Workshop on

Building quality into HTA and Coverage Decision-Making Processes:

What are the features of good practice in HTA?

2nd & 3rd December 2013

Sheraton Heathrow Airport Hotel, UK

PROGRAMME

Organisers:
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Building quality into HTA/Coverage decision-making:
What are the features of good practice in HTA?

Background

Health Technology Assessment (HTA) has been increasingly used to evaluate new technologies and to inform coverage decision-making as to whether the additional benefits of the interventions are worth their cost. There is considerable variability in the organisations and the methodologies employed in the HTA appraisal and coverage decision-making processes across different countries, however, where the function and activities of HTA/coverage bodies are similar in terms of remit and scope, consistency across the underlying processes and procedures would be expected to take place to make sure that safe, effective and affordable medicines are available to improve public health.

The HTA agencies are continuously evolving to adopt the best tools and techniques in order to make high quality decisions about the place of new medicines in their jurisdiction. Initiatives have been seen amongst HTA agencies and other stakeholders (academic groups/industry) to discuss the common methodologies, guidelines, standard processes and good review practices, in order to identify criteria and practices of HTA appraisal. While the HTA agencies are undergoing evolution with regards to their policy, procedures and infrastructure, challenges arise for industry to adjust their submission strategy to this progress. This will lead to the discussion among stakeholders to agree on the core key factors that will facilitate and impact the quality of reviews conducted to support HTA/coverage decision-making, to improve the process of bringing a new medicine to market. An important element is also the need for sponsors to identify their role in enabling the process by providing good quality submissions.

This Workshop follows on from the CIRS September 2011 Workshop, *Understanding HTA and Coverage decision-marking processes*, which focused on the question: what is the key to facilitating transparent access to medicine? This Workshop will address the recommendations of previous Workshops and will focus in particular on how to build process consistency and quality into both the HTA/Coverage decision-making, as well as the quality of the submission so as to improve the process of bring a new medicine to market.

The objectives of the Workshop are:

1) **To ascertain the companies' and agencies' current perspectives** *with regards to the quality of HTA/coverage decision-making processes.*
2) **To identify and discuss the key aspect of a good-practice process** *of HTA/coverage decision-making.*
3) **To identify the key factors** *that enable companies to prepare a quality submission in an evolving HTA environment.*
4) **To make recommendations on** *what key features should be considered or adopted for best practice in HTA processes and decision- making*

Date and Venue:

The Workshop will be held at the Sheraton Heathrow Hotel commencing at 09:00 on Monday 2nd December and finishing at 12.30 on Tuesday 3rd December 2013.

Style and Participation:

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation only to maintain a size that encourages a 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.

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

Centre for Innovation for Regulatory Science Workshop on Building quality into HTA and Coverage Decision-Making Processes -2 & 3 December 2013, Sheraton Heathrow Hotel, UK.

DAY 1: MONDAY 2 DECEMBER 2013

08.30-09.00 hrs: **Registration**

SESSION 1: BUILDING QUALITY INTO THE APPLICATION DOSSIER		
09.00	**Chairman's Introduction**	**Prof Hans-Georg Eichler**, Senior Medical Officer, European Medicines Agency
09:10	**The quality of decisions and the decision-making process for HTA assessment** *The philosophy, principles and practice of building quality into decision making*	**Prof Adrian Towse**, Director, Office of Health Economics, UK
09.40	**Quality management in a Industry HTA Department** Experience of managing quality systems for multi Jurisdictional HTA submissions*, such as a core dossier adapted to local settings. How can companies prepare a good quality submission that meets the requirements for diverse HTA agencies?*	**Marlene Gyldmark,** Head of Modelling, Outcomes Research, Statistics and Epidemiology, F.Hoffmann-La Roche, Switzerland
10:00	**Critical Self Assessment: What companies can learn from analysing their own HTA experience** *Practical experience of the role or the lessons that can be learned from an objective review of successes and failures in the submission and HTA assessment process. What are the elements of a quality dossier for HTA/Coverage agencies review?*	**Louise Timlin**, Director, ACE Health Outcomes and HTA, Eli Lilly and Company, UK
10:20	**Discussion**	
10:30	**Break**	
SESSION 2: BUILDING QUALITY INTO THE HTA/COVERAGE REVIEW PROCESS		
11.00	**Building quality into the HTA Review process** *An agency perspective on what they have done or are undertaking to build quality into their process and procedures.*	**Dr Brian O'Rourke**, President and Chief Executive Officer of the Canadian Agency for Drugs and Technologies in Health (CADTH).
11.25	**Process or data? A HTA perspective on the keys to quality HTA recommendation** *What are the elements and how does one define high quality HTA/coverage decisions. Does 'high quality' mean decisions that are made more quickly, more transparently, or more consistently?*	**Meindert Boysen,** Programme Director, Technology Appraisals, National Institute for Health and Care Excellence
11.50	**What does "Good Quality HTA practices mean" to companies?**	**Company representative**
12.15	**Discussion**	
12.30	**Lunch**	

