REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed 25+
National Authority of Medicines and Health Products, I.P.

In collaboration with WHO Europe

Medicines

Facing the Challenges: Equity, Sustainability and Access

29-30 November 2018 | INFARMED, I.P. - Lisbon, Portugal

Portuguese Medicines Policy and Developments

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November | 29 | 2018

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

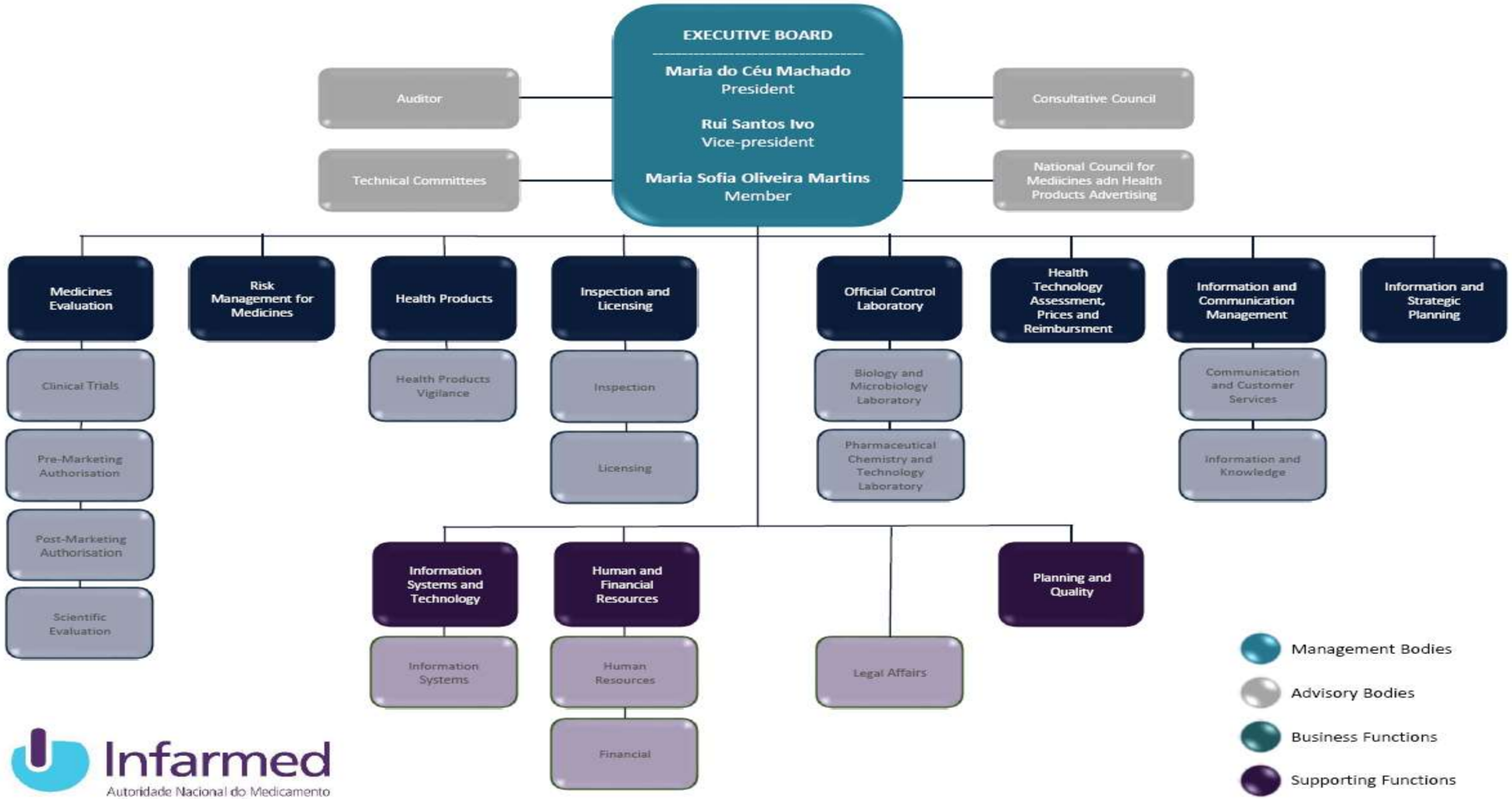
- Maintain the National Health System sustainability facing innovation challenges

