New HTA and Prices & Reimbursement system (SiNATS) in Portugal: impact on the reimbursement of oncologic medicines
Learning Objectives:

• Learn about new and innovative therapies in oncology and cancer treatment and up-to-date instruments used to assess their value.
• Learn the different models of funding for cancer treatment and the impact on access and direct costs to patients.
• Learn about the citizen’s access to therapeutic innovation.
• Discuss the mechanisms countries use to counterbalance barriers with the approval process and rising costs of new cancer treatments.

JOÃO CRISTÓVÃO MARTINS

*Head of Medicines Evaluation (Clinical trials and marketing Authorisations)*

*Acting Head of Economic Evaluation (HTA, P&R and Negotiation)*

Background training:

Pharmaceutical Sciences degree - Universidade de Lisboa
Graduation on Marketing - IPAM- Inst. Port. Administração Marketing
Hospital Administration Specialist- Escola Nacional de Saúde Pública (Universidade Nova de Lisboa)
Executive MBA on Pharmaceutical Business- Universidade Autónoma Lisboa
Advanced Studies in Public Health- Escola Nacional de Saúde Pública (Universidade Nova de Lisboa)
Agenda

1- Objectives and model
2- Involvement of patients and society
3- Patient registries
4- European collaboration
5- Impact on P&R of oncologic medicines

Investing better....
OBJECTIVES

1- To maximize health gains and citizens quality of life

2- To contribute for sustainability of the National Health Service

3- To guarantee efficient use of public resources in health

4- To monitor the use and effectiveness of technologies

5- To reduce waste and inefficiencies

6- To promote and reward relevant innovation development

7- To promote equitable access to technologies
<table>
<thead>
<tr>
<th>Old system</th>
<th>SiNATS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technology:</strong> Medicines</td>
<td><strong>Technology:</strong> Medicines + Medical Devices...</td>
</tr>
<tr>
<td><strong>Assessment:</strong></td>
<td></td>
</tr>
<tr>
<td>a) Relative Effectiveness (Added Therapeutic Value)</td>
<td>a) Relative Effectiveness (Added Therapeutic Value)</td>
</tr>
<tr>
<td>b) Cost-Effectiveness (Economic Value)</td>
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</tr>
<tr>
<td><strong>Decisions:</strong></td>
<td></td>
</tr>
<tr>
<td>a) Maximum price</td>
<td>a) Maximum price</td>
</tr>
<tr>
<td>b) Public financing/reimbursement/public hospital entry</td>
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</tr>
<tr>
<td>c) Control and cost limitation</td>
<td>c) Control and cost limitation</td>
</tr>
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<td></td>
<td>d) Risk sharing</td>
</tr>
<tr>
<td></td>
<td>e) Additional monitoring of use</td>
</tr>
<tr>
<td></td>
<td><strong>Re-assessment of technologies on the market</strong> (ex-post evaluation) – <em>New paradigm</em></td>
</tr>
<tr>
<td></td>
<td><strong>Participation in the european model</strong></td>
</tr>
</tbody>
</table>
PRICES & REIMBURSEMENT MODEL
(and health technology life-cycle)

Source: Giovanni Tafuri, Multistakeholders Workshop on Pharmaceutical Industry, Rome, 2014
MODEL

AUTHORIZATION

MEDICINES
- Quality
- Safety
- Efficacy

MEDICAL DEVICES
- Quality
- Safety
- Performance

Pricing
Assign and Review

Coding
Maximum Prices / Class

EVALUATION EX-ANTE

Technical Evaluation (regulatory)
Therapeutic Evaluation (Relative Effectiveness)
Economic Evaluation (Cost-Effectiveness)

Health Technology Assessment Committee (CATS)
- Peer Review
- Applicant hearings
- All assessors

DETECTION/CONTRACT

Inclusion/Withdraw from use listings
Maximum Price
Risk sharing
Cost Limitation
Additional Monitoring of Use
Public Tenders
Conditions of Use

EVALUATION EX-POST

Technologies re-assessment
Reports

SIATS
Monitorisation of real effectiveness

General recommendations for use
Instructions on using
AUTHORIZATION EVALUATION EX-ANTE DECISION/CONTRACT
Submission
MEDICINES
- Quality
- Safety
- Efficacy

MEDICAL DEVICES
- Quality
- Safety
- Performance

Technical Evaluation (regulatory)
Therapeutic Evaluation (Relative Effectiveness)
Economic Evaluation (Cost-Effectiveness)

Health Technology Assessment Committee (CATS)
- Peer Review
- Applicant hearings
- All assessors

Negotiation: National agency

MAXIMUM PRICE
Pricing
Assignment and Review

Negotiation

DECISION/CONTRACT
Agreement

Inclusion/Withdraw from use listings
Maximum Price
Risk sharing
Cost Limitation
Additional Monitoring of Use
Public Tenders
Conditions of Use

SIATS
Monitorisation of real effectiveness

EVALUATION EX-POST

Technologies re-assessment
Technology Priorization
Reports

General recommendations for use
Instructions on using

Assessment: Independende committee

Decision: Ministry of Health

MODEL
WORKING GROUPS - Engagement of Society
WORKING GROUPS - Engagement of Society

1- SiATS – mapping, needs (cohorts?), priorities and implementation

2- Methodological Guidelines for Economic Health Technology Evaluation Studies

3- Publication of economic studies (information types, formats, supports, deadlines...)

4- Information resulting from technology evaluation (adapting to different public)

5- Engagement of patients and stakeholders in the decision (phases, procedures ...)

6- Medical devices (differences, priorities and gradual adaptation...)

7- Orphan medicinal products (differences, registries, conditional pricing...)

