



International

INSTITUTE FOR REGULATORY SCIENCE

**Workshop on  
Review and Reimbursement:  
A special case for better co-operation**

**29 - 30 September 2009**

**PROGRAMME AND  
WORKSHOP  
DOCUMENTATION**

**Woodlands Park Hotel,  
Surrey, UK**

**INSTITUTE FOR REGULATORY SCIENCE**

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INSTITUTE FOR REGULATORY SCIENCE

## CMR International Institute for Regulatory Science Workshop

### Background

The current dynamics of bringing new medicines to market are being influenced by conflicts between the agendas of regulators and payers. Regulators are under pressure to develop methods to speed the approval process, including mechanisms such as conditional licensing, while maintaining an emphasis on safety, quality and efficacy. By contrast, there is an increasing pressure on payers to control spiralling healthcare costs via the assessment of clinical and cost-effectiveness. The two processes of licensing and reimbursement are, however, starting to overlap, resulting in duplication of effort and introducing an additional uncertainty into industry drug development decisions as market approval does not necessarily mean that the product will be reimbursed. While, historically the regulatory review and the consideration of products for listing and reimbursement by healthcare providers (*health technology assessment* – HTA) have been kept as separate exercises, the current situation makes a special case in which better cooperation and coordination of activities could be of significant benefit in making new medicines available to patients.

This Workshop has been jointly developed by the Institute and the Office of Health Economics UK to specifically address the related issues of overlap in activities as between licensing and reimbursement and the potential for mismatch of outcomes. The current Workshop follows the Institute's January 2008 workshop, Regulation and Reimbursement: Two Sides of the Same Coin? which focussed on the question: *The medicine is approved but will anyone pay for it?* Four main themes where further discussion was needed were identified as; (i) the need to address overlap in the activities of the HTA and regulatory authority organisations, (ii) the importance of dialogue between the stakeholders especially early in development, (iii) the need for conditional licensing and reimbursement to enable earlier access to medicines, and (iv) the desire to see a greater degree of methodologic harmonisation between HTA bodies.

This Workshop will address the recommendations of the earlier Workshop and focus in particular on how *consultation and cooperation* has the potential to improve the process of bringing a new medicine to market for all three stakeholders

### Objectives

- **To improve efficiency of requirements:** by identifying areas of overlap between the activities of HTAs and Regulatory Authorities in drug assessment and to discuss mechanisms by which dialogue and information sharing may minimise duplication.
- **Rationalisation of outcomes:** to identify mechanisms to mitigate the risk of mismatch of outcomes that can occur when licensing bodies grant accelerated approvals that are not compatible with current HTA requirements.
- **To develop a white paper:** the recommendations of the Workshop and supporting survey will be used to create a white paper that addresses the implications of changing the current model of keeping scientific review separate from discussions of pricing in order to achieve greater efficiency of process and predictability of outcome.

### Venue

The Workshop will take place at the Woodlands Park Hotel, Surrey, UK commencing at 09.00 on Tuesday, 29 September and finishing on Wednesday, 30 September 2009.