Human Medicines

Medical Devices

Cosmetics

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

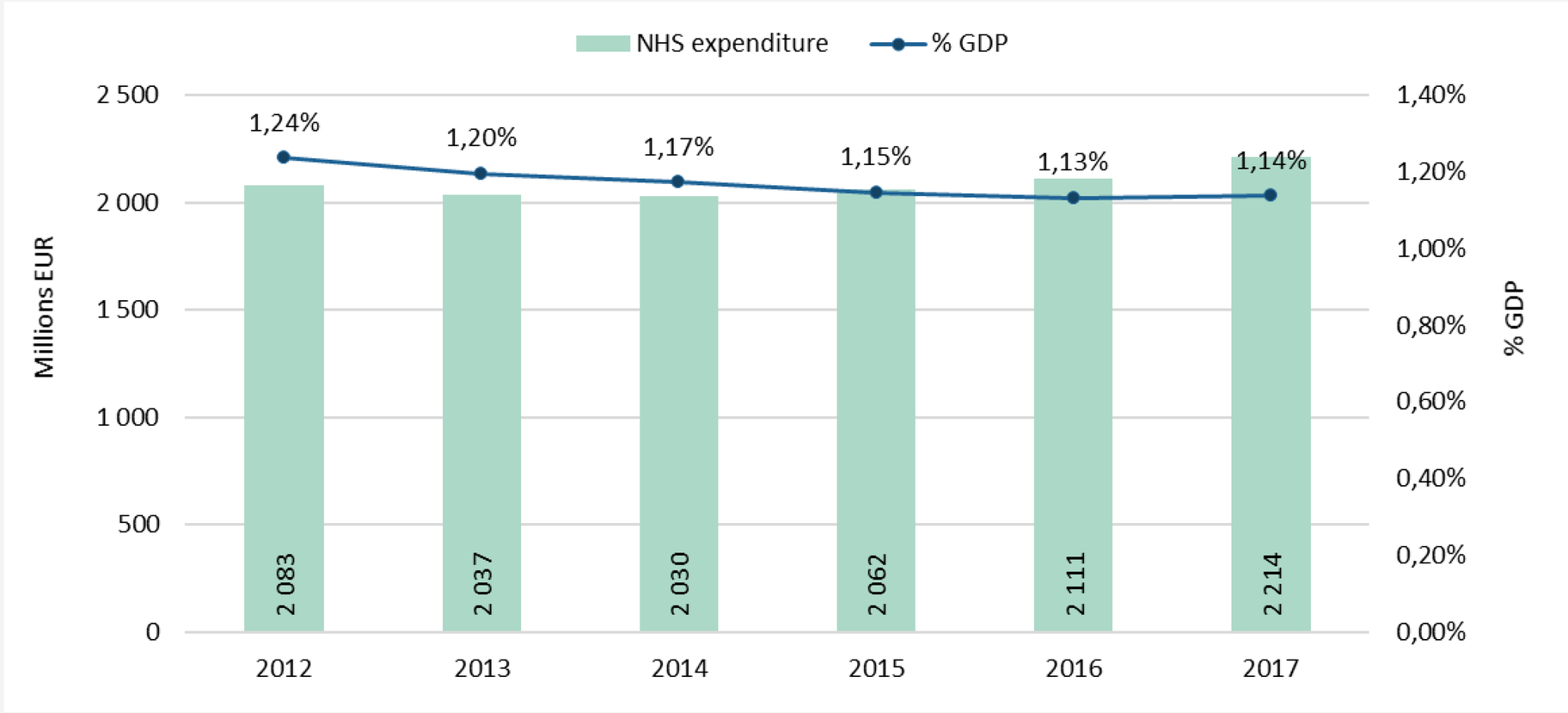
National Context

- **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 (eg, cancer)
- Impact of new and personalized technologies (eg, CAR T cells)
- Uncertain clinical outcomes and consequent benefits
- Improvement of assessment methodologies
- Cooperation at various levels, eg methodologies, assessment, planning, negotiating

Medicines expenditure / % of GDP



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

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

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:

