

# Pharmaceutical Labelling & Packaging

Gain essential feedback on how to get the right information to patients whilst remaining compliant with the evolving regulatory framework

20-21 October 2010, Holiday Inn Regent's Park, London, UK

## Regulatory Panel:

- **Dominique Westphal, Paul-Ehrlich-Institute**, Germany
- **Linda Grohsová, State Institute for Drug Control**, Czech Republic
- **Ilaria Passarani, BEUC – The European Consumers' Organisation**, Belgium
- **Helen Taylor, PAGB (The Proprietary Association of Great Britain)**, UK
- **Dr Michael Wilks, CPME; eHealth Users' Stakeholder Group**, Belgium
- **Janice Kite, GS1 Global Office**, UK
- **Jim Thomson, European Alliance for Safe Medicines**, UK

## Industry Experts:

- **David Howard, J&J**, USA
- **Petra Baddack, Abbott Products GmbH**, Germany
- **Lisa Roberts, GlaxoSmithKline**, UK
- **Fiona Reekie, J&J Pharmaceutical Group**, UK
- **Susanne Sommer, Merck KGaA**, Germany
- **Philippe Auclair, Abbott Vascular International**, Belgium

## 2010 Key Highlights:

- ✓ **Essential regulatory advice** on working with the new SmPC guideline and QRD template from the **Paul-Ehrlich-Institute and Czech State Institute for Drug Control**
- ✓ **First-hand industry feedback** – hear from **Merck KGaA** on readability testing, **Abbott** and **J&J** on the SmPC guideline and QRD template, and **GSK** on company position documents
- ✓ **New for 2010** - gain feedback from key associations moulding legislation including **PAGB, CPME**, and **BEUC – The European Consumers' Organisation** on how industry and Regulators can work to meet patient needs more effectively
- ✓ **Anti counterfeiting and traceability** – discover the role industry can play in protecting products through effective packaging and labelling methods from the **EAASM, J&J** and **GS1 Global Office**
- ✓ **Gain a global perspective** – look beyond the EU into the Americas and learn more on emerging trends and knock-on effects

## PLUS DON'T MISS:

**Pre-Conference Workshop W: Tuesday 19 October 2010**  
**Written Information Provision beyond the EU:**  
**Spotlight on the Americas**

Led by: **Mark Gibson, Consumer Information Specialist, UK**

**Evening Seminar and Dinner S: Wednesday 20 October 2010**  
**Looking at Information about Medicines:**  
**Is it really what we want?**

Led by: **Dr Karel van der Waarde, Avans University, The Netherlands**

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*"Good to see everyone in dialogue with the same issues. Good opportunity to gain contacts for help on common issues"* Delegate, Sanofi Aventis

Pre-Conference Workshop: Tuesday 19 October 2010

## Written Information Provision beyond the EU: Spotlight on the Americas

09.00 Registration • 09.30 Start • 16.30 End of workshop

This workshop is aimed at discussing topics relating to written information provision outside of the EU, with a specific focus on the USA, Canada and emerging markets in South America.

### Topics to be covered:

- The changing face of written information in the USA
- Colliding cultures: will there be future convergence or divergence between the USA and the EU?
- Product information in emerging markets: focus on Argentina and Brazil

### What attendees will gain:

- The opportunity to share information and learn from emerging trends outside the EU
- Knowledge that may affect attendees directly, relating to global product launches and licensing maintenance in the Americas

Led by:

**Mark Gibson**, *Consumer Information Specialist*, UK

Mark spent 9 years in academic research where he developed interests in healthcare professional – patient communication and information provision for 'hard-to-reach' populations. The latter included multilingual communities where proficiency in English is limited, people with low literacy skills and older people with sight loss.

In 2004, Mark co-founded one of the first dedicated readability testing organisations of its kind in Europe. Mark has also been a consultant to several Contract Research Organisations for new product development, linguistic validation, international readability testing strategies and multilingual information design.

## Conference Day 1 – Wednesday 20 October 2010

08.30 Registration

08.50 Chairperson's opening remarks

### Evolving Legislation: Labelling & Packaging to Meet Patient Needs

09.00 **Better Packaging and Labelling for Better Informed Patients**

- Users perception of package leaflets
- What has been done so far (e.g. EMA, user testing)
- Review of ongoing discussions and potential repercussions (e.g. information to patients, pharmacovigilance)
- Respond to patients needs: suggestions for improvement

**Ilaria Passarani**, *Senior Policy Officer*, **BEUC –The European Consumers' Organisation**, Belgium

09.35 **Creative Over the Counter Medicines Packaging to Effectively Meet Patient Needs**

- Current methods to achieve affective communication with patients
- Review of ongoing discussions and potential repercussions
- How can we facilitate patient needs in the future?
- Does good information equal potential knowledge increase?

