HTAi Policy Forum Discussion on HTA, Coverage and Regulatory Processes: relevance to the Green Park Collaborative

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Parallel Panel Discussion on HTA-Payer Methods Guidance and the Green Park Collaborative, HTAi Annual Meeting, Rio, 27 June 2011

Content of Presentation

- HTAi Policy Forum
- Aim of the January 2011 meeting
- Regulatory approval, coverage and HTA
- International Coordination
- Goals of improved interaction
- Opportunities for improved interaction to benefit patients
- Concluding remarks

HTAi Policy Forum

- Provides a unique opportunity for senior people from public and private sector organizations with strategic interests in HTA to meet one another, members of the HTAi Board, and invited international experts, for strategic discussions about the present state of HTA, its development and implications for health care systems, industry, patients and other stakeholders.
- Membership is by application. Each year, HTAi issues a call for Expressions of Interest in joining the PF. Decisions on membership are made by the HTAi Board of Directors on the advice of the Policy Forum Committee
- The discussions are widely disseminated to HTAi members and more widely through published papers, presentations at HTAi Annual Meetings, other HTAi events, and meetings of related societies and groups

Papers from HTAi Policy Forum meetings

- Published in *International Journal of Technology Assessment in Health Care* and freely accessible at www.htai.org
  - ***What principles should govern the use of managed entry agreements?*** (deliberations of 2010 Forum)
  - ***HTA to optimize health technology utilization: using implementation initiatives and monitoring processes*** (deliberations of 2009 Forum)
  - ***Harmonization of evidence requirements in HTA for reimbursement decision-making*** (deliberations of 2008 Forum)
  - ***Coverage with evidence development: an examination of conceptual and policy issues*** (deliberations of 2007 Forum)
- **Forthcoming**
  - ***Interactions between HTA, coverage, and regulatory processes: Emerging issues, goals, and opportunities*** *(deliberations of 2011 Forum)*

Aims of the meeting in January 2011

There is increasing interest in interactions between HTA, coverage and regulatory processes and bodies. The Forum meeting aimed to identify:

- **Goals of improved interactions** – what's driving all this and what are we trying to achieve?
- **Principles that should underlie interactions** – how should we go about it?
- **Challenges** – what's going to get in the way and how can we address these challenges?
- **Opportunities** – what can we do – in the short and longer term - to achieve the goals of improved interactions

Regulatory approval, coverage and HTA

	Regulation	HTA	Coverage
Role	Give market authorisation	Support for clinical and coverage decisions	Decide on coverage or reimbursement
Decision	Do the clinical benefits for patients outweigh the risks? Is quality of production assured?	[HTA supports decisions, taking into account clinical, organizational, ethical, legal, financial dimensions]	Are the expected health benefits useful and affordable?
Evidence	Efficacy and safety from trials; post launch surveillance; QA of production systems	Effectiveness, cost effectiveness and opportunity costs from trials and other studies pre and post launch, and modelling	As for HTA; conditional coverage may be used to improve evidence base for re-appraisal

International coordination

- **Regulation of pharmaceuticals is coordinated formally internationally through:**
  - International Committee for Harmonisation
  - The European Medicines Agency (for EU Member States)
- **There is increasing work to improve international coordination of HTA through**
  - International societies, esp. HTAi and ISPOR (International Society for Pharmaceuticals Outcomes Research)
  - The international Network of Agencies for HTA (INAHTA)
  - The European Network for HTA (EUnetHTA)
  - EuroScan (international network of agencies for assessment of emerging technologies)
- There is no formal coordination of coverage bodies' work, but there is informal contact & attendance by senior staff at global meetings (e.g. HTAi and the HTAi Policy Forum)

Improving Interactions: Goals

- Speed patient access to valuable products
- Remove unnecessary barriers to successful development and appropriate market access for innovative products
- ***Give manufacturers greater clarity about what evidence is required by which bodies and when***
- Improve alignment of the timing and logistics of processes where appropriate
- ***Align methodological guidance and data requirements for establishing safety, efficacy, effectiveness, and comparative efficacy and effectiveness in so far as necessary and possible, and to be clear why requirements differ when they do***
- Give patients and the public better understanding of the reasons for decisions by regulators and coverage bodies, especially where these differ

Opportunities for improved interaction include

1. Develop **joint scientific advice** from regulatory/HTA/ coverage bodies **for industry** on the design of pre- and post-market evaluations (e.g., phase II/III/IV studies) for **specific conditions**, including such matters as appropriate comparators, outcome measures, study populations and subgroups

2. In parallel with condition-specific advice, develop **joint scientific advice** from regulatory/HTA/coverage bodies **for industry** on the **general design of pre- and post-marketing evaluations** (e.g., phase II/III/IV studies) to maximize their value to regulators, coverage bodies, clinicians and patients, covering, eg: **inclusion criteria; subgroups; patient cross-overs in trials; general principles underlying choice of comparator; primary and secondary endpoints, surrogate and patient/clinically relevant outcome measures, QoL measures; relating trial populations to wider populations (e.g., to enhance power of phase IV population studies)**

Conclusions

- It is important that coverage/payer bodies and associated HTA bodies and processes make their evidence requirements clear, prior to the design of studies by manufacturers and/or public funders
- There is need to do this both for general methodological issues and for condition specific issues
- Advice and guidance for manufacturers from regulators already exists. Payers requirements are not the same, but payers should work with regulators and if possible develop jointly owned combined guidance
- The Green Park Collaborative is an important first step in this direction