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

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

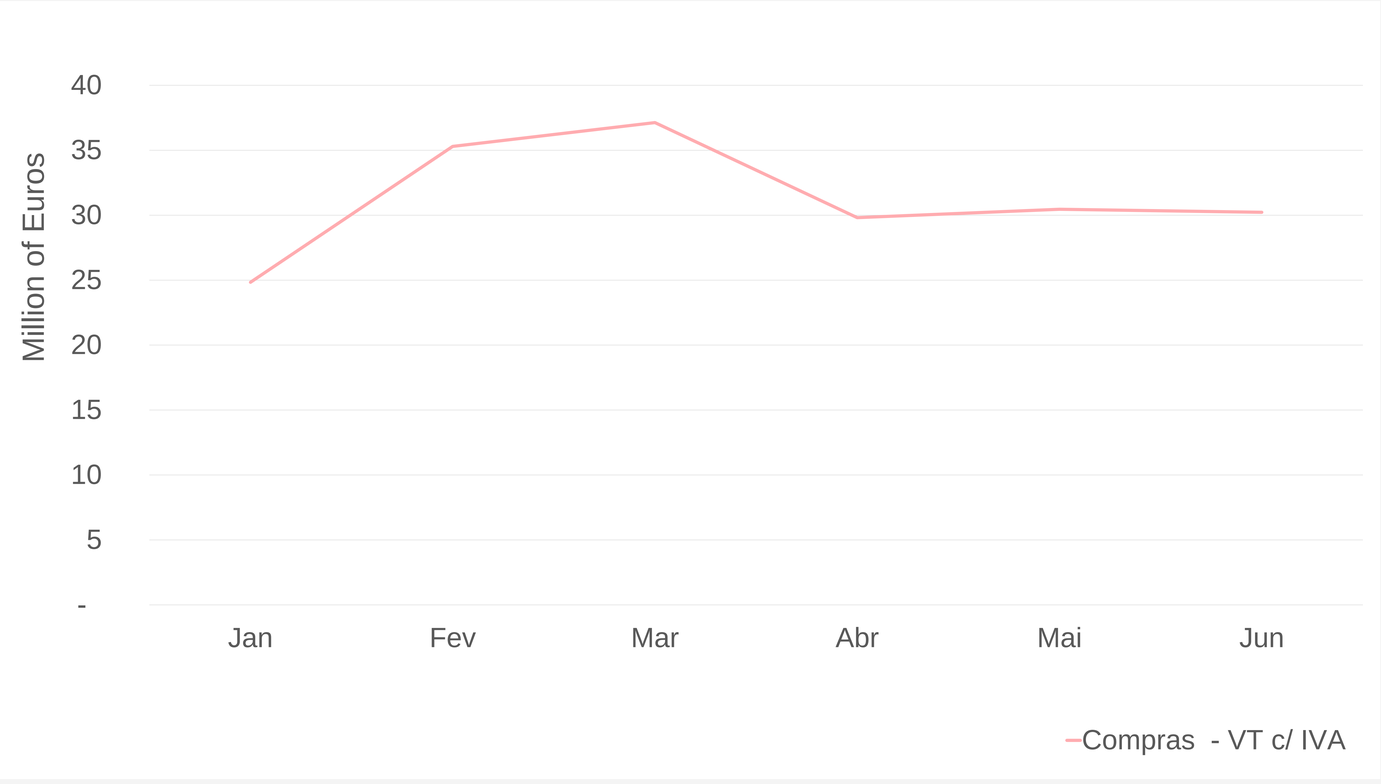
Incentives to generics dispensing

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

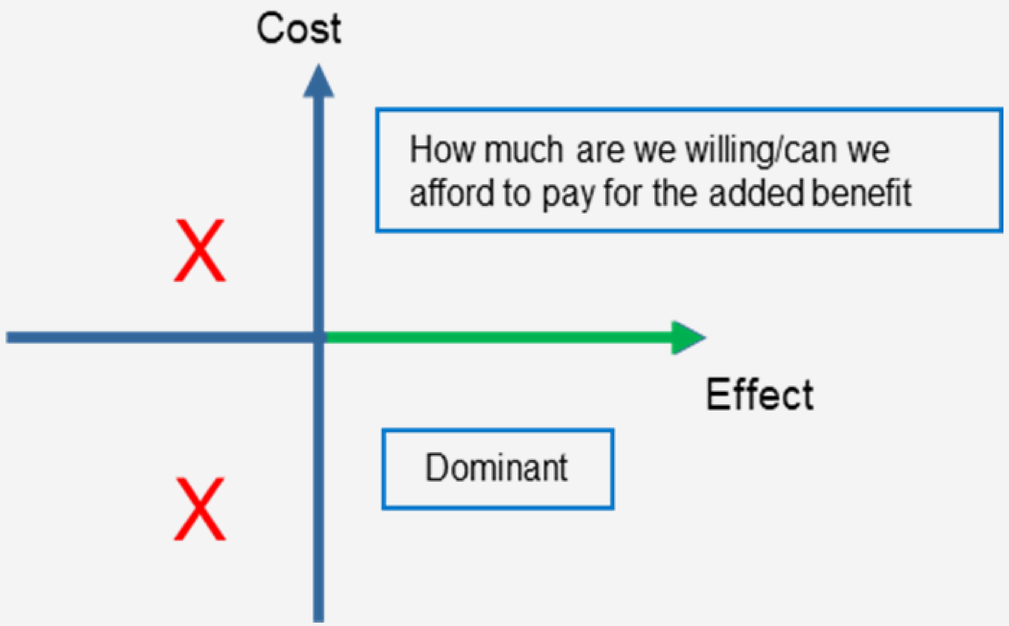
Health Technology Assessment

Legal Decree No 97/2015, 1 June

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:

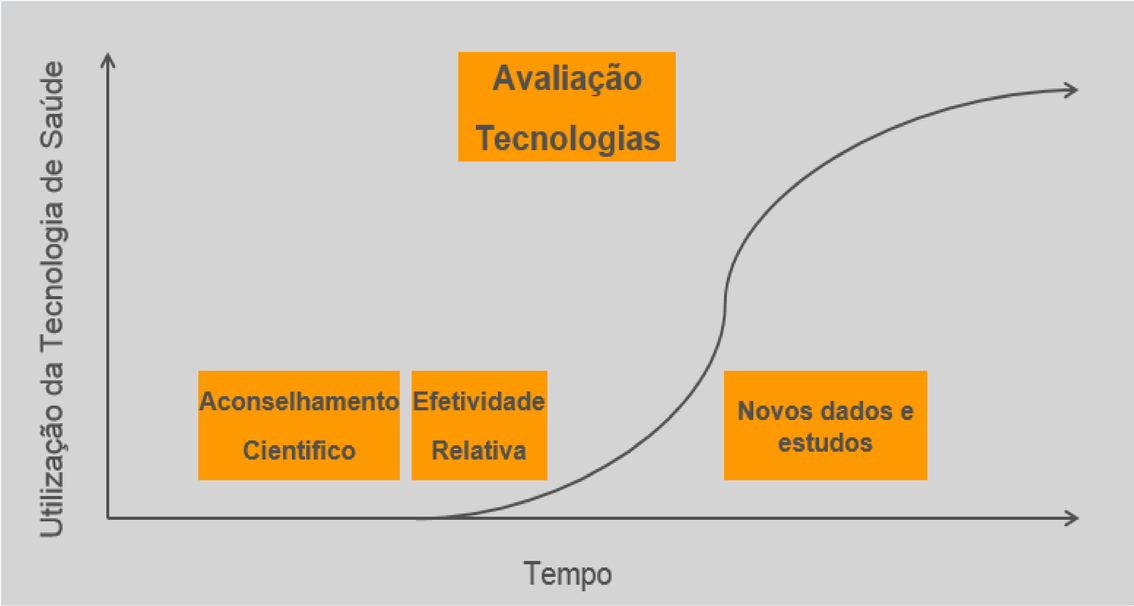
a) *To prove pharmaceutical's Added Therapeutic Value or comparability, in comparison with the appropriate comparator, within its claimed benefit;*

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:

