

SMi Presents the 10th Annual Conference on...

Parallel Trade

Capturing Macro Economics and Regulatory Updates to Implement Best Parallel Trade Model

Holiday Inn Kensington Forum, London, UK

8 - 9
FEB
2016



ADVISORY BOARD 2016:

- **Eric Noehrenberg**, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**
- **Janice Haigh**, Practice Leader, Market Access, **Quintiles**
- **Dr. Shabnam Hanassab**, Senior Consultant, **IMS Health**

EXPERT SPEAKER PANEL INCLUDES:

- **Sigve Sivertsen**, Head of Parallel Trade, **Apotek Hjartat**
- **Gordon Cox**, Director of Operations, **Alliance Healthcare Distribution Ltd.**
- **Richard Freudenberg**, Chief Executive, **European Association of Euro-Pharmaceutical Companies**
- **Katarzyna Kolasa**, Market Access Director Region East, **Lundbeck**
- **Tomasz Dzitko**, Founder & CEO, **Delfarma**
- **Vladimir Zah**, CEE Executive Committee Chair 2015-17, **ISPOR CEE**; Past President, **ISPOR Srbija**

HIGHLIGHTS FOR 2016:

- Assess impacts from **regulatory changes and regional trade controls** for parallel trade
- Understand how a **volatile macro economic environment** is affecting on the parallel distribution market
- Regional market snapshots - **evaluating opportunities across Europe and ensuring business integrity**
- Refine your business model through **better distribution, pricing and market access planning** to protect your brand and revenue stream
- **Online pharmacy - product validation** and minimising risks of **counterfeited drugs**
- Network with your industry colleagues **to share experiences and implement best practices**

PLUS TWO HALF DAY POST-CONFERENCE WORKSHOPS

Wednesday 10th February 2016, Holiday Inn Kensington Forum, London, UK

WORKSHOP A

Parallel Trade - Management Strategies

Workshop Leader:

Janice Haigh, Practice Leader, Market Access, **Quintiles**

8.30am - 12.30pm

WORKSHOP B

Understanding Regulatory and Legal Issues Around Parallel Distribution

Workshop Leader:

Arty Rajendra, Partner, IP Litigation, **Rouse Legal**

13.30 - 16.30pm

www.parallel-trade.com

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Parallel Trade

Day One | Monday 8th February 2016

09.30 Registration & Coffee

10.00 Chairman's Opening Remarks

Eric Noehrenberg, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**

WHAT HAS HAPPENED AND WHAT WILL HAPPEN?

10.10 OPENING ADDRESS: Chairman's Introduction to Parallel Trade

- What is parallel trade?
- Who benefits from parallel trade? What are the negative impacts of parallel trade?
- Key players in parallel trade and their respective strategies?
- Meeting the challenges of parallel trade

Eric Noehrenberg, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**

10.50 PT in Germany (Situation and Perspective)

- Importation dynamics
- AMNOG and Parallel Trade
- Future political and regulatory environment in Germany

Prof. Bertram Häussler, CEO, **IGES**

11.30 Morning Coffee & Networking Break

ALIGN YOUR STRATEGY WITH THE EVOLVING PARALLEL TRADING MARKET

12.00 Parallel Distribution Market in the Benelux

- FOREX, how did exchange rate affect on product flow and distribution
- The challenge of sourcing products with an increasingly tight trade regulations within EU
- Looking beyond, what will drive this market in 2016?

Maarten Kamphuis, Managing Director, Business Development, **FisherFarma***

12.40 The Nordic Scene: Rise of Pharmacies and Wholesalers in PT

- Should this be a competition? Manufacturer vs. wholesaler vs. pharmacy in trade
- Post-oil prices crisis with weakened kroners vs. purchasing patterns
- Channel strategy to manage pharmaceutical product distribution

Sigve Sivertsen, Head of Parallel Trade, **Apotek Hjartat**

13.20 Networking Lunch

14.30 PT in Germany and Europe - From Market Situation to Policy Impacts

- The dilemma of standard products' referencing prices after AMNOG
- Challenges for market access and demonstrating benefit evaluation for new pharmaceuticals
- Latest European policy updates which can impact on parallel distribution

Matthias Heck, Attorney-at-Law, Head of Brussels Office, **German Pharmaceuticals Industry Association**

15.10 European Parallel Trade: Past, Present and Future

- Key trends and dynamics in distribution and dispensing
- Outlook and key factors likely to influence the market going forward

Dr. Shabnam Hanassab, Senior Consultant, **IMS Health**

15.50 Afternoon Tea & Networking Break

16.20 The Importance of External Reference Pricing in the Market Access – A Case from CEE Settings

- What is the impact of the reference pricing on reimbursement decisions
- How to develop innovative pricing solution to secure the access to pharmaceuticals in CEE region
- Why parallel trade can hurt search for the innovative pricing solution

Katarzyna Kolasa, Market Access Director Region East, **Lundbeck**

17.00 Panel Discussion: Understanding the Rationale Behind



- The never-ending debate: should medicinal products and devices be treated the same as other commodities?
- The role played by parallel distributors on fairer prices and competitions
- Harmonising national and European regulatory framework
- Recap of the day and hot topics discussion

