; Rodrigues, J; Antunes, M; Ferrador, F; Ramos, I; Ramos, R; Santos, C; Caldeira, S; Castro, J; Arriegas, M; Dias Almeida, P; Mota-Filipe, H; Castro Alves, E; "SiNATS - Criar o Futuro", (2014).