ISPOR 18th Annual European Congress

Highlights

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ISPOR 18th Annual European Congress, Milan
10 November 2015

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ISPOR 18th Annual European Congress

- 7-11 November 2015
- Milano Congressi, Milan, Italy
- Congress featured 2,450 presentations
- Over 5220 attendees from 90 countries

Payers, health technology assessment (HTA) and regulatory leaders, patient and industry representatives, and key decision makers discussed the New Medical Device Regulation in Europe as well as the work underway within the Adaptive Pathways to Patients initiative for drugs.

The panel presented candid views on adaptive pathways as the preferred approach to developing, licensing, assessing, appraising, and paying for new medicines and treatments.

This session also examined the European Commission's HTA network plans following the transition of the successful EUnetHTA program, which built strength and dialogue both across Europe and globally.
The motion: What happened in the last 5 years?

Scientific advice (SA) - Early Dialogues (ED)
- 2009 individual HTA bodies (NICE and others)
- 2010 EMA + Individual involvement of some HTA bodies (EMA HTA parallel advice)
- 2012: Launch of EUnetHTA Early Dialogues (ED): cooperative advice from multiple HTA bodies
- 2014: Launch of the SEED project multiple HTA ED (HTA only or in parallel with EMA
- ED for medical devices in EUnetHTA and SEED projects
Scientific advice by HTA bodies: objectives

To help product developers generate the evidence which is relevant for future evaluation of the product by HTA bodies

- Robust evidence
- Access for patients
- Uncertainty
- Delay in decision-making

Adapted from NICE
Two dimensions of collaboration

- Across sequential decision makers: regulators, HTAs, payers, policy makers, prescribers, ...

- Across member states: evidence standards, co-steering R&D, assessments, data- (or at least experience) sharing
Access to health technologies... an EU issue?

Council conclusion IT presidency
Mapping on issues to market

HTA only? No way; is part of the overall question of market access and uptake/ disinvestment of health policies.
Which means integration of HTA upwards with regulators and downwards with decision makers
Jerome Boehm
Directorate-General for Health and Food Safety, European Commission

Map on 'decision-making' to Innovative medicines

The 'decision making' course

Development of Therapy
- Clinical Trials Legislation: Dir. 2001/20/EC, Reg. EU S36/2014
- Pharmacological Assessment: Dir. 2001/83/EC, Reg. (EC) 726/2004, etc.
- EMA Committees
- Horizon 2020 Scientific Panel for Health (SPH)
- Active and Healthy Ageing / IMI

Authorization Assessment/Therapeutic value
- Pharmaceutical legislation: Dir. 2001/83/EC, Reg. (EC) 726/2004, etc.
- Cross Border Directive
- EMA Committees
- Pharma Committee (STAMP)
- HTA/ Cost-effectiveness value
- HTA Decision 2013/328/EU
- EUnetHTA
- HTA Competent Authority
- EUnetHTA / payer on MSA clinical protocols

Pricing & Reimbursement / Agreements / Procurement
- Decision 1082 (2013) / JPA
- Committee for JPA
- Competent Authorities for market, trade
- National Medicines Organizations
- Decision on Pricing, Ministries of Health or finance

Market (exclusivity)
- Transparency Directive
- Pharmaceutical legislation including rules on Pharmacovigilance and Falsified
- Internal Market Rules
- PRAC Committee
- Competition Network on Pharma
- Network of CAFR
- D6 GROW Staff Working Document on the Pharmaceutical Industry & Process on Corporate Responsibility in the Pharma Sector (ended 2013)
- D6 SANTE Communication on "Effective, Accessible and Resilient Health Systems" & Studies under the Health Programme
- MS Voluntary Initiatives / Bilateral cooperation / Price or volume Data Bases

Other initiatives EU funded
- Other MS cooperation
- EU Legislation / Decisions
- Regulatory Committees
- EU Expert Groups / Networks

28 Member States, National Level
- National Legislation and National Medicines Organizations, decentralized authorities
- HORIZON Scanning activities?
- Early dialogue initiatives?
Where we should be in 2020?

