Ministério da Saúde

PPRI
Pharmaceutical Pricing and Reimbursement Information

infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

PORTUGAL

High-cost medicines

- No specific funding and reimbursement schemes for high-cost / innovative medicines
- Managed entry agreements mandatory for new medicines for hospital use and optional for new medicines used in ambulatory
- Proposal for a specific committee for reimbursement and price decisions
- Same pricing procedure for all medicines for which the MAH want to receive reimbursement : comparative price analysis *v.s.* alternatives already reimbursed when added therapeutic value was not proved and value based price (economic evaluation analysis) when added therapeutic value was proved
- Innovative medicines could be restricted to specific settings (e.g. hospital setting) depending mostly on security issues. This drugs are purchased by the hospital at the ex-factory price plus VAT
- **Key challenges:** definition of innovation in the perspective of added therapeutic value; combine access to innovation and NHS sustainability
- **Approaches for solutions:** technical guidelines to define relative effectiveness and added therapeutic value; increase the use of managed entry agreements; increase the use of generics

Generic policies

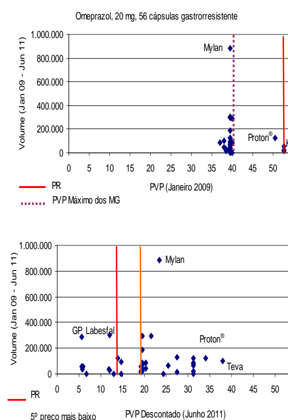
- INN prescribing mandatory for active substances with Generic Medicines approved and with the option to add the brand or MAH name (December 2002)
- Generic substitution in the pharmacy allowed if the prescriber allows it (December 2002)
- From the 5th Generic onwards in the same homogeneous group, the price must be 5% cheaper than the cheapest generic.
- There are NO tendering-like practices in the out-patient sector
- The reference price system is set for the homogeneous group, which includes medicines with the same active substance, dosage, **equivalent pharmaceutical form** and same administration route. The Reference Price is the value of the average of the 5 cheapest generics.
- Several information campaigns where conducted by Infarmed, that included TV, radio, press, leaflets, PR, mailings and other actions.
- **Future actions:** Approval of the mandatory INN prescribing. Development of an application for smart phones with the prices of medicines.
- Generics share in volume **(21,65%)** and value **(18,19%)** in 2011in the out-patient market

Changes in the pharmaceutical system – end 2011/2012

- Margin methodology changes (wholesale, pharmacies) - introducing price ranges with fixed value plus regressive margins
- New countries for external reference pricing (Spain, Italy and Slovenia)
- Price annual review next April according to the new reference countries
- New price difference for generics price – 50% lower than the original
- Created the possibility to have reference price and clusters by ATC level 4

Measures under discussion or planned

- *Revision of special reimbursement conditions (specific pathologies or groups of patients)*
- *Revision of reimbursement decisions (potential for delisting or price negotiation)*



Evaluations and studies on pharmaceutical policies (cont.)

Interface management:

Furtado CI. Differences in cardiovascular drugs prescribing indicators between medical practices

- **Background:** Cardiovascular Drugs accounted for 27% of total outpatient drug expenditure in 2010. This therapeutic group is one in which the previous research shows that the use expressed in DDD per 1000 inhabitants is lower than in other countries but the use of new medicines, with marginal innovation, is higher.
- **Aim:** Analyse the evolution of prescribing quality indicators in the NHS since the introduction of major reforms in primary care and secondary care, describe prescribing patterns by type of prescriber (general practitioners; specialist doctors; private care doctors; others) and explore possible reasons for variation.
- **Key results**: Primary care physicians are responsible for most of the out-patient prescribing (76%) in the cardiovascular area. Despite the lower proportion of prescriptions originated by hospital doctors or private care doctors this matter warrants further attention because of its influence in primary care physicians. Primary care physicians have the lowest percentage of high cost statins (27%) while regarding hospital doctors the proportion was much higher (38%) and presented an increasing trend in the last four years.
- **Conclusions and implications:** Considering the influences between practices quality improvement in prescribing cannot be focused only in one group of doctors or type of care. Special attention should be given to the introduction of drugs for inpatient use that have a major effect on outpatient prescribing.

Evaluations and studies on pharmaceutical policies

Impact analysis of policies:

Norberto RO, Vieira I. Impact analysis of reference price system (RPS) changes on generics price competition

- **Background:** It was observed a high concentration of prices in generic market and were introduced measures o change the situation
- **Aim:** Analysis of the impact of new policies, in particular new methodology to calculate reference price and special reimbursement in RPS introduced in 2010, with regard to levels of concentration and competition in generic market
- **Key results**: The changes increased the competition around generic pricing and decrease the level of concentration. The generic market share relation volume price has changed, with a high volume market share.
- **Conclusions and implications:** Further investigation should be made in order to identify the implication of these changes in the NHS expenditure trend.
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