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SMi presents its 20th annual

European Pricing and Reimbursement

Evaluate HTA Reforms and Market Access Processes to Optimise Business Profit

Marriott Regents Park Hotel, London

13 - 14
OCT
2014

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Benefits of attending:

- Evaluate challenges within **price discrimination**
- Implications of **AMNOG** featuring **IGES Institut**, **EUCOPE** and **Ministry of Health, Germany**
- Case study from **Ipsen** on latest developments in pharmaceutical pricing
- Analyse the impact of **Value Based Assessment** on **SMEs**
- Gain further insight on how to **engage** effectively with **payers**
- Key presentation on the **IMI GefReal consortium**

Chairs for 2014:

- **Peter Hertzman**, Nordic Market Access Director, **BMS**
- **Leslie Galloway**, Chairman, **Ethical Medicines Industry Group (EMIG)**

Key Speakers Include:

- **Leyla Hannbeck**, Head of Pharmacy Services, **National Pharmacy Association**
- **Silke Baumann**, Head of Unit, Pricing, Assessment and Reimbursement of New Medicines, **Ministry of Health, Germany**
- **Rodolphe Perard**, Associate Director, Market Access, **Gilead**
- **Francois Bernard**, Head of Market Access, **Mundipharma**
- **Mike Chambers**, Head of Reimbursement and Value, Market Access and Healthcare Solutions, **GlaxoSmithKline**
- **Linda van Saase**, Manager, Pharmaceutical Care, **National Healthcare Institute**
- **Irma van den Arend**, VP, Global Pricing, Reimbursement and Funding, **Ipsen**
- **Mete Saylan**, Senior Market Access Manager, **Novartis**

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PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Wednesday 15th October 2014, Marriott Regents Park Hotel, London

A: PPRS: A roadmap to understanding the changes and ensuring effective engagement and optimal pricing

Workshop Leader: **Christian Hill**, Director, Market Access and Government Affairs, **Map BioPharma Ltd**

9.00am - 12.30pm

B: A multi-perspective approach to defining value to achieve optimal market access in Europe

Workshop Leaders: **Eimear Lochlainn**, Director, Value Insight & Communication and **Jennifer Cook**, Director, Value Insight & Communication, **Adelphi Values**

1.30pm - 5.30pm

www.pharmaceuticalpricing.co.uk

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

ACADEMIC & GROUP DISCOUNTS AVAILABLE



9.30 Registration & Coffee

10.00 Chairman's Opening Remarks

Peter Hertzman, Nordic Market Access Director, BMS

SPOTLIGHT ON PRICE DISCRIMINATION AND MARKET ACCESS

KEYNOTE ADDRESS

10.10 Price discrimination – gaining an overview

NORDIC

- What does price discrimination mean and why is relevant?
- Evaluating challenges and obstacles for price discrimination
- How are differences in HTA approaches between countries influencing price discrimination?
- Various options to achieve price discrimination, including outcome based contracts

Peter Hertzman, Nordic Market Access Director, BMS

10.50 Examining diverse perspectives on market access

- How do different regions approach and manage market access?
- Assessing different treatment pathways geographically and the impact of these on the industry
- Comparing market access strategies varying to class of drugs

Rodolphe Perard, Associate Director, Market Access, Gilead

11.30 Morning Coffee

CASE STUDIES, REFORMS AND HTA ASSESSMENTS

11.50 AMNOG and Early Benefit Assessment – Situation and trends

GERMANY

- 3 years of AMNOG and EBA – lessons learned
- Implications of the first modification law (effective April 1, 2014)
- Moving forward
- Case study of system in action

Professor Dr. Bertram Häussler, CEO, IGES Institut GmbH

12.30 Value Based Assessment

- What difference will it make?
- Issues for the pharmaceutical industry
- Issues for SMEs

Leslie Galloway, Chairman, Ethical Medicines Industry Group (EMIG)

1.10 Networking Lunch

2.10 Engagement with payers – how to successfully engage with payers and be heard

- How payers work with the pharma industry and what are the key foci
- What does a successful payer/pharma relationship look like
- How to approach payers using a patient-centric approach

Leyla Hannbeck, Head of Pharmacy Services, National Pharmacy Association

2.50 Pharmaceutical Pricing & Market Access Opportunities and Limitations in Turkey after Implementation of Health Transformation Reform

TURKEY

- Brief overview of Turkish Health Transformation Reform to understand current Pricing & Market Access environment : What does HTR include? What are the implications?
- Overview of marketing authorisation, pricing and reimbursement process in Turkey: delays, limitations, potential risks in reference price
- Early access opportunities (Pre-license reimbursement via importation from EU or US)
- Managed Entry Agreements in Turkey: What do current regulations allow you to do? What are the opportunities in the near future with the implementation of new pricing decree and reimbursement guideline?
- Are there price increase opportunities?
- Case studies related to above topics

Mete Saylan, Senior Market Access Manager, Novartis

3.30 From value based pricing to value based buying

- How to support health systems in making the right value based decisions
- Making the transition from product value to value delivered in the real environment
- How can the industry engage with local payers and deliver value
- Supporting value based decisions by demonstrating measurable results of new drugs

Janice Haigh, Practice Leader, Market Access, Quintiles

4.10 Afternoon Tea

4.30 AMNOG - Value Based Pricing in Germany

- What do we know now? Lessons learned
 - Explaining the latest legislation
 - Evaluating changes in P&R and the German landscape
- Silke Baumann, Head of Unit, Pricing, Assessment and Reimbursement of New Medicines, Ministry of Health, Germany

5.10 AMNOG and its international implications

- Choice of comparators
- International reference pricing
- Price transparency
- How are orphan medicines and products handled?