*Upgrade of actors and stakeholders*

- HTA capacity in all MS, health prof. and patients
- Trust in sharing work and expertise; joint national/ EU teams in place for EU assessments
- Transparent dialogue between promoters/ regulators/ decision makers
- Transparent provisions for reuse at national level
- Self-sustainable cooperation in place

*Type of production: BE CUSTOMERS/ USERS ORIENTED*

- Well established IT tools
- Rapid assessments of single technologies
- Reassessments: integrated post market surv.
- Parallel scientific advices
- Joint input to coverage evidence schemes
Common challenges

Challenges for MS

- Legal and organisational impact: scoping, processing of HTA
- Need for effective and conclusive reports without interfering national competence
- HTA truly guiding payers and payers not bypassing HTA's

Challenges for companies

- Risk taking
- Coherence of goals: defragmentation of markets or not?
- Internal organisation
Finn Børlum Kristensen
EUnetHTA Secretariat

Scope of EUnetHTA’s work

EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through

• facilitating efficient use of resources available for HTA
• creating a sustainable system of HTA knowledge sharing
• promoting good practice in HTA methods and processes
Finn Børlum Kristensen
EUnetHTA Secretariat

The Domains of the HTA Core Model®
- assessing dimensions of value

HTA Core Model DOMAINS

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects

Value

Reliable, timely, transparent, information

Comprehensive
Full HTA
Rapid REA
The POP Database

Description
The EUnetHTA Planned and Ongoing Projects (POP) database allows EUnetHTA Partners and Associates to share information on planned, ongoing or recently published projects of participating agencies and identify similar projects through a matching system provided by the online database.

Purpose
To facilitate collaboration among European HTA agencies and reduce duplication of work.
14 Methodological Guidelines for HTA and Rapid Relative Effectiveness Assessment

Development
9 Methodological Guidelines for Rapid REA of Pharmaceuticals developed in JA1 and revised in JA2 to include medical devices plus 5 new for HTA

Content
Guidelines on methodological challenges that are encountered by health technology assessors while performing a rapid relative effectiveness assessments and HTA

Primary Aim
To help the assessors of evidence interpret and process the data that are presented to them as part of an HTA.
Mirella Marlow, 
Devices and Diagnostics Systems, NICE

Characteristics of medical technologies

• Regulation does not require high level of clinical evidence
• Rapid iterations and new versions
• Operator learning curve
• Disruptive to services
• First in class and fast followers
• Lack of price transparency
• Implementation hurdles

In 2010, NICE set up bespoke programmes of activities for evaluating and supporting research in medical devices and diagnostics
Commissioning Through Evaluation (1)

- Coverage with evidence development in England
- 6 schemes (5 involving implantable or other medical devices)
- Contracts let for specified period with limited no. of centres
- NICE oversees evidence development process
- Contract payment depends on data submission
- Data analysis based on registers, published evidence and modelling
In the last four decades, the assessment of outcomes has been moving from the mere ground of research into daily practice.

The session provided researchers and policy makers with an update on current practices, challenges, opportunities, and future perspectives on the assessment of outcomes in different fields of health care:

- reimbursement of drugs and devices,
- evaluation of public health interventions,
- validation of new technologies
- financing of complex health services.
The regulatory challenge

- Countries are facing:
  - Limited general financial resources
  - Increasing costs in healthcare budgets
  - High-cost therapies

- How to cope with uncertainty when deciding on pricing and reimbursement?

- What is the cut-off to be considered between therapeutic utility of a new medicine and its major cost?

