Is there a Commonality across the Structured Decision Frameworks used by HTA & Regulatory Agencies

2 - 3 October 2013

PROGRAMME

Frimley Hall Hotel, Surrey, UK

CENTRE FOR INNOVATION IN REGULATORY SCIENCE
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4 September 2013

Centre for Innovation in Regulatory Science Workshop

Background

Over the last five years there has been initiatives by regulatory agencies and companies to develop Benefit-Risk methodologies, all of which have a number of common elements. In 2012 at the CIRS annual Benefit-Risk workshop in Washington DC there was a consensus from those who are developing Benefit Risk methodologies for assessing medicines that there were four key stages to Benefit-Risk decision-making; Framing the decision; Identifying the benefits and risks; Assessing the benefits and risks; and Interpretation and Recommendation.

Underpinning these was an overarching eight step framework characterised by; 1.Decision context; 2.Building the Value Tree; 3.Value Tree refinement; 4.Assessing relative importance; 5.Evaluating options; 6.Evaluating uncertainty; 7.Concise presentation of results – visualisation; 8.Final recommendation

All the methodologies currently being developed by regulators and companies have these steps within their assessment whether explicitly or implicitly. This overarching framework provides the basis for common agreement and discussion on the benefit-risk assessment of medicines by the regulatory agencies and between the relevant stakeholders.

In addition to these approaches other groups such as those agencies undertaking Health Technology Assessments of new medicines have also developed methodologies to aid them in making benefit/risk/value decisions. As the role of both the licensing bodies and HTA agencies become aligned in terms of data requirements and timing of decisions, can the discussions and methodologies being developed for the licensing of medicines learn anything from the methodologies used by HTA groups and vice versa?

This workshop is being designed to bring together the various stakeholders to address the question "**Is there a Commonality across the Structured Decision Frameworks used by HTA & Regulatory Agencies?".** It is well understood that decision context is different between the two bodies but the ability to use the same decision frameworks would enable the articulation of the decision made by HTA and Regulatory agencies to be transparent.

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Workshop Objectives

- **Discuss the similarities and differences** between the decision frameworks used by regulatory and HTA agencies **;**
- **Further the thinking** as to what can be learnt from evaluating different methodologies used by both HTA and Regulatory agencies for making benefit risk decisions explicit?
- **Identify the common elements** across methodologies and discuss how to achieve a consensus on a scientifically acceptable framework for making decisions that are broadly applicable to these stakeholders.

Venue

The Workshop will take place at the Frimley Hall Hotel in UK, commence at 09:00 on 2 October and finishing at 13:00 on 3 October 2013.

Style and Participation

Following the agreed practices for Institute Workshops, the meeting will be closed and the size will be limited to allow productive networking and discussions.

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Day 1: 2nd October 2013

08:30: Registration

SESSION 1: ALIGNING DECISION FRAMEWORKS FOR BENEFIT-RISK ASSESSMENT BETWEEN HTA AND REGULATORY AGENCIES: IS THIS PRACTICAL?

09.00	**Chairman's welcome and introduction:** Prof Hubert Leufkens, Chairman, Medicines Evaluation Board, The Netherlands
	How important is it for patients that licensing bodies and HTA agencies can explain their respective benefit-risk decisions by utilising an aligned overarching framework? *As companies develop new medicines, they are now faced with two key decision makers prior to patients gaining access to their medicines, that of the Licensing bodies and HTA agencies. Is the decision that the benefits outweigh the risk of a new medicine the primary domain/decision of licensing bodies and can this be accepted by those working in HTA agencies? If not and why not?*
09.10	**Patients Viewpoint** Jean Mossman, Policy Lead, European Brain Council, UK
09:30	**Industry Viewpoint** Lars Bruening, Head of Global Market Access, Bayer Healthcare Pharma, Germany
09:50	**Regulatory Viewpoint:** Dr David Lyons, Senior Medical Officer, Irish Medicines Board
10.10	**HTA Viewpoint** Prof Angela Timoney; Chair, Scottish Medicines Consortium
10.30	**Discussion**
10.45	**Break**
	Methodologies to build structured approaches to decision making in the context of licensing and in relation to HTA: What can be learnt? *Regulatory agencies and HTA organisations are evolving structured frameworks to enable improved decision making, ability to share common data and provide support for those undertaking the review.*
11.10	**The CORE HTA Model: What is it, and how does this aid a Structured Decision making Process** Dr Kristian Lampe, Senior Medical Officer, Project Manager (EUnetHTA Joint Action WP8), FINOHTA, National Institute for Health and Welfare, Finland (THL)
11.30	**A structured Benefit Risk decision making framework – Does this give clarity and transparency to the regulatory decision for both internal and external stakeholders?** Professor Hans Georg Eichler, Senior Medical Officer, European Medicines Agency
11.50	**Canadian Perspective** Barbara Sabourin, Director General, Therapeutic Products Directorate, Health Canada Dr Chander Sehgal, Director, Drug Review Programs, Canadian Agency for Drugs and Technologies in Health
12.20	**A Perspective from NICE** Dr Elizabeth George, Associate Director, Centre for Heath Technology Evaluation, NICE
12:40	**Discussion**
13.00	**Lunch**