**Helen Taylor**, *Codes of Practice Executive*, **PAGB (The Proprietary Association of Great Britain)**, UK

10.10 **Joined Up Information for Patients and Healthcare Professionals**

- The changing face of healthcare
- The challenge of information delivery
- The role of eHealth
- How and where is information best delivered
- How information about medication fits in

**Dr Michael Wilks**, *Immediate Past President*, **CPME**, *Chairman*, **eHealth Users' Stakeholder Group**, Belgium

10.45 Coffee break

### QRD Template and SmPC Guideline – Have we Achieved the Right Balance of Risk vs. Benefit?

11.15 **The Revised QRD Template and its Implication on the Creation of Package Leaflets and SmPC – Regulation and Legal**

- First experiences working with the revised QRD template
- Practical experience working with the revised SmPC guideline
- Is it really an improvement for the package leaflet?
- How can the revised template help industry in reality?

**Petra Baddack**, *GRA - Head of Europe, Regulatory Affairs Coordination*, **Abbott Products GmbH**, Germany

11.50 **How to Effectively Implement the Revised QRD Template for SmPC and PIL – Case Study**

- Practical advice for implementation of the revised QRD template for SmPC and PIL
- Revision and formatting of SmPC and PIL for a marketed product
- Timing for update of product information
- Experiences gained with the revised QRD templates

**Ines Becker-Schnoor**, *Manager Global Regulatory Affairs Liaison*, **Abbott Product GmbH**, Germany

12.25 **Spotlight session**



This session will be hosted by a leading company offering services in the packaging & labelling field, who can offer information on the latest developments in the field. To host a session, contact **Linda Cole**, [linda.cole@informa.com](mailto:linda.cole@informa.com) tel: +44 (0)20 7017 6631

12.55 Lunch

14.00 **The Revised QRD Product Information Template – Regulator's View**

REGULATOR

- Reflection of comments received during the external consultation phase
- General findings and specific issues
- Realisation - what do we have to expect?
- Special focus on the patient leaflet

**Dominique Westphal**, *EU-Cooperation*, **Paul-Ehrlich-Institute**, Germany

### Anti Counterfeiting and Serialisation

14.35 **How Manufacturers Can Implement Standards-Based AIDC and Traceability: Update on GS1 Standards**

- Important regulatory and industry developments affecting AIDC and standardisation
- AIDC Application Standards for Healthcare
- Specific marking requirements for different packaging levels
- Standardising traceability processes

**Janice Kite**, *Director Healthcare Traceability*, **GS1 Global Office**, UK

15.10 Afternoon tea

15.40 **Advancements in the Internet – Anti Counterfeiting**

- Review of project and results recently released
- A look into the imminent Regulation
- Monitoring methods and recent improvements

**Jim Thomson**, *Chair*, **European Alliance for Safe Medicines**, UK

16.15 **Review of Anti Counterfeit Strategies Available**

- Summary of technologies in pilot
- Aegate vs EFPIA strategies and related political issues
- Authenticating the database and data capture opportunities
- A look into emerging markets – China and India
- Ongoing work in North and South America

**David Howard**, *Director, Global Brand Protection*, **Johnson & Johnson**, USA

16.50 Final Q&A

17.00 Chairperson's closing remarks and end of conference day 1



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Evening Seminar and Dinner: Wednesday 20 October 2010

## Looking at Information about Medicines: Is it really what we want?

18:15 Registration • 18:30 Start • 21:30 End of seminar,  
Dinner and refreshments will be provided

The development of information about medicines in Europe over the last 20 years has led to standardised package leaflets and packaging. Conversations with patients, nurses or pharmacists reveal that this information does not optimally enable them to act appropriately. Furthermore, the current framework of directives, guidelines and advice that is meant to aid regulatory authorities and pharmaceutical industries, is hard to follow and difficult to control.