Moderated by:

Eric Noehrenberg, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**

17.40 Chairman's Closing Remarks and Close of Day One

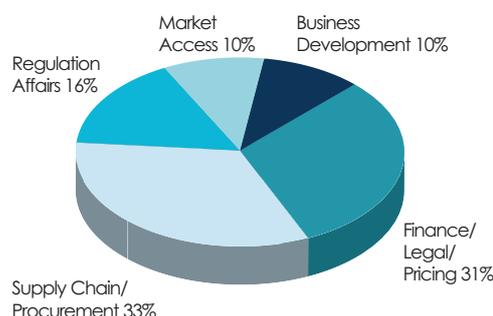
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Who Should Attend:

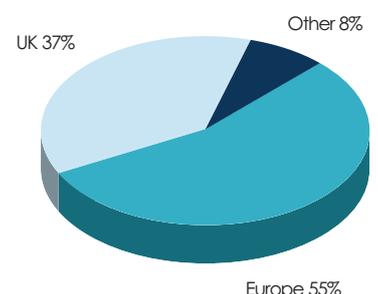
VPs, MDs, Chiefs, Heads, Managers, Principals of:

- Parallel Trade/ Import/ Export/ Distribution
- Wholesale
- Regulatory Affairs
- Legal Counsel/ General Counsel
- Supply Chain/ Demand Planning
- Market Access & Pricing
- Commercial Effectiveness
- Operations
- Country Manager
- Business Development
- Finance

Parallel Trade 2015 Attendees by Industry Sector



Parallel Trade 2015 Attendees by Geo Location



08.30 Registration & Coffee

09.00 Chairman's Opening Remarks and Setting the Scene
Eric Noehrenberg, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**

A CROSS-DEPARTMENTAL SUBJECT

09.10 OPENING ADDRESS: Antitrust in the Pharmaceutical Sector: The Key Issues and Recent Cases in the UK and Europe

- Explanation of the role of the CMA
- Discussion of antitrust cases in the sector – such as Napp, Genzyme, Gaviscon, AstraZeneca, Servier and Lundbeck
- Discussion of issues around excessive pricing (including phenytoin)

Andrew Groves, Director, Competition, Consumer & Markets Group, **CMA**

09.50 Restricted Export Control – What Should Parallel Traders Do?

- The story from parallel distributors – why and how?
- Dealing with regional export restrictions and temporary bans
- Short- and long-term impacts on product prices and trading routes

Kalo Georgiev, CEO, **Nippon Bells Pharma Bulgaria**

10.30 Morning Coffee & Networking Break

11.00 Are You Ready? Implementation of Falsified Medicines Directive and Implications on Parallel Trade

- Deadline of 2018 - are you on the right track and preparing for implementation?
- Latest updates and requirements from regulators
- Challenges of compliance for small- and mid-sized companies
- Clear benefit of improving patient safety and combating counterfeited medicines from parallel trade

Gordon Cox, Operations Director, **Alliance Healthcare Distribution Ltd.**

11.40 Initiatives of Parallel Distributors in the Context of Falsified Medicines Directive

- Good parallel distribution guidelines
- Early warning of anti-CF platform
- Joint audits initiative
- European Medicines Verification Organisation

Tomasz Dzitko, Founder & CEO, **Delfarma**

12.20 Parallel Distribution – A View from the Top

- How parallel distribution integrates into the coming medicine verification system
- The role of the EAEPC on current supply chain safety issues

Richard Freudenberg, Chief Executive, **European Association of Euro-Pharmaceutical Companies**

13.00 Networking Lunch

COMMERCIALITY OF PARALLEL DISTRIBUTION AND MARKET DISRUPTION

14.00 A Macro View - Product Range vs. Product Value for Parallel Trade in Europe

- The increasingly diversified product portfolio for parallel distribution: what are upcoming?
- Which categories of products are favoured by parallel distributors?

Vladimir Zah, CEE Executive Committee Chair 2015-17, **ISPOR CEE**; Past President, **ISPOR Srbija**

14.40 The Community Pharmacy Perspective?

- Parallel trade – the pharmacist perspective
- Cost efficiency for NHS and network distribution
- Online pharmacy and product authentication

Nick Kaye, Superintendent, **Narrowcliff Pharmacy**; Director, **National Pharmacy Association**; Chair, **Local Pharmacy Forums**

Gareth Jones, Public Affairs Manager, **National Pharmacy Association**

15.20 Afternoon Tea & Networking Break

15.50 Rebuilding Your Business Model Protect Revenue Stream

- Reviewing your national and global market access and distribution strategy for an integrated and optimal supply chain
- Challenges and opportunities presented by market access vs. parallel distribution
- Pricing and volume – best practice to ensure business integrity and continuity

Speaker to be announced shortly

16.30 Recap of the 2016 Meeting - Ask the Panel and Audience

Delegates will have the final chance to ask speakers and colleagues plus summing up what they've learnt over the 2-day meeting. It'll be a recap for objectives set on Day 1 and sharing of key takeaways.