(....)
Relatórios de avaliação prévia à utilização em meio hospitalar

<table>
<thead>
<tr>
<th>DCI da Substância Ativa</th>
<th>Nome do Medicamento</th>
<th>Forma(s) Farmacêutica(s)</th>
<th>Dosagem(ens)</th>
<th>Relatório de avaliação</th>
<th>Relatório da Comissão de Farmácia e Terapêutica Hospital report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abatacept</td>
<td>Orencia</td>
<td>Pó para concentrado para solução para perfusão</td>
<td>25 mg/ml</td>
<td>Relatório de avaliação</td>
<td>Relatório CFT</td>
</tr>
<tr>
<td>Acetônido de fluociclona</td>
<td>Buven</td>
<td>Implante intratéreo em aplicador</td>
<td>100 µg</td>
<td>Relatório de avaliação</td>
<td>Relatório</td>
</tr>
<tr>
<td>Agente 5-aminolevulinico</td>
<td>Gilelan</td>
<td>Pó para solução oral</td>
<td>1,5 g</td>
<td>Relatório de avaliação</td>
<td>Relatório</td>
</tr>
</tbody>
</table>

### Relatório de Avaliação Prévia do Medicamento para Uso Humano em Meio Hospitalar

**DCI - Acetônido de Fluociclona**

<table>
<thead>
<tr>
<th>N.º Registo</th>
<th>Nome Comercial</th>
<th>Apresentação/ Forma Farmacêutica/Dosagem</th>
<th>PVA</th>
<th>PVH com IVA</th>
<th>Tipo de Ação</th>
</tr>
</thead>
<tbody>
<tr>
<td>54349128</td>
<td>Buven</td>
<td>100 µg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fonte: INFARMED

**Avaliação Económica, Preços e Comparticipação**

Source: INFARMED

http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AVALIAACAO_ECONOMICA_E_COMPARTICIPACAO
COMUNICATE BETTER- Engagement of Society

Health technology assessment (HTA) of public access defibrillation

1 December 2014

Source: HIQA Ireland - Dra Mairin Rian (HTA).
Good example from Ireland on how to communicate with society
Involvement of Society, Patients and other Stakeholders

Activities:
- Mapping the Portuguese patients associations (associations registry)
- How to integrate the engagement of patients and other stakeholders (procedures and training for advocates)
- Main constraints on participation: identification and solving proposal

Source (figures): Nicola Bedlington; Innovative systems and health horizons; Milan, 2014
SiATS – Information System for HTA (patient registries and data monitoring sources)

Patient registries (priority):
1- Oncology (national oncologic registry)
2- HIV/AIDS
3- Rare Diseases/Orphan Med Products
4- Medical Devices (Cardiology)
5- Hepatitis C (already in use)
SiATS – Monitoring Registries

- Clinical development
- Market entry
- Real world effectiveness and safety
- Further regulatory/policy actions

- Early dialogue/scientific advice
- Conditional Reimbursement (MEAs)
- Monitoring Registries
- Re-assessment

Risk-sharing monitoring
Re-assessment (RWD: Real world data)
Risk Sharing agreements

Based on clinical factors (performance-based)

Based on financial factors

Risk sharing schemes

Participation on the European model

Source: EUnetHTA (core model)
European Commission (documents)

Transport Model

Tools

(a) The HTA Core Model (important for Joint Assessments Reports and national/regional assessment reports)
(b) Submission templates (important for Joint Assessments Reports and national/regional assessment reports)
(c) Methodological standards for HTA
(d) Training material
(e) ICT tools (including databases, web-based solutions etc.)

Support of (initial and additional) Evidence Generation initiatives appropriate for HTA purposes
(a) Early-Dialogues
(b) Coordination of additional evidence generation
«(...) Launched a National Health Technology Assessment System, advanced basis of evidence NHS, that the study recommends.»

Health Minister (Launch of the report “The Future for Health – Everyone has a role to play”, 23 September 2014)

3. **NHS-EVIDENCE.** The NHS-Evidence will be a new body that will combine the existing standards of clinical guidance with new processes for the assessment of new technologies and therapies, ensuring that the system provides, always updated and critically, the best available scientific knowledge (scientific evidence). This body shall disclose their deliberations and outcomes available among citizens for those, as well as physicians and other health professionals, may know such evidence.
IMPLEMENTATION:

- Gradual

- Participation and engagement of society

- In adaptation and continuous improvement

Social debate: *Added value for the society and for the NHS*
Impact on the reimbursement of oncologic medicines:

- Value for money
- Price negotiation
- Risk sharing agreements (financial and performance-based)
- Clinical guidelines (use and prescription)
- Effectiveness monitorization on patient registries (real world data)
- Value reassessment (ex-post evaluation)
References:

Portuguese NHS reform report:
http://www.gulbenkian.pt/Institucional/en/Activities/ProgrammesAndProjects?a=4119

European HTA documents:
http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/SINATS/GUIDE
http://www.eunethta.eu/eunethta-guidelines
http://meka.thl.fi/htacore/BrowseModel.aspx
http://www.eunethta.eu/
http://eprints.lse.ac.uk/50513/1/ Libfile_repository_Content_Ferrario,%20A_Ferrario_Managed_%20entry_%20agreements_2013_Ferrario_Managed_%20entry_%20agreements_2013.pdf

Stakeholders working groups for the implementation of SiNATS:
http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES/sinats.PDF
http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES/sinats.PDF

(2015/08/07)
Thank you

Please see also:

www.infarmed.pt
http://m.infarmed.pt

https://twitter.com/INFARMED_IP
http://www.linkedin.com/company/infarmed