Dr Alexander Natz, Director General, EUCOPE

5.50 Chairman's Closing Remarks and Close of Day One

6.00 Drinks Reception sponsored by



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8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**
Leslie Galloway, Chairman, **Ethical Medicines Industry Group (EMIG)**

PRICING AND MARKET ACCESS SYSTEMS – CASE STUDIES

KEYNOTE ADDRESS

FRANCE

9.10 **EU Pricing & Market Access from a Global Perspective**

- Examining the latest developments in pharmaceutical pricing
- Price management in the context of International Price Referencing and Class Referencing
- Discussion of market access strategies and a case study of a system in action

Irma van den Arend, VP Global Pricing, Reimbursement and Funding, **Ipsen**

9.50 **Case study presentation: developing a co-creation model with payers**

- Understand payer preferences on patient pathway optimization
- Identify and develop solutions to co-create incremental value with external stakeholders including payers
- Moving our customer market access model from a "push" to a "pull" approach

Francois Bernard, Head of Market Access, **Mundipharma**

10.30 Morning Coffee

DEVELOPMENTS IN MEDICINE DEVELOPMENT

11.00 **Is there room for real world data in medicine development?**

- The emerging environment: conditional and adaptive processes for marketing authorisation and reimbursement
- The use of 'real world' data in generating early estimates of relative effectiveness
- The IMI GetReal consortium: towards a shared framework for decision making

Mike Chambers, Head of Reimbursement and Value, Market Access and Healthcare Solutions, **GlaxoSmithKline**

11.40 **Market access for innovative products: what's new in France?**

- Examining Actual Benefit (SMR) and Improvement Actual Benefit (ASMR) since 2005
- New legislation for France since October 2013: What is the impact?
- Demonstrating medical and economic values in real life

Côme de Sauvebeuf, Associate, Price and Market Access Department, **Kamedis Conseils**

12.20 Networking lunch

DISCUSSION OF FUTURE IN P&R

JAPAN

1.40 **Japanese Pricing and Reimbursement After the 2014 Reforms**

- Changes to launch pricing rules
- Role of premium for new drug development
- New measures for off-patent brands and generics
- Whatever happened to demands for cost effectiveness?

Donald Macarthur, Global Pharmaceutical Business Analyst, **DM Pharma Issues Ltd**

2.20 **The future scenario of P&R: health reforms and companies' strategies**

- Demand and offer of pharmaceuticals as public health criticism
- Actions by pharma agencies: NICE and others
- Sustainability of innovation
- Approaching new paradigms for companies

Professor Fabrizio Gianfrate, Professor of Healthcare and Pharmaceutical Economics, **University LUISS, Rome**

3.00 Afternoon Tea

3.30 **The proposed reform of the EU Transparency Directive – an Update**

- Introduction
- Transparency Directive (89/105)
- ECJ case law interpreting the Directive
- Problems with the current framework
- Review timeline
- Objective of the Commission's Proposal
- Effects of the proposed reform
- Conclusions

Strati Sakellariou, Associate, **White & Case LLP**

NETHERLANDS

4.10 **A Dutch Approach to Reimbursement**

- The impact of personalised medicine on Pricing and Reimbursement
- Clarifying the conundrum of reimbursement authorities
- The dutch solution – implementing boundaries for all stakeholders
- Negotiating the best outcome for healthcare – illustrated with examples

Linda van Saase, Manager, Pharmaceutical Care, **National Healthcare Institute**

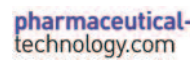
4.50 **Panel discussion – managing international challenges of HTA**

- Clarifying the impact of European developments on industry
- What is the future of HTA?
- Debating the positives and negatives in future HTA approaches

Janice Haigh, Practice Leader, Market Access, **Quintiles**
Peter Hertzman, Nordic Market Access Director, **BMS**
Francois Bernard, Head of Market Access, **Mundipharma**

5.30 Chairman's Closing Remarks and Close of Day Two

Supported by



PPRS: A roadmap to understanding the changes and ensuring effective engagement and optimal pricing

In association with:



Overview of workshop:

Introduced in January this year, the new PPRS pricing scheme represents a major change in how the UK pays for branded medicines. The Pharmaceutical Price Regulation Scheme (PPRS) has been around since the 1950s, but this new version has evolved greatly from its previous incarnation that was running from 2009 to 2013. Until January 2014, the PPRS was a 'profit cap and price cut' system, which controlled the overall UK drugs bill, and allowed free pricing setting at launch by pharmaceutical companies. The new PPRS has a number of novel components introduced alongside existing provisions from the previous PPRS. This workshop will enable attendees from the biotech and pharmaceutical industry to understand the implications for their portfolio of medicines, how the new changes to the PPRS will impact them and ensure optimal pricing strategy is developed and maintained/monitored.