### 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.

**DAY 1: TUESDAY, 29 SEPTEMBER 2009**

**SESSION 1: EARLY INVOLVEMENT OF LICENSING AND REIMBURSEMENT AUTHORITIES IN DEVELOPMENT: A RECIPE FOR SUCCESS?**

09.00	<b>Chairman's welcome and introduction:</b>	<b>Prof. Hubert Leufkens</b> , <i>Chairman, Medicines Evaluation Board, The Netherlands</i>
	<p><b>Enabling effective and efficient drug development: Where are HTA's and licensing authorities going in the next 10 years and what is the pathway to the future?</b>  <i>Should HTA and Regulators be partners with companies in the development process? If not, then where can they cooperate to enable effective and efficient development? What will be the main barriers and how can these be resolved?</i></p>	
09.10	<b>An HTA perspective</b>	<b>Prof. Sir Michael Rawlins</b> , <i>Chairman, National Institute for Clinical Excellence (NICE), UK</i>
09.40	<b>A licensing authority perspective</b>	<b>Dr Eric Abadie</b> , <i>Chair, CHMP, EMEA, France</i>
10.05	<b>A company perspective</b>	<b>Dr Hilary Malone</b> , <i>Senior Vice President and Head of Global Regulatory Affairs, Wyeth, USA</i>
10.30	<b>Discussion</b>	
10.35	<b>Break</b>	
	<p><b>Utilisation of biomarkers and surrogate endpoints in development of a new medicine: What value is put on them to aid decision making of license and HTA authorities?</b></p>	
11.00	<b>An HTA perspective</b>	<b>Dr Andrew Mitchell</b> , <i>Chair, HTAi Working Group on Surrogate Outcomes, Australia</i>
11.20	<b>A licensing authority perspective</b>	<b>Dr Leonie Hunt</b> , <i>Head, Office of Regulatory Integrity and Compliance, Therapeutic Goods Administration, Australia</i>
11.40	<b>What are the benefits and implications of early dialogue between the stakeholders?</b>	<b>Dr Martin Backhouse</b> , <i>Head of Pricing and Market Access Operations, Global Pricing and Reimbursement, Novartis Pharma AG, Switzerland</i>
	<p><b>HTAs and licensing authorities being included in joint advice: What is the value for each agency?</b></p>	
12.00	<b>A perspective from both viewpoints</b>	<b>Prof Robert Peterson</b> , <i>Chairman, Canadian Expert Drug Advisory Committee (CEDAC); Clinical Professor, University of British Columbia, Canada</i>
12.15	<b>The Swedish joint scientific advice pilot project</b>	<b>Niklas Hedberg</b> , <i>Head of Department, Dental and Pharmaceutical Benefits Agency (TLV), Sweden</i>
12.30	<b>Is conditional reimbursement an answer to increasing access to innovative medicines that are being approved through conditional reviews?</b>	<b>Clare McGrath</b> , <i>Senior Director, HTA Policy, Europe/ROWD, Pfizer, UK</i>
12.50	<b>Discussion</b>	
13.00	<b>Lunch</b>	

<b>SESSION 2: SYNDICATE SESSIONS</b>			
14.00	<b>Introduction to the Syndicate Sessions</b>	<b>Dr Franz Pichler</b> , <i>Portfolio Manager, CMR International Institute for Regulatory Science, UK</i>	
<p><b>Review and reimbursement: the current environment and the implications for the future?</b></p> <p><i>Outcome of the Institute and OHE Survey of stakeholders (Company, HTA and Licensing agencies) as background for the syndicate discussion: What is the impact of the current reimbursement environment on drug development programs and the regulatory review process? What are the similarities and differences in the way HTA and regulatory authorities assess new products? What are the areas that each stakeholder considers to be amenable to data sharing or methodological coordination</i></p>			
14.45	<b>Syndicate</b>	<b>Chair</b>	<b>Rapporteur</b>
	<b>Topic A-1</b>	<b>Prof. Robert Peterson</b> <i>Chairman, Canadian Expert Drug Advisory Committee (CEDAC); Clinical Professor, University of British Columbia, Canada</i>	<b>Dr Pierre Sagnier</b> <i>Vice President, GHEOR, BayerSchering, Germany</i>
<p><b>Getting to the right evidence for licensing and HTA authorities at the point of launch: An achievable endpoint?- Licensing body perspective</b></p> <p><i>What are the gaps between licensing review and HTA appraisal and can these be accommodated within the development plan? How are biomarkers and surrogate end points viewed? Are licensing studies robust enough to answer questions on clinical and cost effectiveness? Is early dialogue the key?</i></p>			
	<b>Topic A-2</b>	<b>Prof. Ulf Persson</b> <i>Professor of Health Economics, Lund University, CEO Swedish Institute for Health Economics, Sweden</i>	<b>Dr David Williams</b> <i>Section Director, HEOR, Clinical Development, AstraZeneca, UK</i>
<p><b>Getting to the right evidence for licensing and HTA authorities at the point of launch: An achievable endpoint? – HTA agency perspective</b></p> <p><i>What would be required for agreement prior to the drug development process on the health priorities for new medicines in order to meet regulatory authority and HTA criteria for approval and reimbursement? Can reimbursement commitments be made prior to development?</i></p>			
	<b>Topic B</b>	<b>Dr Brian O'Rourke</b> <i>Acting President and CEO, Canadian Agency for Drugs and Technologies in Health (CADTH), Canada</i>	<b>Dr Tracy Baskerville</b> <i>Vice President, Head of Global Regulatory Affairs, Liaison, Cardio-Metabolic, Solvay, France</i>
<p><b>How can patients have rapid access to new medicines where there is an unmet medical need? Conditional approvals and conditional reimbursement</b></p> <p><i>Can we avoid a mismatch of outcomes between a regulatory authority giving conditional approval and an HTA refusing to pay for the same product due to incomplete data? Should conditional approval and conditional reimbursement be linked? What do HTA agencies think about accelerated licensing? What is the best way to decide upon the required endpoints and information to enable conditional licensing to be acceptable to HTAs?</i></p>			
	<b>Topic C</b>	<b>Dr Franz Waibel</b> <i>Senior Vice President, Global Market Access, Bayer Schering, Germany</i>	<b>Dr Mel Walker</b> <i>Director, Global Integrated Payer Strategy, GSK, UK</i>
<p><b>Stakeholder partnerships, what mechanisms are required to bring the partners together?</b></p> <p><i>At what stages of development would information sharing and partnership be of greatest benefit? What are the issues that currently prevent information sharing, partnerships and dialogue between the stakeholders? How can these be addressed? What are the alternatives? Can HTA and licensing bodies offer joint scientific advice, what are the advantages and limitations? Who would represent the different licensing bodies and HTA stakeholders when advice on global development is sought?</i></p>			
16.00	<b>Break</b>		
16.30	<b>Syndicate resumes</b>		
18.30	<b>End of Syndicate Discussion and end of day one</b>		
19.00	<b>Reception</b>		
19.30	<b>Dinner</b>		

