Workshop

How is the value proposition driving the development and reimbursement process in major markets?

What are the strategies and practical steps companies can take in development?

2 -3 December 2014

Venue: Rosewood Hotel Georgia, Vancouver, Canada

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

The Johnson Building, 77 Hatton Garden, London EC1N 8JS, UK, Telephone:

+44 (0) 207 433 4247 Email: ghepton@cirsci.org

Organiser
Neil McAuslane nmcauslane@cirsci.org
Tina Wang twang@cirsci.org

15 July 2014

Centre for Innovation in Regulatory Science Workshop

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Background

Over the past decade, there have been rapidly increasing interest in the demonstration of value for health technologies and ongoing discussions about the definition, interpretation and measurement of value and innovation. In 2013, the HTAi Policy Forum discussed the topic "HTA and Value", and concluded that most decision-making systems take into account similar elements to assess "value" and although these are assessed in different ways by different stakeholders, they all agreed that impact on clinical benefits and harms were the primary elements While the forum identified actions to improve alignment in definitions and assessment of value, the key areas remaining for debate are the identification of methods for building the relevant elements of value into drug development design and the underpinning components that demonstrate and effectively articulate the value of new medicines.

Constructing a value proposition has become the principal step for defining the need for a product in the marketplace. This needs to be integrated into a company's early decision-making processes as the value proposition provides an essential roadmap for a product's development and reimbursement processes.

The evidence used to develop a value proposition helps position the new product against an established market leader or innovator by identifying significant endpoints of clinical differentiation and by capturing the benefit that matter most to patients, their doctors and society — such as symptom burden, financial costs, family disruption and ability to work. This involves ensuring the right information is collected during the clinical development phase and that companies can create dynamic Therapeutic Product Profiles that have a clearly stated value proposition so as to aid companies in their go/no go decision making.

This Workshop will focus on how companies need to be able to integrate their target stakeholders' different perspectives of value into their development decisions as well as using these insights to construct a viable value proposition to meet the needs of diverse stakeholders.

Workshop Objectives are to:

- **Identify** the key elements and the evidentiary requirements of a robust value proposition in order to build it into the early drug development phase
- **Discuss** the key barriers for building the value proposition early into the development of new medicines and discuss the best approaches to addresses these challenges, including how, when and which stakeholders (health technology assessors, payers, clinicians and patients) need to be engaged
- **Consider** how companies can more effectively use the value proposition to drive their development strategies and address reimbursement challenges
- **Recommend** approaches for the development, evaluation and utilisation of value propositions in the era of value-driven healthcare systems

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation 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.

1. HEALTH TECHNOLOGY ASSESSMENT, VALUE-BASED DECISION MAKING, AND INNOVATION *International Journal of Technology Assessment in Health Care*, 29:3 (2013), Page 1 of 7.

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Day 1: Tuesday 2 December 2014

08:30 - Registration

SESSION 1: BUILDING THE VALUE PROPOSITION INTO DRUG DEVELOPMENT - WHAT ARE THE KEY ELEMENTS, CHALLENGES AND BEST APPROACHES?		
09:00	**Chairman's introduction**	**Prof Robert Peterson,** Executive Director, Drug Safety Effectiveness Network Canadian Institute of Health
09:10	**Development of a general framework for defining and assessing value** *What are the key elements of the framework? Who will be driving the development of the framework and what need to be considered? How can the concept of "value" be generally defined early and interpreted appropriately to form the value proposition for new medicine?*	**Dr Nick Crabb**, Programme Director for Scientific affairs, National Institute for Health and Care Excellence, UK
09:30	**Discussion**	
	Building value proposition for new medicines in drug development - What are the key elements and what needs to be considered? *What are the evidentiary needs to demonstrate value from different stakeholder's perspectives? What principles and criteria should be considered for inclusion in the value proposition and application of the criteria?*	
09:35	**HTA Agency perspective**	**Dr Chander Sehgal,** Director, Common Drug Review and Optimal Use , CADTH
09:55	**Patient perspective**	**Frank Gavin,** Public Member of Canadian Drug Expert Committee, CADTH, Canada
10:15	**Discussion**	
10:20	**Break**	
	How can companies effectively use the value propositions for new medicines to make good development decisions? *What needs to be considered and prepared by companies to drive strategic planning? What are the key barriers and hurdles for building the value proposition early into the development of new medicines?*	
10:50	**Case study one**	**Gergana Zlateva,** Payer Insights & Access North America Lead, Pfizer Inc, USA
11:10	**Case study two**	**Koen Torfs,** Vice President, Global Reimbursement and Real World Evidence, Janssen NV, Belgium
11:30	**How could companies improve approaches to embed value into development process?**	**Dr James Murray**, Research Fellow, Global Patient Outcomes and Real World Evidence Center for Expertise, Eli Lilly and Company, USA
11:50	**Key economic consideration to address/manage the need to demonstrate value across jurisdictions**	**Prof Lou Garrison,** Professor and Associate Director, Pharmaceutical Outcomes Research and Policy Program, University of Washington, USA
12:10	**Discussion**	
12:30	**Lunch**	