### Topics to be covered:

- Developing information for 'real users' or 'average citizens'
- Starting from the SPC: promotion and information
- Standardisation does not enable users in all circumstances
- The necessity to develop alternative prototypes
- Most problematic issues when guidelines are applied
- Most urgent issues in checking guidelines

### What attendees will gain:

Attendees will learn about continuously re-occurring practical issues and limits of the systems that prevent us from providing patients with information that is personalised, appropriate, relevant and respectful. The seminar will show how a shift from 'clear and understandable' towards 'enabling users to act appropriately' could make changes possible.

Led by: **Dr Karel van der Waarde**, Consultant, Professor, Graphic Design – Research, **Avans University**, The Netherlands

## Conference Day 2 – Thursday 21 October 2010

08.50 Chairperson's opening remarks

### Worksharing and Global Company Position Documents

09.00 **Best Practice Guide for PSUR Assessment Work Sharing**

- Work sharing and difficulties encountered
- Paediatric concerns
- PSUR submissions
- Synchronisation programmes
- Virtual SmPC

**Dr Maria Belle**, Drug Safety & Pharmacovigilance, Manager Aggregate Reports, **Novartis Consumer Health SA**, Switzerland (tbc)

09.35 **CCDS, CCDI, GDS – Company Position Document**

- Constructing and maintaining the company position
- What should be in the company position?
- Local differences to the company position
- How to keep the history traceable

**Lisa Roberts**, Regulatory Project Manager, Global Regulatory Affairs – Labelling, **GlaxoSmithKline**, UK

### Practical Feedback on Working with the SmPC Guideline

10.10 **Regulatory Feedback on Working with the New SmPC Guideline**

- Regulatory update on the SmPC – are any other changes expected to come in the near future?
- Level of expectation for industry – how quickly do they expect industry to adapt and implement the new requirements?
- Regulatory view on the scope of room for interpretation within the guideline

**Philippe Auclair**, Senior Director, Regulatory Strategy and Advocacy, Abbott Quality & Regulatory EMEA, **Abbott Vascular International**, Belgium

10.45 Coffee break

11.15 **SmPC and Patient Information Leaflet: A New Concept**

- Current SmPC and PL do not meet stakeholders needs
- Several initiatives ongoing / pending to improve communication of information on medicinal products
- Technological advances and emerging new media facilitate a totally new approach
- Industry views on a possible new concept will be presented

**Fiona Reekie**, Director, Global Regulatory Affairs Strategic Policy & Support, **Johnson & Johnson Pharmaceutical Group**, UK

11.50 **SmPC Guideline - Focus on the Non-clinical Data**

REGULATOR

- Safety information based on non-clinical data
- Non-clinical data related to the paediatric population
- Non-clinical data within sections 4.6 and 5.3
- Section 4.8 - adequate information?
- Environmental risk assessment

**Linda Grohsová**, Non-Clinical Assessor, **State Institute for Drug Control**, Czech Republic

12.25 **Spotlight session**



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12.55 **Lunch**

### Readability Testing and Translations

14.00 **Regulatory Feedback on Readability Testing**

REGULATOR

- Why this can still be problematic for industry and what can be done
  - Changes in readability testing in line with the QrD template
  - Summary of best practices in the eyes of the Italian Medicines Agency
  - How industry can successfully meet regulatory expectations
- Maria Grazia Evandri**, **Italian Medicines Agency (AIFA)**, Italy (tbc)

14.35 **Case Study – How to Effectively Manage Changes Resulting from Readability Testing**

- Problems encountered by industry and how they can be overcome
- Challenges due to different regulatory processes within the EU (CP, MRP, DCP, purely national)
- Changes required after testing and how best to deal with them
- Practical feedback

**Dr Susanne Sommer**, MDRA, Labelling Expert, Global Regulatory Product Information, **Merck KGaA**, Germany

15.10 Afternoon tea

15.40 **Falling at the Last Hurdle? Translation Issues and Dossier Submissions**

- The nature of translation
- Common problems with PIL translations
- Encountering and overcoming cultural issues
- Options for the translation review process
- Translation issues in other areas of the pharma industry
- Translation issues in non-EU languages

**Mark Gibson**, Consumer Information Specialist, UK

### Best Practices for Design of the Leaflet and Label

16.15 **The Visual Design of Information about Medicines**

- The writing-design-testing processes
- Applying guidelines and templates in practice
- Listening to real users: pharmacists and patients
- The use of relevant and suitable criteria
- Developing alternative prototypes

**Dr Karel van der Waarde**, Consultant, Professor, Graphic Design – Research, **Avans University**, Germany

16.50 Final Q&A

17.00 Chairperson's closing remarks and end of conference

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