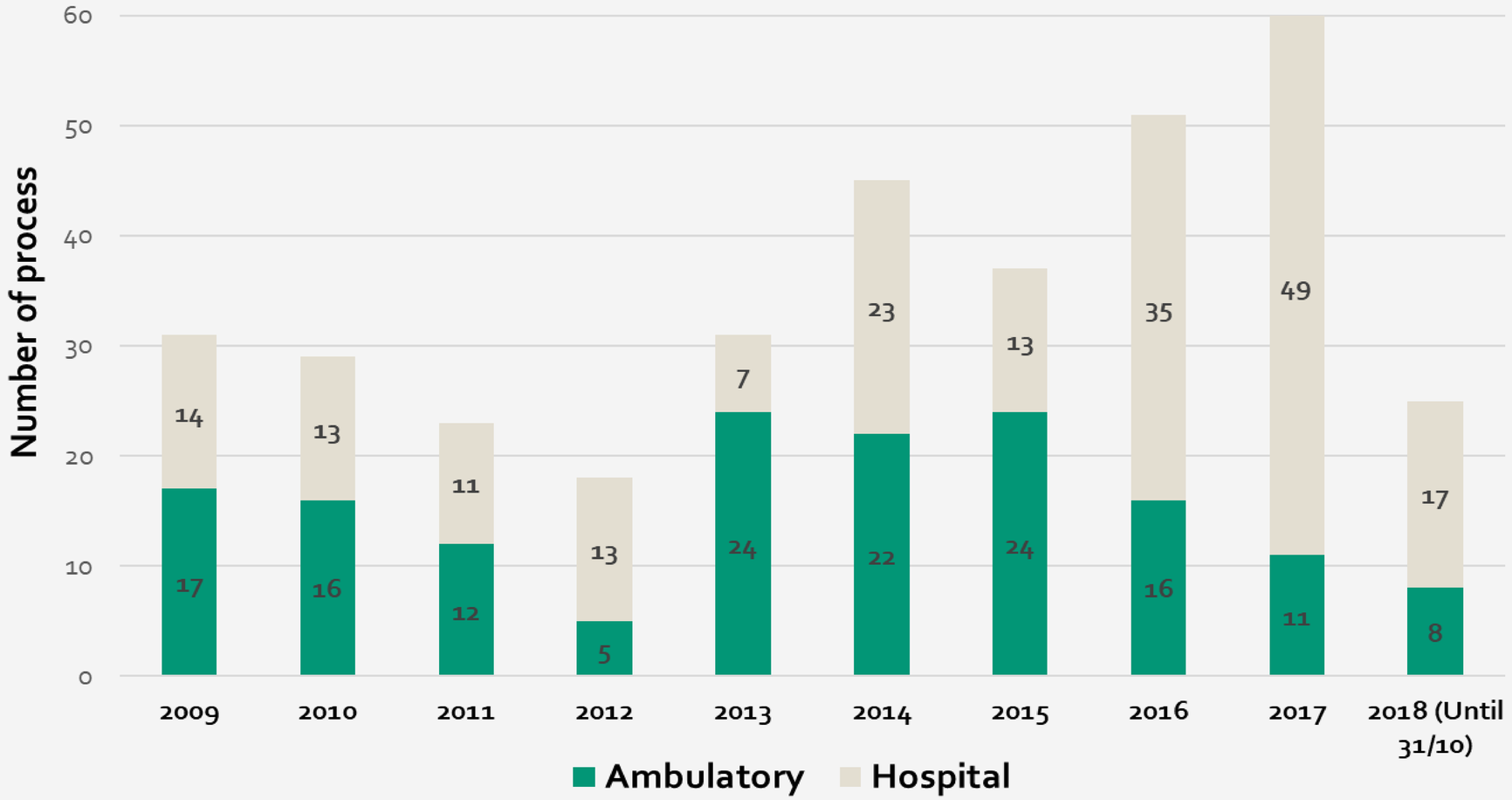
a. Price
b. Financing/reimbursement
c. Control and limitation of costs
d. **Risk Sharing**
e. **Additional monitoring**

Reassessment of technologies (emphasis)