- How can we make difficult decisions in the absence of ideal information?
Uncertainty of payers related to new technologies

- efficacy
- effectiveness (adherence and persistence)
- relative effectiveness to competitor technologies
- risks (e.g. rare serious adverse events)
- surrogate outcomes → hard endpoints
- cost-effectiveness
- number of patients (eligible patients + market penetration)
- risk of off-label use (i.e. inappropriate targeting; longer therapy; etc.)
Answer to uncertainty of payers: risk-sharing (1)

- **efficacy**
  - outcome guarantee

- **effectiveness**
  - Manufacturer-funded treatment initiation – probation period
  - conditional treatment continuation

- **relative effectiveness**
  - coverage only with research - patient registry funded by manufacturers

- **rare serious adverse events**
  - coverage only with research - patient registry funded by manufacturer
Answer to uncertainty of payers: risk-sharing (2)

- surrogate outcomes
  - coverage only in research

- cost-effectiveness
  - revision of previous policy decisions (coverage only with research)

- number of patients (eligible patients + market penetration)
  - mandatory budget impact analysis
  - price-volume agreement

- risk of off-label use (i.e. inappropriate targeting; longer therapy; etc.)
  - financial risk-sharing based on market share
  - utilization cap
A Managed Entry Agreement is an arrangement between a manufacturer and payer/provider that enables access to (coverage/ reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize effective their use, or limit their budget impact.¹

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**Managed Entry Agreements**

*What principles should govern the use of MEAs?*

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**Financial**

- **Goal:** Distributes financial risk for drug between manufacturer and payer, regardless of the drug’s clinical performance (i.e., fixes payer expenditure)
- **Examples:** Cap on drug utilization or spend (either on a population or individual patient basis)

**Performance**

- **Goal:** Distributes risk associated with the drug not performing as expected between payer and manufacturer (i.e., payers only pay when drug is effective)
- **Examples:** Payment conditional upon patient achieving key clinical outcome

**Value-add**

- **Goal:** Adds additional value to a contract in order to support the price of the drug itself
- **Examples:** Provision of services such as support and education programs for patients taking the manufacturer’s drug

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¹ Klemp M. et al. 2011 – “What principles should govern the use of managed entry agreements?”

Performance-based Scheme Components by Country

Total Schemes: 259

CED: Coverage with evidence development; CTC: Conditional treatment continuation; PLR: Performance linked reimbursement; FU: Financial or utilization based agreements

*Note: Many schemes had multiple performance-based components

Source: UW PBRSA Database
Italian Experience: Managed Entry Agreements

Refusal
- Reimbursement (without conditions)

Managing budget impact
- Managing uncertainty relating to clinical benefit and cost-effectiveness.
- Managing utilisation to optimize performance

Non-Outcome based MEAs
- Volume Agreements
- Cost sharing
- Budget cap

Monitoring Registers
- Oncologicals
- Orphans
- Psoriasis
- Antidiabetics
- Cardiovascular
- Antireumatics

Outcome based MEAs
- Payment by Results
- Risk Sharing

Therapeutic plan
- AIFA Notes
Italy Results

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<td>Total Schemes Implemented</td>
<td>68</td>
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<tr>
<td>Active</td>
<td>53</td>
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<td>Revised</td>
<td>9</td>
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![Graph showing time to access in Italy](image)

- By Year
- Cumulative

A mean shortening of 256 days

Garrison et al., ISPOR, 2015
Managed entry agreement forces clinicians to focus on patient outcomes
Evolution of MEAs over time

The field is evolving from financial towards outcomes based schemes

Source: International experience with innovative price scheme – Specific case studies - M. Marchetti November 25th, 2013

Note: Setting of the price will be in line with applicable laws and regulations
Italian reimbursement landscape

- The AIFA Registry was set up on December 2005 and published online on April 2006
- The registration of the patients in the AIFA Registry is mandatory to get the reimbursement of the drug by NHS
- The first drug with MEA included in the Registry was Tarceva (erlotinib)

Purpose of the Registry

1. Monitoring appropriate use of drugs according to approved therapeutic indications
2. Assessing and tracking patient eligibility
3. Evaluating utilisation in clinical practice
4. Collecting epidemiological data including safety profile
Indications and Drugs registered in the AIFA system

The majority of drugs being monitored have MEAs in multiple indications

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<th>Drugs</th>
<th>Indications</th>
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<th>Oncology indications</th>
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<th>Oncology indications with MEAs</th>
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<th>Oncology indications without MEAs</th>
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<th>Off-label indications by law 648/96</th>
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Counts

