



Workshop on

Understanding HTA and Coverage Decision-Making Processes:

The key to facilitating transparent access to medicines

28 & 29 September 2011

Woodlands Park Hotel, Cobham, Surrey, UK



Workshop Prepared By

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Date and Venue:

The workshop will be held at the Woodlands Park Hotel, Surrey commencing at 09:00 on Wednesday 28 September and finishing with lunch on Thursday, 29 September, 2011.

Style and Participation:

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation to maintain a size that encourages neutral environment that promotes productive dialogue and networking. We aim to advance the debate and discussion around the subject of the workshop and to produce constructive recommendations based on the workshop activities.

To help achieve this we apply the Chatham House Rule as follows: all formal presenters are identified in Workshop material and following the Workshop, a synopsis of their presentation is prepared by CIRS for inclusion in summary and full meeting reports. Participants receive PDFs of slides provided by the speakers; further, speakers are asked to verify the content of the synopsis prior to publication. Open discussion and also discussions that form part of Syndicate groups are summarized but not attributed, to encourage open exchange.

Please contact Gill Hepton at ghepton@cirsci.org for further information and a registration form.

Understanding HTA and coverage decision-making processes: the key to facilitating transparent access to medicines

Background

In general, most countries share a similar goal of wanting to improve their population's health by providing medicines that are safe and effective. For new medicines, most countries take a broadly similar approach whereby the first requirement for access to the population is market authorisation, obtained from the regulatory authority, based on the criteria of safety, efficacy and quality. Following market authorisation, a coverage decision is often required to determine whether a medicine will be reimbursed. Increasingly, Health Technology Assessment (HTA) is being used to evaluate new medicines and to inform coverage decision making about the added benefit to population covered and sometimes also whether the new medicine represents value for money. Although the overall process leading to market access is similar, at more granular level, considerable differences exist between countries in the processes and requirements for decision making leading to inefficiencies in resource sharing, decision making and impacting upon the drug development process and availability of access to patients.

While the technical requirements of international regulatory authorities are broadly similar, due to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), their review and approval processes can differ substantially. However, clarity of these processes has enabled the identification of common elements which has in turn provided the regulatory agencies with the ability to compare and learn from each other and additionally has enabled at least some of these agencies to become relatively predictable in their time to approval and decision making.

By contrast, there is considerable diversity between countries in the requirements of, the processes for, and the extent of transparency in, HTA appraisal and coverage body decision making. At present there is increasing interaction between different HTA agencies in order to better align their requirements and methodologies and also between regulatory agencies, HTA and coverage bodies in terms of defining how to measure relative efficacy, how to provide shared early advice and otherwise co-ordinate their activities. The diversity of process and transparency represents a challenge to agencies as they try to learn from one another's strengths and capabilities and in addition hinders understanding and trust between the all the stakeholders involved.

Therefore, we believe that it is the right time to examine how to improve the transparency and understanding of the HTA and coverage processes in different healthcare systems and from this to determine how to compare these processes in such a way that meaningful learning's can be had.

This workshop therefore addresses the question that given that the diversity in the processes of HTA evaluation, coverage decision making and reimbursement between countries, *how can such different systems be compared?*

The objectives of the workshop are:

- 1) **To determine if the different HTA and Coverage systems are comparable.** *For comparisons to be valid it is important to know on what basis they are made and to understand that the HTA and Coverage bodies operate within very different frameworks. Can a systematic approach to mapping the processes from regulatory approval to reimbursement provide an understanding of where each process fits into the organizations and health-care systems, the nature of the organizations and hence the meaningfulness of cross comparisons.*
- 2) **To ascertain if there is value in developing HTA-related industry benchmarking.** *Companies routinely use internal targets to drive performance but can comparison between companies in terms of the inclusion of HTA requirements into clinical development and the outcome on the following roll-out be used to provide an understanding of the influence of HTA on development plans and rollout? Can such benchmarking provide insight into predictability of time or success across jurisdictions?*
- 3) **To ascertain if there is value in developing performance indicators for HTA- and Coverage bodies.** *Such indicators could be used for the purpose of measuring ongoing reforms and change, for identifying existing procedural obstacles and for learning by comparison with peer agencies. Is it possible to develop an international set of performance indicators, or should such comparisons be best conducted by region or by similarity of organization?*

Key issues for discussion:

- Can milestones be identified to allow for meaningful comparison between different systems, HTA- or coverage bodies?
- What are good review practices and what is the expectation of the healthcare system?
- What is the benefit of HTA benchmarking or performance indicators to each of the stakeholders?
- What are companies doing to determine which HTA requirements to include into their development plans and how this might then influence the success of their products?
- What are the measures that agencies have in place to ensure a quality review and whether they have delivered the expected outcomes?

Day One: Wednesday 28 September 2011

08:30 Registration and coffee

09:00	Welcome	Larry Liberti Executive Director, CIRS
09:10	Chairman's Introduction	Bengt Jönsson Professor of Health Economics, Stockholm School of Economics (SSE), Sweden

Session One: Why transparency in the process of evaluating new medicines for coverage decisions should be a common goal

09:20	Learning from shared experience <i>Why HTA and Coverage Bodies would benefit from shared learning and how greater transparency of process can enable agencies to better share experiences.</i>	Brian O'Rourke President and CEO, Canadian Agency for Drugs and Technologies in Health (CADTH), Canada
09:40	Why Innovators want greater HTA clarity and predictability <i>Process transparency leading to predictability of timing and decision making is critical to both internal decision-making on which drugs to bring forwards and in planning for roll out to different markets.</i>	Greg Rossi Vice President, R&D Payer Evidence, AstraZeneca, UK

10:00 Discussion

10:30 Coffee Break

Session Two: Comparing different healthcare systems: how is transparency, quality and predictability built into review systems