**DAY 2: Wednesday 30 September 2009**

<b>SESSION 3: REVIEW AND REIMBURSEMENT UNDERSTANDING THE DYNAMICS AND HOW THEY ARE EVOLVING</b>		
08.30	<b>Chairman's Introduction</b>	<b>Prof. Sir Alasdair Breckenridge,</b> <i>Chairman, MHRA, UK</i>
08:35	<b>Feedback of syndicate discussion</b>	
09.35	<b>Panel Discussion</b>	<p><b>Dr Supriya Sharma</b> <i>Director General, Therapeutic Products Directorate, Canada</i></p> <p><b>Dr Petra Doerr</b> <i>Head of Management Services and Networking, Swissmedic, Switzerland</i></p> <p><b>Prof Claire Le Jeune</b> <i>Vice Chair, Transparency Committee, Haute Autorité de Santé, France</i></p> <p><b>Dr Meindert Boysen</b> <i>Director, Technology Appraisals Programme, NICE, UK</i></p>
10.15	<b>General Discussion</b>	
10.55	<b>Break</b>	
	<b>Price, value and innovation: Can these be balanced to ensure incentives for companies to develop innovative medicines</b>	
11.20	<b><i>What is the role of risk sharing in ensuring access to patients for innovative medicines?</i></b>	<b>Prof Adrian Towse,</b> <i>Director, Office of Health Economics, UK</i>
11.40	<b><i>Understanding what the customer's will pay for is the key to developing reimbursable medicines: How are companies now working with the payors and how is this relating to development?</i></b>	<b>Dr Lawson Macartney,</b> <i>Senior Vice President of Global Product Strategy, GSK, USA</i>
12.00	<b>HTA collaboration on scientific assessment for the purpose of Reimbursement: MEDEV and EUnetHTA: current status and future prospects – is EURO-NICE a possibility?</b>	<b>Dr Ad Schuurman,</b> <i>Head, Reimbursement Department Dutch Health Care Insurance Board (CVZ); President Medicine Evaluation Committee (MEDEV); The Netherlands</i>
12.20	<b>The USA paradigm: What are the options and how will this affect drug development?</b>	<b>Dr Zeba Khan,</b> <i>Vice President, Pricing and Market Access, Celgene, USA</i>
12.40	<b>Chairman's Summary</b>	
13.20	<b>Chairman's close of session and end of workshop</b>	