The present role and perspectives for development of economic evaluation of pharmaceuticals in Portugal

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Research of new molecules

From Investigation to Marketing Authorization:

• In average 10-12 years
• Of 3000 researched molecules: only one reaches the market
• Spenditure of 200 million USD
Market Access
Pharmaceutical System

- INFARMED
- EMA
  Quality, Safety, Efficacy

• INFARMED
  International reference prices

• INFARMED
  Effectiveness /Relative efficacy and Economic evaluation

• Industry
  Community Pharmacies/ Hospitals
  Internet
  Non-prescription points of sale

Population

Market Access
Pricing

Price Formation

Elements for medicine pricing (art. 5º, DL nº 112/2011)

Wholesaler price of sale (PVA)

Wholesaler Profit

Elements of the public price of sale (PVP)

VAT (6%)

Commercialization Tax (0.4%)
Need to assess the medicines to be financed by the Government

- Growing complexity and specificities of new medicines
- Demonstration of therapeutic added value vs alternatives and patient groups
- Harmonization of decisions at national level
- Rational use of medicines
- Efficiency in management of public resources
**Definition of value**

Value of medicine = \( f(\text{clinical impact}) + f(\text{economic impact}) + f(\text{societal impact}) \)

**Clinical Trials**

**Economic Evaluation**

**Decision / Adrecessees:**
- Payers
- Industry
- Physicians/ Hosp. Mngers
- Patients
- Society

**Pharmacotherapeutic Evaluation**

**Therapeutic Added Value**

**Economic Evaluation**

**Cost – Effectiveness**

“value for money”

**Decision proposal based on evidence**

**Efficiency**

Reaching the best results using the best resources available
Generics Policy
Generics and faster access

Generics as value generators

Government/Society have a clear:

- pressure over medicines consumption
- pressure over traditional sources of financing of medicines

Generating value and transferring it to Society in a understandable and direct way is imperative for the government in the medicines domain

Generic medicines are one of the most effective tools at present:

- Reduction of costs
- Accessibility and Equity in access to “medicines” technology

Some figures of medicines market in Portugal

<table>
<thead>
<tr>
<th>Mercado do Medicamento - 1º Semestre de 2013</th>
<th>Valor</th>
<th>Δ Hômologa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercado Ambulatório*</td>
<td>1 265 M€</td>
<td>-4,00%</td>
</tr>
<tr>
<td>Mercado Hospitalar (SNS) Hospitals NHS</td>
<td>511 M€</td>
<td>-0,50%</td>
</tr>
<tr>
<td>Mercado Hospitalar (não SNS)**Hospitals não-NHS</td>
<td>95 M€</td>
<td>***</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1 871 M€</td>
<td>***</td>
</tr>
</tbody>
</table>

* Farmácias e Locais de Venda de Medicamentos Não Sujeitos a Receita Médica
** Instituições Privadas, ARS, Hospitais Militares, PPP
*** Informação apenas disponível no final de 2014
Generics Policy
Generics and faster access

Some figures of medicines market in Portugal

Analysis of market growth of Total market – 1st semester 2013

<table>
<thead>
<tr>
<th>Medicamentos</th>
<th>Despesa ao IPV (€uros)</th>
<th>NF de embalagens</th>
<th>Preço médio de embalagem</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1º sem 2012</td>
<td>1º sem 2013</td>
<td>Var.</td>
</tr>
<tr>
<td>Não Genericos</td>
<td>1,693,503.679</td>
<td>1,031,031.229</td>
<td>-34%</td>
</tr>
<tr>
<td>Genericos</td>
<td>234,649.614</td>
<td>234,299.905</td>
<td>4%</td>
</tr>
</tbody>
</table>

Analysis of market growth of NHS market – 1st semester 2013

<table>
<thead>
<tr>
<th>Medicamentos</th>
<th>Despesa ao SNS (€uros)</th>
<th>NF de embalagens</th>
<th>Preço médio de embalagem para o SNS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1º sem 2012</td>
<td>1º sem 2013</td>
<td>Var.</td>
</tr>
<tr>
<td>Não Genericos</td>
<td>490,203,480</td>
<td>407,705,518</td>
<td>-13%</td>
</tr>
<tr>
<td>Genericos</td>
<td>118,871,587</td>
<td>117,089,150</td>
<td>-2%</td>
</tr>
</tbody>
</table>

Generics Policy
Generics and faster access

Generics market in particular

Market share of generic medicines in the NHS

In the NHS market in June
- In volume: 39,3%
- In DDD :52,4%
Main measures to stimulate the generic market growth

“GreenWay” - INFARMED reinforces generic reimbursement procedure

INFARMED reduced evaluation times for generics
“GreenWay” implemented since 15-03-2013

Main measures already implemented to stimulate the generic market growth

- **Creation of Monthly Homogenous Groups** for new generic medicines (keeping with the quarterly revision of groups already ongoing) — **estimate of NHS cost reduction 14,7M€.**

- **Publication of Order** determining that **NHS hospitals cannot commit to acquire from 2014 onwards** branded medicines, that have in its composition certain active substances or combinations. (Order 98/2013 3 april 2013, State Secretary for Health)

- **Added competences for Infarmed** to include or exclude generic medicines in the reimbursed medicines listing. (Order 6251/2013 3 may 2013; Order 98/2013 3 april 2013, State Secretary for Health, published in official journal 14 may 2013)
Some measures in study to stimulate the generic market growth

- Definition of a lower threshold from which generic medicines prices can't decrease
- Fostering the market access of generic medicines in low penetration therapeutic areas
- Fostering the market access of INNs without patent protection and without generics in Portugal
- Designing promotional and educational campaigns to stimulate consumption and to keep all the actors of the medicines chain informed

Health Technology Assessment

Objectives

1. Maximizing health gains and citizens quality of life
2. Contributing for the sustainability of the national health service
3. Guaranteeing the efficient use of public resources for health
4. Monitoring the use and effectiveness of technologies
5. Reducing waste and inefficiencies
6. Promoting and awarding relevant innovation development
7. Promotion of equitable access to technologies
Currently:

- **Technology**: Medicines

- **Evaluation before market entry** (ex-ante evaluation):
  a) Relative Effectiveness (Therapeutic Added Value)
  b) Cost–Effectiveness (Economic Value of Medicines)

- **Decisions**:
  a) Pricing
  b) Financing/reimbursement
  c) Control and cost containment

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**Health Technology Assessment National System**

- **Technology**: Medicines + Medical Devices

- **Assessment**:
  a) Relative Efficacy (Added Value)
  b) Cost–Effectiveness (Economic Value)

- **Decisions**:
  a) Price
  b) Financing/reimbursement
  c) Control and Cost Containment
  d) Risk Sharing
  e) Additional Use Monitoring

- Re-assessment of technologies on the market (ex-post evaluation)

- Participation in European model
Thank You for Your Attention