11:00	Value drivers of performance and the assessment of new technologies: a US coverage plan perspective	Marc Berger Executive Vice President & Senior Scientist, OptumInsight, UnitedHealth Group, USA
11:20	Improving regulatory agency performance: measuring time, performance and quality <i>A regulators perspective on how the use of performance indicators of regulatory agencies has benefited the agencies.</i>	Petra Dörr Head of Management Services and Networking, Swissmedic, Swiss Agency for Therapeutic Products
11:40	Discussion	

Day One: Wednesday 28 September 2011 [Afternoon]*Session Three: Case studies of performance indicators for a national HTA agency*

12:00	Activity indicators for the Pharmaceutical Benefits Scheme <i>The timelines and results of all PBAC reviews are reported in order to provide a means by which to identify trends in the in the outcomes of the review of new medicines and their reimbursement has been developed.</i>	Lloyd Sansom Emeritus Professor, Division of Health Sciences, University of South Australia
12:20	Performance indicators for NICE <i>NICE internal measures of process will be discussed in relation to how these measures are used in practice for improving performance and for reporting.</i>	Nina Pinwill Associate Director, Centre for Health Technology Evaluation, National Institute for Health and Clinical Excellence (NICE), UK
12:40	Discussion	
13:00	Lunch	

Session Four: Learning from each other: how can comparison, performance indicators and benchmarking be used to enable shared learning?

14:00	Identification of good practice when using HTA for resource allocation decisions. <i>Evaluation of 15 Key Principals of HTA across different agencies highlights similarities and differences in support for these principals.</i>	Bengt Jönsson Professor of Health Economics, Stockholm School of Economics (SSE), Sweden
14:20	Benchmarking pilot study of HTA impact on industry <i>How identification of comparative performance indicators across industry sheds insight into the impact of HTA on drug development and roll-out.</i>	Franz Pichler Manager, HTA Programme, CIRS
14:40	Discussion	

Session Five: Syndicate Discussions

15:00	Break-out to syndicate discussion meetings (see below)	
18:00	Break	
19:00	Reception	
19:30	Dinner	

15:00 – 18:00: *Syndicate discussions*

15:00 Introduction to syndicates

Syndicate A: Can milestones be identified to allow for meaningful comparison between different systems, HTA- or coverage bodies?

How comparable are the different systems? What framework could exist to facilitate shared learning?

Chair:

Bruno Flamion

Chairman, Belgian Committee for Reimbursement of Medicines (CTG/CRM), Belgian National Institute for Health and Disability Insurance (INAMI-RIZIV)

Rapporteur:

Pierre Sagnier

Vice President, Development Projects, Global Market Access, Bayer Health Care Pharma, Germany

Syndicate B: Removing barriers to equitable patient access to new medicines.

This syndicate will look at the question of why different patient populations have differential access to new medicines and whether there are aspects in the system to either encourage industry to submit earlier to different populations or to encourage agencies to reduce administrative barriers – potentially via development of standardized submission templates. What are the benefits and challenges to doing this?

Chair:

Katrine Frønsdal

Senior Researcher, Norwegian Knowledge Centre for the Health Services (NOKC), Norway

Rapporteur:

Angus Grant

Vice President, Business Development and Global Strategic Alliances, Celgene Corporation, USA

Syndicate C: Beyond benchmarking time and process: can we assess quality?

What is quality in the context of HTA? How can the quality of dossier submissions to HTA agencies and the quality of the review process by these agencies be improved?

Chair:

Barbara Sabourin

Senior Executive Director, Therapeutic Products Directorate (TPD), Health Canada

Rapporteur:

Iga Lipska

Senior Research Fellow, CIRS

Day Two: Thursday 29 September 2011		
08:45	Chairman's Introduction	Adrian Towse Director, Office of Health Economics (OHE), UK
<i>Session Six: Building quality into the application dossier through creation of a standard submission template: a common technical document for HTA</i>		
08:50	Implementation of good practice principals for relative effectiveness based on the EUnetHTA core HTA model	Finn Børlum Kristensen Director, European Network of Health Technology Assessment (EUnetHTA)
09:10	Discussion	
<i>Session Seven: What is the view from other key stakeholder on comparison of timeliness, quality, predictability and transparency in HTA and coverage?</i>		
09:30	How increased transparency and the ability to compare systems will benefit HTA-Regulatory interactions	Hans-Georg Eichler Senior Medical Officer, European Medicines Agency, (EMA), UK
09:50	What does industry want to see from HTA agencies in terms of time, quality, predictability and transparency?	Ed Godber Vice President, Access to Medicines Centre of Excellence, GlaxoSmithKline, UK
10:10	Discussion	
10:30	Coffee Break	
<i>Feedback from syndicate discussions</i>		
11:00	Feedback from Syndicate A	Pierre Sagnier Vice President, Development Projects, Global Market Access, Bayer Health Care Pharma, Germany
11:15	Feedback from Syndicate B	Angus Grant Vice President, Business Development and Global Strategic Alliances, Celgene Corporation, USA
11:30	Feedback from Syndicate C	Iga Lipska Senior Research Fellow, CIRS
11:45	Panel Discussion	
<p>Jens Grueger, Vice President, Head Global Market Access, Pfizer Primary Care Business Unit, UK</p> <p>Thomas Lönngren, Strategic Advisor</p> <p>François Meyer, Advisor to the President, Assessment Division, Haute Autorité de Santé, (HAS), France</p> <p>Barbara Sabourin, Senior Executive Director, Therapeutic Products Directorate (TPD), Health Canada</p>		
12:45	Chairman's summary	Adrian Towse Director, Office of Health Economics (OHE), UK
12:55	Conclusion of workshop	Larry Liberti Executive Director, CIRS