Day 1: Tuesday 2 December 2014

SESSION 2: EVALUATION OF THE VALUE PROPOSITION IN DECISION MAKING: MULTI-STAKEHOLDER INVOLVEMENT AND HOW TO MANAGE DIVERGENCE ACROSS JURISDICTIONS		
13:30	**Chairman's introduction**	**Prof Robert Peterson,**
	How and when should different stakeholders be engaged to develop and test the value proposition during drug development and roll-out?	
13:40	**Company viewpoint**	**Ludwig Steindl**, Vice President, Head of Strategic Access and Operations, Global Market Access, Bayer Pharma AG, Swizerland
13:55	**HTA reflection**	**Niklas Hedberg,** Chief Pharmacist, the Dental and Pharmaceutical Benefits Agency (TLV), Sweden
14:10	**Patient Involvement**	**Dr Katharina Kovacs Burns,** Founding Member of the Canadian Best Medicines Coalition
14:25	**Discussion**	
	What are the current initiatives that can aid companies in identifying the evidence to support the value proposition and its role in innovation?	
14:30	**Green Park Initiative**	**Dr Donna Messner,** Vice President and Senior Research Director, Center for Medical Technology Policy (CMTP), USA
14:50	**Early scientific advice during development phase**	**Prof Finn Børlum Kristensen**, Head of Coordinating Secretariat of EUnetHTA, Danish Health and Medicines Authority, Denmark
15:10	**Discussion**	
SESSION 3: SYNDICATE DISCUSSIONS		
15:25	**Introduction to the Syndicate Discussions** **Syndicate 1: How can the company ensure the value proposition plays a role through the lifecycle of the product?** **Chair: Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency **Rapporteur: Dr Anke Hövels**, Assistant Professor, Department of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University. The Netherlands **Syndicate 2: What is the best practice for engaging stakeholders to enable development of value proposition?** **Chair: John Sproule,** Senior Policy Director**,** Institute of Health Economics, Canada **Rapporteur: Nicola Allen**, PhD Student, CIRS	
18:15	**Close of session**	
19:00	**Reception and dinner**	

Day 2: Wednesday, 3 December 2014

SESSION 3: SYNDICATE DISCUSSIONS CONTINUED		
09:00	**Chairman's introduction**	**Prof Robert Peterson,** Executive Director, Drug Safety Effectiveness Network Canadian Institute of Health
09:10	**Syndicate feedback and discussion**	All participants
09:40	**Panel reflection**	
	HTA perspective	**Prof Bruno Flamion,** Professor of Physiology and Pharmacology University of Namur, Belgium
	Payer perspective	**Barbara Walman,** Assistant Deputy Minister, Medical Beneficiary and Pharmaceutical Services, BC Ministry of Health, Canada
	Industry perspective	**Dr Sanjay Gupta,** Head of HEOR, Daiichi Sankyo Inc, USA
	Patient perspective	**Lona Vincent**, Senior Associate Director, Research Partnerships, Michael J Fox Foundation, USA
10:40	**Break**	
SESSION 4: VALUE-BASED HEALTHCARE: HOW CAN THE VALUE PROPOSITION BE USED TO SUPPORT FURTHER HEALTHCARE REVOLUTIONS?		
	Working toward value-based healthcare systems *What is the changing landscape of the healthcare systems? What are the opportunities and challenges? What is the best approach for value-based healthcare provision? How can value-based healthcare incentivise and promote high-quality and cost-effective care? What are the practical steps?*	
11:10	**Patient perspective**	**Patricia Furlong,** Founding President and CEO, Parent Project Muscular Dystrophy, USA
11:30	**Payer perspective**	**Dr Don Juzwishin**, Director HTA and Innovation. Alberta Health Services, Canada
11:55	**Regulatory perspective**	**Barbara Sabourin,** Director General, Health Canada, Canada
12:10	**Industry and HTA Agency perspectives from the floor and general discussion**	
12:50	**Chairman's summary**	
13:00	**Close of Workshop**	