Medicines

Facing the Challenges: Equity, Sustainability and Access

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Portuguese Medicines Policy and Developments

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AGENDA

• Introduction
• Policy Objectives & Drivers
• Developments
• Challenges
Introduction
INFARMED, I.P. - Mission

Regulate and supervise

- Ensure the assessment of human medicines in terms of quality, safety and efficacy
- Ensure higher standards of expertise in Portugal and Europe

Access

- Ensure the cost-effectiveness of medicines for human use
- Guarantee equitable access to quality, efficient and safe medicines

Health Technology Assessment – HTA

- Maintain the National Health System sustainability facing innovation challenges
INFARMED, I.P. - Organization
INFARMED, I.P. – H. Resources

- Solid structure with a prestigious critical mass
  - Recognized at international level
- Qualified staff and external experts from:
  - Universities | Hospitals | Research centers
- Establishing a cohesive network
  - National scientific communities and EMA
    Multidisciplinary Team
- Participating regularly in European scientific procedures

350
- Qualified professionals

300
- External experts
Policy
Objectives & Drivers
Health policy context

Government pursues some key objectives:

- Maximizing citizens' quality of life
- Ensure the sustainability of the NHS and an efficient use of health resources
- Improve access to medicines and increase efficiency in new medicines introduction
National Context

- **Citizens**: Profound change in the demographic profile, due to population ageing and growing prevalence of chronic diseases

- **Health System**: Over the past few years, pharmaceuticals pose major challenges to the NHS
  - Establishment of cost-containment policies.
  - Access to Innovation.

- **Budget and Expenditure**: after a certain stabilization, it starts increasing
International Context

- Increase in prices for new medicines - affordability and effectiveness in some areas (e.g., cancer)
- Impact of new and personalized technologies (e.g., CAR T cells)
- Uncertain clinical outcomes and consequent benefits
- Improvement of assessment methodologies
- Cooperation at various levels, e.g., methodologies, assessment, planning, negotiating
Medicines expenditure / % of GDP

![Graph showing medicines expenditure as a percentage of GDP from 2012 to 2017.](image-url)
Policy Orientations

- Ensure access to medicines with more efficiency
- Ensure sustainability of the National Health System
- Reinforce intervention in therapeutic compliance and monitoring
- Balancing health budget with access to therapeutic innovation
- Investment on planning and prioritization frameworks (Horizon Scanning)
- Strengthen European Cooperation
- Value the role of pharmacies as health care providers
- Promote OTC - Pharmacy Only Medicines
Developments
Financial Agreements

Agreement with the major representative associations: Pharmaceutical industry, Pharmacies, Wholesalers, Medical Devices - Establish main guidelines to control NHS expenditure with medicines and medical devices for a 3 years:

<table>
<thead>
<tr>
<th>Agreement with Pharmaceutical industry</th>
<th>Agreement with pharmacies associations</th>
<th>Clawback since 2015</th>
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<tbody>
<tr>
<td>Promote control of public expenditure</td>
<td>Payment of a fee to promote the dispensing of medicines with lower price started 1st January 2017</td>
<td>Equity principle;</td>
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<td>Introduction of innovation</td>
<td>Reinforce their role in health programs</td>
<td>Compulsory contribution by all companies;</td>
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<td>Percentage of total market share for each company;</td>
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<td>Quarterly contribution through Ministry of Finance</td>
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Sustainability Measures ongoing

Annual price revision in ambulatory and hospital

Reference countries 2018: Spain, France and Italy (estimated savings of 30 M€)

Health Technology Assessment and Price&Reimbursement:

Reassessment and global approach for specific areas of medicines: HIV, Anti-Diabetic medicines (IDPP-4) and New oral anticoagulants;

Key changes on the HTA and P&R legal framework:

• New timeframes for assessment: 180 days (innovation), 30 days (generics and biosimilars) and 75 days (other medicines);
• New approach to early access programmes;
• Increased price competition for generics and biosimilars (at least 20% cheaper than biologic medicine);

Horizon scanning: be aware of the coming disruptive technologies and anticipate measures
Sustainability Measures ongoing