Most drugs are monitored within multiple indications

Half of the indications account for Oncology

Registries are also used to monitor appropriate usage

Note: The AIFA Registry doesn't allow the off label use of a drug (with the exception of the indications approved by AIFA for an off label use accordingly to the Law 648/96). The physicians can prescribe the drug for an off label indication without reimbursement by NHS after receiving the approval from the hospital and the informed consent from the patient. NO DATA AVAILABLE TO COMPARE THE APPROPRIATE USE OF DRUG BEFORE AND FATER THE AIFA REGISTRY.

Traditional drug licensing approaches

License

- Patients treated, no active surveillance
- Patients in observational studies, registries, etc
- Patients in RCTs (or other interventional studies)

Number of patients treated

Time (years)
Adaptive licensing scenario

Number of patients treated

Time (years)

Initial license

“Full” license
From the perspective of Pharmaceutical company

- Since in the medium-long term, the health care systems cannot sustain the incremental costs of pharmaceutical expenditure, a new overall business model should be considered.

- The business model in the pharmaceutical companies is always the same, today the only difference respect to the mee-too era is an extreme segmentation of the market.

- A transparent definition of medicine’s price from the pharmaceutical company should be solicited and welcome.
1. Let’s change the conversation from Patient Reported Outcomes to Patient Important Outcomes.

2. Early dialogue between manufacturers and the HTA/Payer community is essential.

3. Evidence generation needs to reflect the real world.
HTA agencies inform technology-related decision-making in health care.

Across the lifespan of a technology

- Early HTA
- Adoption
- Ongoing assessment
- Appropriate Use
- Disinvestment
How CADTH Engages Patients

- Public/patient members sit on Board and committees
- Patient groups provide input to drug and device reviews
- Patient input to early dialogue with industry
- Patient Liaison Forum with umbrella patient groups
- Annual broad consultation sessions
Message 2: Early dialogue between manufacturers and the HTA/Payer community is essential.

- Pre-phase 3
- Joint or parallel with regulator
- To discuss issues of importance for market access
  - Outcomes
  - Comparators
  - Quality of life measures
  - Economic model
Message 3: Evidence generation needs to reflect the real world

**Drugs**
- Adaptive pathways
- Real world evidence generation

**Devices**
- Post-market safety and effectiveness evidence generation
Medicines Adaptive Pathways for Patients – Is this the Future?

- Moving from binary decision-making to iterative approach.
- Earlier approval and coverage for limited populations.
- Indications broadened as evidence develops.
- Earlier access to promising therapies.
Mario Strazzabosco, Yale University

Value-Based Competition Can help Health Care Sustainability while Improving Outcomes
-The Case for Value Based Medicine-

Michael E. Porter
Elizabeth Olmsted Teisberg

Redefining Health Care
Creating Value-Based Competition on Results

VALUE = LONG-TERM OUTCOMES / COSTS
"you cannot manage ... what you do not measure"

"in God we trust, all others must show data"
Multi-criteria decision analysis (MCDA) is an emerging new practice using a broad set of methodological approaches to assist in decision making, especially in an era of expensive but valuable technologies trading multiple criteria.

The ISPOR MCDA Task Force Report discussed different approaches for conducting MCDA.

Panelists presented emerging good practice recommendations presented in the Task Force report and identified remaining areas of controversy.
Belton and Stewart
“An umbrella term to describe a collection of formal approaches which seek to take explicit account of multiple criteria in helping individuals or groups explore decisions that matter”

Keeney and Raiffa
“An extension of decision theory that covers any decision with multiple objectives. A methodology for appraising options on individual, often conflicting criteria, and combining them into one overall appraisal”
How MCDA implementation can help in CEE countries?

- MCDA: comprehensive approach to improve the evidence base and **transparency** of policy decisions related to health technologies.
- Budget impact is only one aspect which should be taken into account in decision making.
- MCDA implementation helps:
  - Policymakers – objective and verifiable criteria for policy decisions.
  - Society and patients – less resources are sacrificed for inappropriate health care services and technologies.
  - Health care manufacturers – clear criteria for market access.
How is MCDA Being Used In Health Care?

