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SMi present the 22nd annual conference on...

European Pharmaceutical Market Access and Pricing & Reimbursement

Holiday Inn Kensington Forum, London, UK

CONFERENCE:
10TH - 11TH
WORKSHOPS: 12TH
OCT 2016

Thinking ahead – exploring future P&R strategies for Europe and beyond

CHAIRS FOR 2016:

- **Bertram Häussler,** Chairman of the Board of Management, **IGES**
- **Gordon Spencer,** Regional Market Access Lead - EU & Canada, **Shire International GmbH**

KEYNOTE SPEAKERS INCLUDE:

- **Simone Breitkopf,** Head HEOR, Governmental and Public Affairs, **Alcon**
- **Ulf Staginnus,** Head Market Access Oncology, Region Europe, **Baxalta**
- **Alexander Natz,** Secretary General, **EUCOPE**
- **David Watson,** Director of Pricing and PPRS, **Association of the British Pharmaceutical Industry**
- **Panos Kefalas,** Head of Health Economics and Market Access, **Cell & Gene Therapy Catapult**
- **Ken Walsh,** Senior Principal, Global Payer Strategy Consulting, **Evidera**

Exclusive Highlights in 2016:

- Updates on **AMNOG** and its implication on pricing and reimbursement
- How **biosimilars** are affecting your pricing strategy
- Capture on **emerging markets' regulatory framework** to adapt your market access and P&R models
- **Orphan drugs** using recent examples to highlight the impact on pricing
- **Cancer drug funding,** budget cuts and **Accelerated Access Review** in the UK

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 12th October 2016, Holiday Inn Kensington Forum, London, UK

A: HTA and reimbursement decisions for innovative medicines

08.30 – 12.30

Workshop Leader: **Patrick Mollon,** Former Director of Health Economic & Outcomes Research, **Novartis;** HEOR Director, **PMHE2020**

B: Managing the global to local challenge

13.30 – 17.30

Workshop Leader:
Janice Haigh, Practice Leader, **Quintiles**

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European Pharmaceutical Market Access and Pricing & Reimbursement

Day One | Monday 10th October 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Bertram Häussler, Chairman of the Board of Management, **IGES**

REGULATORY UPDATES

09.10 **OPENING ADDRESS: Current challenges in European market access, pricing and reimbursement**
- A better understanding of pricing issues: Euripid Database
- EUnetHTA
- Differential pricing vs international reference pricing

Alexander Natz, Secretary General, **EUCOPE**

09.50 **New Cancer Drugs Fund (CDF) UK 2016: What have we learned from the transition period?**
- Is the new process working as well as expected?
- How has this new process increased market access?
- What to expect next

Smita Sealey, UK Engagement Manager, Market Access, **IMS Health**

10.30 **Morning Coffee & Networking Break**

11.00 **AMNOG: strengths, challenges and where next?**
- Strengths and challenges of AMNOG
- How well is AMNOG working for orphan drugs?
- Potential healthcare reform steps

Bertram Häussler, Chairman of the Board of Management, **IGES**

CHANGES IN BUSINESS ENVIRONMENT

11.40 **CASE STUDY: Gene and Cell Therapies - focusing on expensive and process-intensive therapies**
- What is different about reimbursement strategies for gene and cell therapies?
- Challenges associated with the reimbursement and adoption of these therapies
- Looking to the future – how to overcome these challenges

Panos Kefalas, Head of Health Economics and Market Access, **Cell & Gene Therapy Catapult**

12.20 **Networking Lunch**

13.20 **Rare diseases and orphan drugs: A market access outlook**
- What's new in this field?
- How innovation can be measured in terms of orphan drugs
- Government funding and incentive in orphan and rare disease drugs

Gordon Spencer, Regional Market Access Lead - EU & Canada, **Shire International GmbH**

14.00 **Market Access trends in oncology**
- The structure of the oncology market – P&R outlook
- What's new in generic oncology?
- How to build the optimal market access strategy for cancer drugs

Ulf Staginnus, Head Market Access Oncology, Region Europe, **Baxalta**

14.40 **Afternoon Tea & Networking Break**

15.10 **SPOTLIGHT ADDRESS: Japan: 2016 P&R reforms**
- The changes and their implications
- New cost effectiveness demands
- Is Japan still a pharmaceutical pricing paradise?

Donald Macarthur, Global Pharmaceutical Business Analyst

DATA COLLECTION

15.50 **How to effectively use global pricing data to maintain a sustainable business model**
- Challenges with obtaining and standardising pricing data
- Quantitative analysis and setting the parameters for your model – how and why?
- Taking HEOR into account

Session reserved for sponsor

16.30 **Chairman's Closing Remarks and Close of Day One**

European Pharmaceutical Market Access and Pricing & Reimbursement

Day Two | Tuesday 11th October 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Gordon Spencer, Regional Market Access Lead - EU & Canada, **Shire International GmbH**

09.10 **OPENING ADDRESS: Biosimilars and the impact on pricing and reimbursement**
- The economics of biosimilars
- How should we price biosimilars?
- What can be done by payers to ensure long term savings?

Jorge Mestre-Ferrandiz, Director of Consulting, **Office of Health Economics**

REGIONAL UPDATES

09.50 **A Nordic update – market access outlook**
- The transition to the new system – how well is this working?
- What are the challenges?
- How is this affecting market access?