Why you should attend:

Learn about:

- Planning for PPRS and the leveraging it as part of the wider strategy across European markets
- The link between PPRS and HTA organisations in the UK and managing the interrelationship effectively
- Avoiding nasty surprises
- How to negotiate a price rise

Programme:

- 8.30 Registration and coffee**
- 9.00 Welcome and introductions**
- 9.10 Icebreaker**
- 9.30 Presentation: Overview of the changes in PPRS**
- 10.00 Case studies: the good, the bad, the ugly**
- 10.40 Coffee break - questions on a postcard collected during coffee break**
- 11.00 Interactive discussion: Answers on a postcard session**
- 11.45 Summary and key messages**
- 12.00 Meeting close**

About the workshop host:



Christian Hill is Director of Market Access and Government Affairs at Map BioPharma and Map MedTech. He is a seasoned market access professional with over 15 years of experience in the international life sciences industries. He has a broad range of expertise and experience including pricing, HTA submission strategy leading to positive guidance, health economic modeling development, and relationships with access and reimbursement bodies and their influencers across Europe, with a specific focus on the UK and Ireland.

He is also a member of the board at EUCOPE, a trade body in Europe representing Medtech and BioPharma companies; and a member of the steering group of EMIG, a UK trade body representing primarily SMEs.

About Map BioPharma

Map offers consultancy services that help MedTech and BioPharma clients achieve optimal market access in Europe with a special focus on the UK & Ireland and Germany. This is achieved through a combination of a web based subscription service which aims to act as a 'virtual' expert to hold your hand as you navigate the processes; and through one to one strategic advice, support for product profiling, pricing and dossier development and to support lobbying activity for when a plan B is needed.

**A multi-perspective approach to
defining value to achieve optimal
market access in Europe**

In association with:



ADELPHI VALUES

Overview of workshop:

The workshop will provide an overview of the EU healthcare environment, challenges as well as the processes. Key aspects of the workshop will include:-

- An EU perspective of market access, with insights into upcoming changes/developments highlighting differences and similarities between countries and regional differences where applicable
- Identification of key stakeholders and decision makers, how they assess value and what their needs and decision drivers are
- Review of the general clinical and economic evidence requirements and consideration for clinical development programmes to meet regulatory/HTA hurdles

Why you should attend:

This workshop will provide an understanding of the EU healthcare systems, P&R processes, increase your understanding of the challenges and opportunities within the EU market access environment and identify how to define value for different stakeholders and customize value propositions to optimize P&R success.

Programme:

- 13:00 Registration & Coffee**
- 13:15 Examining diverse perspectives on market access**
- 14:00 Why is value important – moving away from price**
- 14:45 Coffee break**
- 15:15 Assessing value for different stakeholders - meet the payer**
- 16:00 Interactive discussion – how do you assess value?**
- 16:40 Reviewing requirements to meet HTA challenges**
- 17:15 Close of workshop**

**agenda may be subject to change*

About the workshop host:

Eimear Lochlainn, Director, Value Insight and Communication. With over 20 years international experience in the pharmaceutical & biotechnology industry, NHS Scotland, Scottish Medicines Consortium (SMC), academia and consulting, Eimear has managed, led, developed and implemented global market access strategies for new pharmaceuticals, diagnostics and vaccines. She has also been an economic assessor and advisor to the SMC, appraising reimbursement submissions from the pharmaceutical industry seeking a positive formulary listing. Eimear has extensive experience managing multidisciplinary collaborative teams with various stakeholders and has technical expertise in information science and synthesising statistical, clinical, economic, public health and commercial evidence to formulate strategic market access plans.

Jennifer Cook, Director, Value Insight and Communication. Jennifer has broad and extensive experience within the pharmaceutical industry; immediately prior to joining Adelphi Values she worked as a Global Pricing and Market Access Director for AstraZeneca, developing payer pricing and market access strategies and shaping evidence needed for payer value stories, to gain reimbursement. Her earlier industry experience includes roles in sales, marketing, and market analysis. As one of the directors at Adelphi Values, Jennifer informs client decisions through the investigation, demonstration and communication of healthcare value, working across a range of therapeutic areas.

About Adelphi Values

Adelphi Values is a global patient-centered research and healthcare value consultancy combining strategic thinking with a reputation for excellence in outcomes research, health economics, and market access. By understanding and addressing the challenges of our clients, we help bring healthcare products and services to the market successfully by investigating, developing and communicating scientific evidence that defines value, informs decisions and benefits patients.

EUROPEAN PRICING AND REIMBURSEMENT

Conference: Monday 13th – Tuesday 14th October 2014, Marriott Regents Park Hotel, London | Workshops: Wednesday 15th October 2014, London

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