**British Columbia:** The HTA Committee uses MCDA to assess non-drug health technologies.

**IQWiG:** 2 types of MCDA “can contribute to determining the most important outcomes for patients as part of economic evaluation”

**EMA:** “MCDA is valuable, providing clarity, particularly where the benefit-risk balance is uncertain”

**Hungary:** MCDA has been used to evaluate new hospital medical technologies since 2010.

**Thailand:** MCDA used to inform coverage decisions for HIV/AIDS interventions.

**Italy:** Lombardy introduced MCDA in 2008 to decide on the introduction and delisting of health technologies.
## Steps in MCDA

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision problem</td>
<td>Problem structuring to establish the decision problem i.e. identify objectives, alternatives and decision makers</td>
</tr>
<tr>
<td>Identify criteria</td>
<td>Identify value criteria relevant to the decision problem</td>
</tr>
<tr>
<td>Measure performance</td>
<td>Gather evidence on the performance of the alternatives on the criteria</td>
</tr>
<tr>
<td>Performance scoring</td>
<td>Convert performance measures into scores that describe the desirability of achieving different levels of performance for each criterion</td>
</tr>
<tr>
<td>Weight criteria</td>
<td>Elicit the opinions of the stakeholders on the relative importance of different criteria or their preferences for criteria.</td>
</tr>
<tr>
<td>Aggregation</td>
<td>Combine or ‘aggregate’ criteria scores and weights to estimate the overall value of an option</td>
</tr>
<tr>
<td>Supporting decision making</td>
<td>Use the outputs from the MCDA exercise to support decision making</td>
</tr>
</tbody>
</table>
Diversity in MCDA

How these are done differentiates the MCDA methods
Implementation of MCDA

Questions regarding development of MCDA

- *Selection* of criteria
- *Weighting* of each criterion
- *Scaling* of each criterion

Application of MCDA

- One-off or reusable model
- Rule vs. Tool
# Example: potential elements of an MCDA tool for orphan drugs

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Indication uniqueness</td>
<td>Number of approved indications of the active substance</td>
</tr>
<tr>
<td>Therapeutic alternative (unmet need)</td>
<td>Availability of alternative treatment options for given target group</td>
</tr>
<tr>
<td>Availability and quality of scientific evidence for clinical effectiveness</td>
<td>Credibility and robustness of clinical evidence</td>
</tr>
<tr>
<td>Disease rarity</td>
<td>Prevalence of the condition</td>
</tr>
<tr>
<td>Disease severity</td>
<td>Disease prognosis without treatment</td>
</tr>
<tr>
<td>Advancement of technology</td>
<td>Treatment innovation (new mechanism of action + improved patient outcome)</td>
</tr>
<tr>
<td>Manufacturing technology complexity</td>
<td>Manufacturing process requirements</td>
</tr>
<tr>
<td>Safety and adverse effects</td>
<td>The impact of drug treatment on a patient’s health and comfort as a result of reducing adverse events (safety profile)</td>
</tr>
<tr>
<td>Budget impact</td>
<td>The impact on public payer budget</td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>ICER</td>
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</tbody>
</table>

Ref: Kolas K, Zwolinski K M, Hermanowski T, Kalo Z. manuscript in submission, 2015
# Hungarian Multiple Criteria Point System for Hospital Technologies