*(evaluation ex-post) – **New paradigm***

Participation at EU level

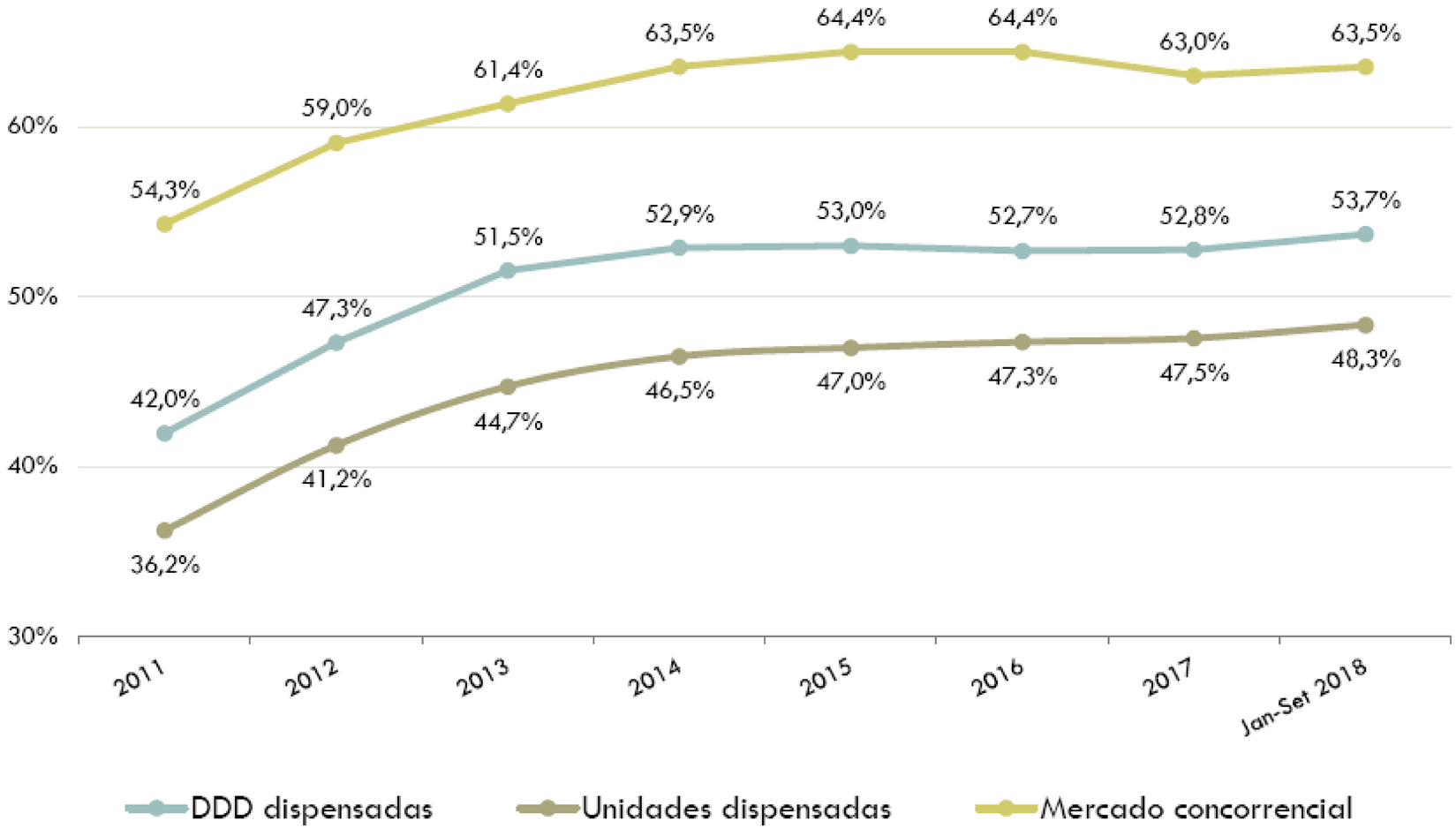
Access to innovation - PT



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

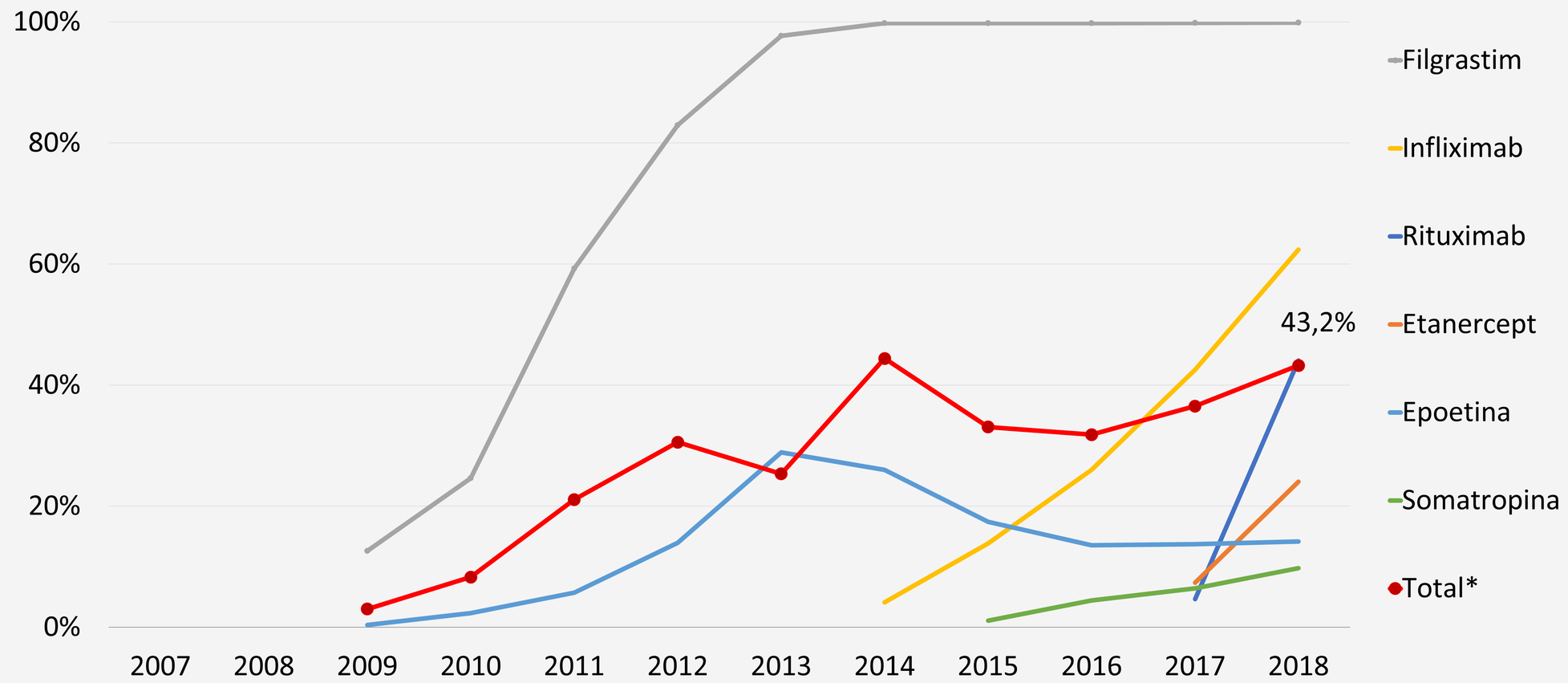


Promotion of biosimilars

- Recommendations related to Biosimilars: for Infliximab, Rituximab and Etanercect, 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

Hospital market



*** Biosimilar share within the group of substances with marketed biosimilar**

Reinforcement of linkage to NHS

National Pharmacy and Therapeutics Committee

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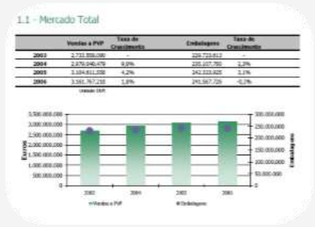
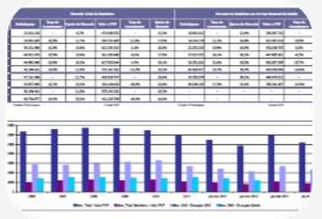
Ensure the coordination and sharing of information between NHS Hospitals and Regional Health Administrations