DAY 1 (CON'T): MONDAY 2 DECEMBER 2013

SESSION 3: MEETING FUTURE EXPECTATIONS

13.30	**Chairman's Introduction**	**Prof Hans-Georg Eichler**, Senior Medical Officer, European Medicines Agency
	Measuring industry and HTA performance *How does one measure HTA performance, time and quality? The ongoing CIRS HTA benchmarking and mapping studies will be summarised and their objectives to aid both companies and HTA agencies to share practices that can underpin improvements in practices and procedures will be discussed.*	
13.35	**Measuring Industry HTA Performance: CIRS Study**	**Lawrence Liberti**, Executive Director, CIRS
13.55	**Discussant – Industry Perspective**	**Shane Kavanagh**, VP, Health Economics, Janssen Pharmaceutica, Belgium
14.10	**Measuring Agency HTA Performance: CIRS**	**Dr Iga Lipska**, Senior Research Fellow, CIRS
14.30	**Study Discussant – HTA/coverage Perspective**	**Anne Lee,** Chief Pharmaceutical Adviser, Scottish Medicines Consortium
14:45	**The Canadian HTA Process Project**	**Nicola Allen**, PhD Student, CIRS
15:05	**Discussant – Canadian Process Project**	**Don Juzwushin,** Director HTA and Innovation. Alberta Health Services, Canada
15:20	**Discussion**	

SESSION 4: SYNDICATE DISCUSSIONS

15.30	**Introduction to the Syndicate Discussions** *Workshop participants will form syndicates for free ranging, informal discussions from which recommendations will be formulated and discussion points identified. The topics to be discussed will include: What is the definition of good review practice in the context of HTA/coverage decision-marking, and what is the expectation from the healthcare system? What are the key elements of an HTA focussed GRevP process?*	
	Is it possible to develop an international set of performance indicators to measure the quality of the review process? What process and procedures would an ideal agency adopt?	Chair: **Prof Robert Peterson**, Executive Director Drug Safety Effectiveness Network, Canadian Institutes of Health Rapporteur: **Deven Chauhan,** Strategy Director, Global Health Economics, GlaxoSmtihKline, UK
	What are the key elements of a quality dossier or submission that can enable the HTA/coverage review process and decision-making? What process and procedures should companies be adopting?	Chair: **Prof Bruno Flamion**, Professor of Physiology and Pharmacology, University of Namur, Belgium Rapporteur: **Julia Chamova**, Director of Operations – EUnetHTA Secretariat, Danish Health and Medicines Authority
18:00	**Close of session**	
19:00	**Reception and dinner**	

DAY 2: TUESDAY 3 DECEMBER 2013

SESSION 4: SYNDICATE DISCUSSIONS *continued*		
08.30	**Chairman's remarks**	**Meindert Boysen,** Programme Director, Technology Appraisals, National Institute for Health and Care Excellence
08.40	**Syndicate feedback and discussion**	All participants
9.15	**Panel Discussion**	
	HTA Perspective - Europe	**Dr Wim Goettsch**, Project leader of the EUnetHTA JA2 WP5 Rapid Assessments, Health Care Insurance Board (CVZ), The Netherlands
	HTA Perspective - USA	**Dr Sanjay Gupta**, Executive Director and Head, Health Economics and Outcomes Research, Daiichi Sankyo Inc, USA
	Industry Perspective	**Representative** from Pfizer, USA
10.15	**Break**	
11:00	**Measuring quality of the regulatory review process – Can this be a useful model for HTA agencies?**	**CIRS Speaker**
11:25	**What has been the EUnetHA experience with the pilot industry submissions project?**	**Dr Wim Goettsch**, Project leader of the EUnetHTA JA2 WP5 Rapid Assessments, Health Care Insurance Board (CVZ), The Netherlands
11:45	**Discussion**	
12:00	**Chairman's Summary**	
12:15	**Close of workshop**	