<table>
<thead>
<tr>
<th>I</th>
<th>Health Care Priority</th>
<th>20 point</th>
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<tbody>
<tr>
<td>I.1.</td>
<td>Public Health Programme</td>
<td>6 point</td>
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<tr>
<td>I.2.</td>
<td>Health Policy priorities</td>
<td>7 point</td>
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<tr>
<td>I.3.</td>
<td>Aggregated health gain of population</td>
<td>7 point</td>
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<table>
<thead>
<tr>
<th>II.</th>
<th>Severity of disease</th>
<th>15 point</th>
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<tbody>
<tr>
<td>II.1.</td>
<td>Life-threatening acute disease</td>
<td>13-15 point</td>
</tr>
<tr>
<td>II.2.</td>
<td>Life-threatening chronic disease</td>
<td>10-12 point</td>
</tr>
<tr>
<td>II.3.</td>
<td>Non life-threatening acute disease</td>
<td>8-9 point</td>
</tr>
<tr>
<td>II.4.</td>
<td>Non life-threatening chronic disease</td>
<td>6-7 point</td>
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<tr>
<th>III.</th>
<th>Equity</th>
<th>15 point</th>
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<tbody>
<tr>
<td>III.1.</td>
<td>Size of patient population (i.e. rare diseases)</td>
<td>8 point</td>
</tr>
<tr>
<td>III.2.</td>
<td>Accessability</td>
<td>7 point</td>
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<tr>
<th>IV.</th>
<th>Cost-effectiveness, QoL benefit</th>
<th>30 point</th>
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<tbody>
<tr>
<td>IV.1.</td>
<td>ICER</td>
<td>15 point</td>
</tr>
<tr>
<td>IV.2.</td>
<td>QALY gain per patient</td>
<td>15 point</td>
</tr>
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<tr>
<th>V.</th>
<th>Aggregated budget impact</th>
<th>10 point</th>
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<tr>
<th>VI.</th>
<th>Local and National professional opinion</th>
<th>10 point</th>
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<tbody>
<tr>
<td>VI.1.</td>
<td>Opinion of Professional College</td>
<td>3 point</td>
</tr>
<tr>
<td>VI.2.</td>
<td>International guidelines</td>
<td>3 point</td>
</tr>
<tr>
<td>VI.3.</td>
<td>Level of scientific evidence</td>
<td>4 point</td>
</tr>
</tbody>
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**Total** | **100 point**
National Cancer Drugs Fund Prioritisation Tool in England

- **Progression Free Survival**
  - range: <2 months = 0 point to >12 months = 7 points

- **Overall Survival**
  - range: <2 months = 0 point to >12 months = 7 points

- **Quality of life**
  - range: significant improvement = 2 points to deterioration in QoL = -2 points

- **Toxicity compared to the existing active standard therapy**
  - range: significant improvement = 2 points to significantly worsened = -2 points

- **Degree of clinical unmet need**
  - range: No alternative treatment = 3 points to alternative active standard treatment exists = 0 points

- **Cost per QALY – if available**
  - range: £30-40,000 = 2 points to >£80,000 = -2 points

- **Cost**
  - range: superior efficacy and cost saving compared to currently used alternative = 3 points to no QALY calculation and increased costs = 0 point

- **Strength of Evidence**
  - range: two or more good quality published Phase III RCT to unpublished data (e.g. in abstract)
Policy Forum on off-patent medicines

- What is healthcare system efficiency framework? Lesson learn for good IRP practice and EU tender directive

- Diverse definition, bioequivalence and quality standard, what does it mean in real life for HCPs and patients?

- Drug policy challenges in Emerging Markets

- Would MCDA be a good vehicle to design resilient drug policies in Emerging Markets?

- MCDA parameters for off-patent products
Objectives of generic drug policies

- Not only cost-savings

The objective of the generic drug policies can be approached from two aspects:

- *Disinvestment aspect*: Reduce health care expenditure without compromising health outcomes

- *Investment aspect*: Increase population health gain by improved patient access without increasing health expenditure

Potential impact of mandated regular switch on outcomes of generic drug policy

Success criteria of generic drug policies

- reduced health care expenditure
- equal or improved health outcomes (effectiveness)

- generic price erosion
- Increased market share of generic drugs
- reliable supply of preferred generic products
- no switch to other patented drugs to prevent pharmacy substitution
- no increase in the utilization of health care services
- bio- and clinical equivalence at registration
- constant product quality
- maintained adherence & persistence
- improved patient access to therapy

Need for Multicriteria Evaluation of Generic Drug Policies