Rasmus Jensen, Owner; Former Director and Head of Market Access, **Drewes Jensen Consult; Lundbeck**

10.30 **Morning Coffee & Networking Break**

11.00 **The UK pricing and reimbursement landscape**
- Accelerated Access Review (AAR) – an update
- Current pricing strategies and market access arrangements
- The future of UK pricing

David Watson, Director of Pricing and PPRS, **Association of the British Pharmaceutical Industry**

11.40 **East meets West: The Turkish story on market access**
- A fast-growing, high-potential emerging market
- Access strategies including named-patient use
- 'Alternative reimbursement model' pilots

Donald Macarthur, Adviser, **Proceutica**

12.20 **Networking Lunch**

13.20 **An update from the U.S**
- New biosimilars that have been approved
- Lessons to learn and the impact this has had on pricing strategies
- The recent price-hiking scandal – how did this happen?

Ken Walsh, Senior Principal, Global Payer Strategy Consulting, **Evidera**

FUTURE IN PRICING AND REIMBURSEMENT

14.00 **PANEL DISCUSSION:**
Innovative solutions: Improve quality and reduce costs
- New technology in the pipeline
- Performance base pricing – is this sustainable?
- Is a "beyond the pill revolution" near?

Moderated by: Simone Breitkopf, Head HEOR, Governmental and Public Affairs, **Alcon**

14.30 **Afternoon Tea & Networking Break**

15.00 **Current trends in Health Technology Assessment (HTA)**
- Synergy between payers and European HTA bodies
- Current requirements for harmonisation of HTA and challenges associated with this
- Early dialogue for medical devices

Simone Breitkopf, Head HEOR, Governmental and Public Affairs, **Alcon**

15.40 **Value based pricing - is it affordable?**
- Cost of the product vs value to the patient
- What effect would value based pricing have on market access?
- Is there potential for this strategy?

Patrick Mollon, Former Director of Health Economic & Outcomes Research, **Novartis;** HEOR Director, **PMHE2020**

16.20 **Chairman's Closing Remarks and Close of Day Two**

HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 12th October 2016
08.30 – 12.30
Holiday Inn Kensington Forum, London, UK

A: HTA and reimbursement decisions for innovative medicines

Workshop Leader:
Patrick Mollon, Former Director of Health Economic & Outcomes Research, **Novartis;** HEOR Director, **PMHE2020**

Overview of Workshop:

Beyond getting regulatory approval, getting through HTA reviews successfully is key for market access. HTA requirements vary across countries, however a global strategy for value demonstration at launch is required for timely and successful submission.

The workshop will cover the requirements for establishing an HEOR strategy addressing market access and pricing requirements including real world evidence, from an European perspective. This will be done from a practical and interactive approach. This workshop will enable you to develop best practice approaches for value demonstration of novel medications.

Programme:

08.30 **Registration and Coffee**

09.00 **Value-based development**

- Explore different approaches to value in the European setting
- Understand the common need for value in an ever-changing environment
- Roadmap to develop, validate and implement HEOR value demonstration in a context of uncertainty and cost-containment
- Gain an economic perspective
- Learn how to comprehensively addressing stakeholders perspectives and incorporate RWE early on

11.00 **Coffee Break**

11.30 **Case study and break-out sessions**

12.00 **Q&A**

12.30 **Close of workshop**

About the Workshop Leader:

Patrick Mollon, MD, ESSEC MBA, MSc worked initially as a Clinician, practicing General Medicine as well as being a Registrar in Emergency Medicine and Intensive Care in an University Teaching Hospital in Lyon, France.

A Director, Global HEOR at both Pfizer and Novartis he has been instrumental in developing and implementing Health Economic strategies to support developmental compounds in a number of therapeutic areas, including Cardiovascular, Urology, Anti-Virals, Immunology, leading the value identification and demonstration efforts for market access and Health Technology Assessment from a global perspective. As such, he has led the development of Patient Reported Outcomes tools, Health-Economic and Budget-Impact models, and Value Dossiers.

He is currently an Independent HEOR Consultant at PMHE2020

Patrick has a number of Health-Economics and Outcomes Research publications, his main interests are in health-economic modelling methods and applications as well as patient-reported outcomes and decision-making.

About the Organisation:

Capitalising on 20+ years experience in medical practice, drug development and HEOR, PHME2020 provides HEOR consultancy services supporting the value demonstration of innovative developmental therapies.

Activities include development and review of HEOR, PRO and RWE strategies and plans.

HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 12th October 2016
13.30 – 17.30
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B: Managing the global to local challenge

Workshop Leader:
Janice Haigh, Practice Leader, **Quintiles**

Overview of Workshop:

When designing market access strategies, companies are doing a good job in getting their overall strategy right but then they fall short in local implementation. Usually, there is a lot of knowledge about the product at a global level and market knowledge at a local level. However in reality, quite often this gap isn't closed when it comes to trying to get a new drug approved in different markets.

Programme:

13.30 **Registration and Coffee**

14.00 **How to overcome internal challenges between global and local organisations**

- Frame the evidence packages for key markets
- Get all required information for HTA submission
- Make sure to use HTA knowledge to drive drug usage at the desired price

16.00 **Coffee Break**

16.30 **Case study**

17.00 **Q&A**

17.30 **Close of workshop**

About the Workshop Leader:

Janice joined Quintiles Consulting in January 2012. Janice has 25 years' of pricing and market access strategy experience gained through a variety of consulting roles and in pharma.

She was with IMS/Cambridge Pharma for almost 10 years before joining Astellas Pharma Europe as senior director of pricing and market access in 2006.

About the Organisation:

Quintiles (NYSE: Q) helps biopharma and other healthcare companies improve their profitability of success by connecting insights from our deep scientific, therapeutic and analytics expertise with superior delivery for better outcomes. From advisory through operations, Quintiles is the world's largest provider of product development and integrated healthcare services.

EUROPEAN PHARMACEUTICAL MARKET ACCESS AND PRICING & REIMBURSEMENT

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Workshops: Wednesday 12th October 2016, London, UK

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