Day 1: 2nd October 2013

SESSION 2: BENEFIT RISK DECISION MAKING	
14.00	**Chairman's introduction**
14.05	**Assessing HTA and Regulatory Approval Decisions: A cohort study** Dr Iga Lipska, Senior Research Fellow, CIRS
14.25	**Assessing HTA and Regulatory Approval Decisions – Two company case studies showing different aspects of alignment or transparency of the benefit-risk decision between HTA and Regulators** Case study one **–** Dr Jens Grueger; Vice President, Head of Global Health Economics and Pricing, Roche, Switzerland Case study two – Indranil Bagchi, Vice President, Specialty Care Market Access, Pfizer, USA
15.10	**Discussion**
15.30	**Introduction to the syndicate sessions**
15.35	**Break**
16.00	**Syndicate sessions** Each syndicate will undertake the following using a structured format to answer the syndicate question. Based on a set of questions or outline, the syndicate is asked to review debate and make recommendations to answer the question. **Syndicate Session 1: Mapping HTA frameworks onto UMBRA** **Chair: Prof Robert Peterson**, Executive Director Drug Safety Effectiveness Network, Canadian Institutes of Health **Rapporteur: Eddie Reilly,** Vice President, Head of Global Regulatory Affairs, GlaxoSmithKline Vaccines, Belgium **Syndicate Session 2: Communicating Regulatory and HTA benefit-risk decisions to patients** **Chair: Dr Thomas Lönngren,** Independent Strategy Advisor, Pharma Executive Consulting, UK **Rapporteur: Dima Samaha,** Advisor- innovation and external affairs, INESSS, Canada **Syndicate Session 3: Collaboration between HTA and Regulatory in the development space - how could this improve alignment?** **Chair: Dr Linda Harpole,** Vice President Global Health Outcomes, GlaxoSmithKline, USA **Rapporteur: Dr Franz Pichler,** Director, Global Public Policy, Eli Lilly and Company, UK
17.30	**End of Session**
19:00	**Reception**
19:30	**Dinner**

DAY 2: 3rd October 2013

SESSION 3: SYNDICATE SESSIONS & FEEDBACK	
08.30	**Syndicate sessions resume**
10.00	**End of Syndicate sessions and Break**
10.30	**Chairman's Introduction** Professor Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency
10.35	**Feedback of syndicate discussion and general discussion**
11.35	**Can the utilisation of patient academies aid patients in understanding the differential decisions made by Licensing and HTA Bodies?** Dr Panos Kanavos*, Reader in International Health Policy, London School of Economics, UK
12.00	**Discussion**
	Panel Discussion: Communication and Transparency of Decisions: How good is the presentation and documentation of decisions made by Licensing and HTA Organisations?
12.05	**A perspective on HTA decisions** Dr Jan Mueller-Berghaus; Paul Erlich Institute, Germany
12.10	**A perspective on Licensing decisions** Dr Wim Goettsch – Deputy Secretary Medicinal Products Reimbursement Committee. Health Care Insurance Board ; The Netherlands
12.15	**Industry Perspective** Dr Jens Grueger; Vice President, Head of Global Health Economics and Pricing, Roche, Switzerland
12.20	**A Patient's Perspective** Dr Mary Baker, President, European Brain Council
	Open Discussion
12.50	**Summary**
13.00	**Close of Workshop and Lunch**