National Health System:
- As part of the contracting system - Incentives to hospital biosimilar use, focusing on specific substances: infliximab, etanercept and rituximab
- Benchmarking Information to hospitals to monitor the evolution of medicines consumption and expenditure
- Incentives to generics dispensing

Medical Devices:
- HTA and economic evaluation of specific groups of medical devices
- Creation of a monitoring system for hospital consumption – launched January 2018
Monitoring medical devices

Data collection (until now):

. 38 health institutions (70%)

. Value - 189,3M€

. NHS medical device market (540M€ to 590M€)
HTA in Portugal

- Since 1998 for outpatient sector
- Since 2007 for inpatient sector
- 2015 creation of SiNATS
- 2017 SiNATS is re-designed to guarantee the efficient use of public resources for health, monitoring the use and effectiveness of technologies, promoting and awarding relevant innovation development and equitable access to technologies.

2018 - 2019 Review of economic assessment guidelines on economic assessment
Regardless of other technical-scientific criteria for the assessment of health technologies, as further defined by regulations from INFARMED, reimbursement of medicines should meet the following requirements:

a) To prove pharmaceutical’s Added Therapeutic Value or comparability, in comparison with the appropriate comparator, within its claimed benefit;

b) To prove economical advantage
SiNATS

Technology: Medicines + Medical Devices....

Assessment:

a. Relative effectiveness (Added therapeutic value)

b. Cos-Effectiveness (economic value)

c. Other dimensions of value

Decisions:

a. Price

b. Financing/reimbursement

c. Control and limitation of costs

d. Risk Sharing

e. Additional monitoring

Reassessment of technologies (emphasis)  
(evaluation ex-post) - New paradigm

Participation at EU level
Access to innovation - PT
Promotion of generics

• Creating monthly Homogeneous Groups for new generic drugs (keeping the quarterly dynamic review of existing groups) - reduce the NHS burden;

• Speed of reimbursement decision for generic medicines;

• Establish a minimum threshold for generics’ prices;

• Allocation of an additional fee per package of medicines dispensed by pharmacies in order to promote the dispensing of medicines with lower price;

• Promotional / educational campaigns encouraging generics’ consumption.
Generics market share
Promotion of biosimilars

- Recommendations related to Biosimilars: for Infliximab, Rituximab and Etanercept, switch is encouraged if the biosimilar is cheaper and patient is stable;
- Incentives to hospital biosimilar use, as part of the Hospital contracting system;
- **Speed of reimbursement decision** for biosimilar medicines;
- Increased price competition for biosimilars (at least 20% cheaper than biologic; medicine and 30% cheaper when the biosimilar market share is higher than 5%);
- Information sessions at NHS Hospitals.
Biosimilar market share evolution

* Biosimilar share within the group of substances with marketed biosimilar
Reinforcement of linkage to NHS

National Pharmacy and Therapeutics Committee

Ensure the coordination and sharing of information between NHS Hospitals and Regional Health Administrations
Monitoring medicines use

• Permanent and continuous monitoring of accessibility of medicines

• Real World Data - initiatives within our National Health Service - RON

• Better planning and prioritization
Utilization & Information

• Qualification of prescription and utilization of medicines:

  o Reinforced role of the National Pharmacy and Therapeutics Committee by issuing recommendations and developing the National Medicines Formulary with positioning of medicinal products
Utilization & Information

- New tools for dissemination of information
  - Launch of a new app “Infarmedia”: Aims to reinforce communication with health professionals, working as a tool to inform prescribers about new available medicines (innovation, biosimilars, 1st generic), as other relevant aspects.
Interaction with Patients

Engage Patients/Patient Associations in the process of health technology assessment and in other areas

- INFARMED’s project that aims to structure and deepen involvement with patients and patient associations
International collaboration

- EUnetHTA JA3
  - Product Assessment

- VALLETTA
  - Price Negotiation
Challenges
Challenges

Synergies between the Regulatory System and HTA and Financing are essential

Need to develop efficient collection of real utilization data and assess performance

New technologies and uncertainty of outcomes

New Payment Models

Horizon scanning and more planning in view of health needs

Involvement of patients

Reinforce existing cooperation and develop concrete areas, eg assessment, pricing negotiation
A more integrated system for Medicines and other technologies
THANK YOU

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