FNM FORMULÁRIO NACIONAL DE MEDICAMENTOS

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

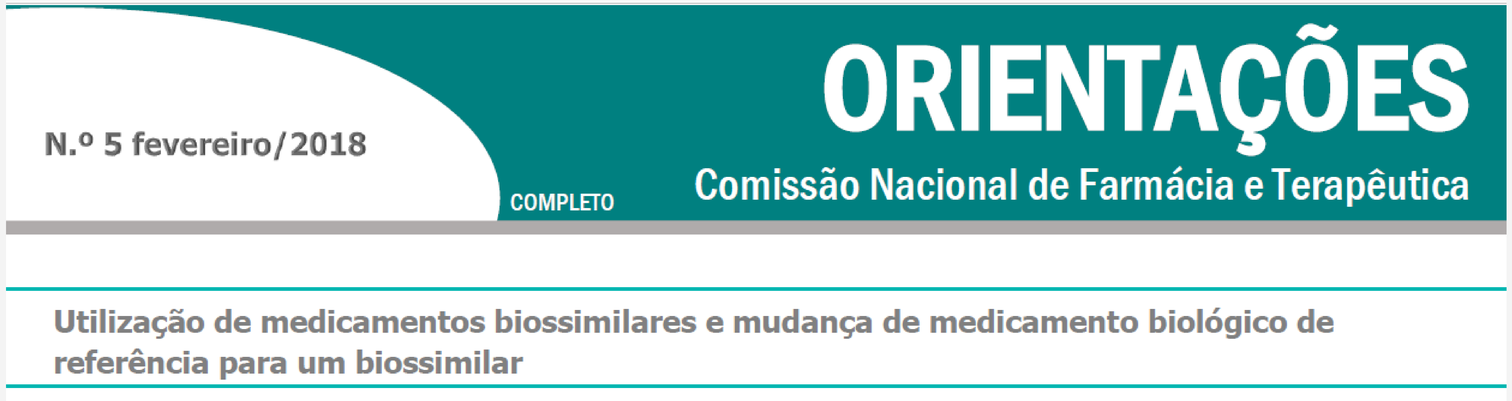




DASHBORDS ONLINE

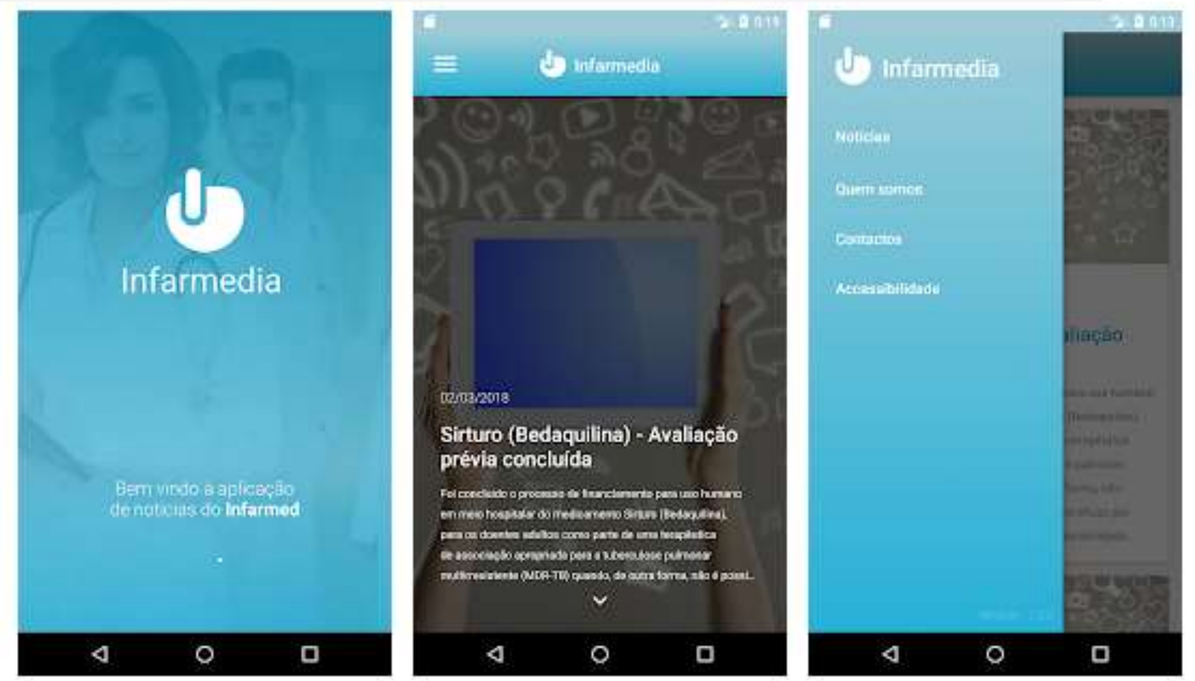
Utilization & Information

- **Qualification of prescription and utilization of medicines:**
  - 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

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- **INFARMED´s project that aims to structure and deepen involvement with patients and patient associations**

International collaboration

EUnetHTA JA3

Product Assessment

VALLETTA

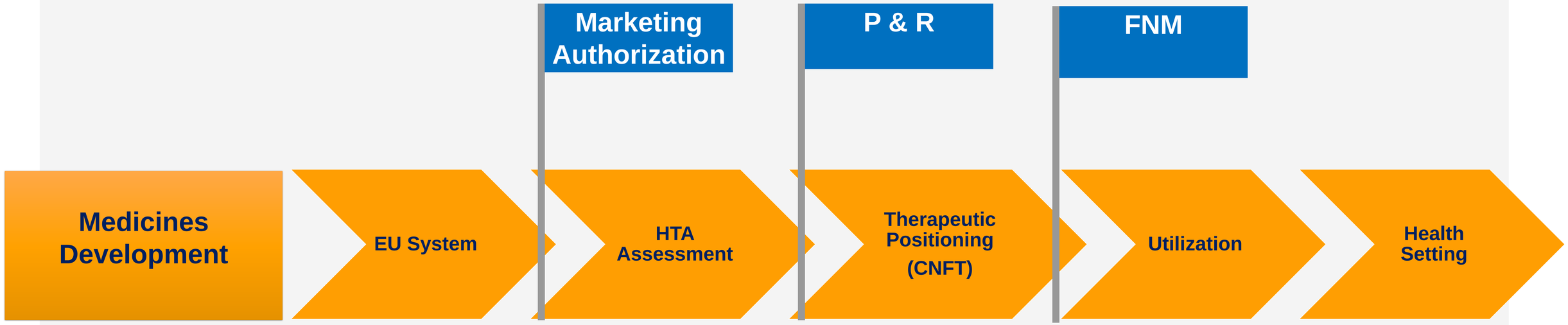
Price Negotiation

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



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THANK YOU

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