Moderated by:

Eric Noehrenberg, Director, Regional Market Access Lead, Latin America, **Shire International GmbH**



17.00 Chairman's Closing Remarks and Close of Day Two

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HALF-DAY POST-CONFERENCE WORKSHOP A

Wednesday 10th February 2016

8.30am – 12.30pm

Holiday Inn Kensington Forum, London, UK

Parallel Trade - Management Strategies

Workshop Leader:

Janice Haigh, Practice Leader, Market Access, **Quintiles**

Overview of Workshop:

With a volatile macro-economic and evolving regulatory environment, parallel trade activities have introduced new dynamics to pharmaceutical market in 2015. Pharmaceutical manufacturers now recognise it is a cross-departmental effort to ensure business integrity. This workshop educate attendees on the followings:

- Challenges of logistics and supply
- Importance of accurate measurement and affiliate partnerships in import and export markets
- Revenue and profit
- Ensuring patient supply

Key Benefits of Attending:

Through interactive discussions and case reviews, this workshop will help you to address all the above challenges relating to parallel trade. You will be able to re-assess the best strategy and option suitable to your business including pricing and supply management.

Programme

08.30 Workshop registration and morning coffee

09.00 Workshop leader introduction

09.10 Background to Parallel Trade (PT)

09.15 PT Management Options

09.50 An Overview of Supply Management

10.20 Coffee Break

10.50 Critical Success Factors

11.20 Review of Tactical Details

12.00 Discussion and Q&A

12.30 End of Workshop

About the Workshop Leader:

Janice Haigh, Practice Leader, Market Access, **Quintiles**



- Joined Quintiles Consulting in January 2012 as Practice Leader for Market Access in Europe
- From 2006 to December 2011, Senior Director Pricing and Market Access for Astellas Pharma Europe
- Responsible for development and implementation of pricing and market access strategy for new and in-market products, working closely with brand teams and affiliates
- Responsible for all price management, analysing effect of price changes on other markets
- Designed, implemented and managed Astellas's supply chain integrity program which ensured the matching of supply and demand of products in Europe
- Before joining Astellas in 2006, Janice worked in consultancy for 20 years, including almost 10 years at IMS Health/Cambridge Pharma Consultancy

Responsible for leading projects involving pricing, parallel trade, health economics and health policy. Clients included European and global pharmaceutical companies but also trade associations and government bodies such as the European Commission

About the Organisation:

Quintiles (NYSE: Q) is the world's largest provider of biopharmaceutical development and commercial outsourcing services with a network of more than 29,000 employees conducting business in approximately 100 countries. We have helped develop or commercialize all of the top-50 best-selling drugs on the market. Quintiles applies the breadth and depth of our service offerings along with extensive therapeutic, scientific and analytics expertise to help our customers navigate an increasingly complex healthcare environment as they seek to improve efficiency and effectiveness in the delivery of better healthcare outcomes. To learn more about Quintiles, please visit www.quintiles.com

Understanding Regulatory and Legal Issues Around Parallel Distribution

Workshop Leader:

Arty Rajendra, Partner, IP Litigation, **Rouse Legal**

Overview of Workshop:

Regulatory affairs and legal issues are still the key challenge for parallel distribution, as reflected from recent cases. This workshop will provide an interactive environment with practical examples for delegates to learn about scenario planning as well as in-depth snapshot of regional pharmaceutical markets.

Key Benefits of Attending:

Attendees will gain invaluable takeaways from this workshop on

- Critical regulatory landscape and legislations that can impact on their business planning and operations
- How to mitigate legal risks and when to act?
- Ensure business continuity and integrity on a pan-European landscape

Programme:

13.30 Registration & Coffee

14.00 Workshop Leader Introduction

14.10 Regulatory Landscape of Parallel Trade

- Regional legal updates – from export to import to licensing applications
- From politics to IP to branding – recent cases reviews and lesson learnt
- How to manage temporary restrictions from regional markets?

14.45 Coffee & Networking Break

15.15 Delegates will be asked to participate in an interactive case study

16.00 Q&A

16.30 Workshop Leader's Closing Remarks and End of Workshop

About the workshop host:



Arty Rajendra, Partner, IP Litigation, **Rouse Legal**
Arty Rajendra is a partner in the London office of global IP firm Rouse. She is a well-known authority on parallel trade having acted in *Glaxo Group v Dowellhurst* – one of the leading cases in this area. In addition, Arty can advise on the full range of IP rights, and has extensive experience in patent and trade mark litigation.

In the last 12 months, Arty has advised clients on parallel imports in the following industries: automotive, consumer electronics, fast-moving consumer goods (FMCG) and pharmaceuticals.

About Rouse Legal:



Rouse is an international firm that specialises in IP. They provide the full range of IP services and solutions from strategic consultancy through to IP management, enforcement and commercialisation for a range of clients from start-ups to some of the world's largest owners of IP rights. Whatever your IP needs, we can help with experts in 16 offices across the globe working as one integrated team. www.rouse.com

PARALLEL TRADE

Conference: Monday 8th & Tuesday 9th February 2016, Holiday Inn Kensington Forum, London, UK
Workshops: Wednesday 10th February 2016, London, UK

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