IRISH MEDICINES BOARD

Wholesale Distribution Information Day
September 28th 2012
The Crowne Plaza Hotel, Santry Demesne, Santry, Dublin 9

7:30	**Registration**	
8:30	**Welcome and Opening Address**	
8:45	**Introduction to Voting Pads**	***Facilitator:*** *Anne Hayes*
	Some general instructions on use of the voting pads and collection of general information – e.g. what types of organizations are represented in the audience etc.	
9:00	**Session 1**	***Session Coordinator:*** *Anne Hayes*
	Wholesale Distribution: Regulatory Developments *This session will explore the Falsified Medicines Directive (FMD), Revisions to the EU GDPs and IMB Policy Developments and the impact of these on the industry.*	
	Speaker	***Title of Presentation***
	Lorraine Nolan	*Falsified Medicines Directive: Impacts for Wholesalers*
	Alfred Hunt	*Revision of the EU GDPs and Implications for Wholesalers*
	Catherine Neary	*Wholesale Distribution and Continuity of Supply*
	Panel Discussion	
10:45	**Morning Break - Tea/Coffee**	
11:15	**Session 2**	***Session Coordinator:*** *Paul Sexton*
	Practical Steps to Implementation of New Requirements: *This session will discuss and provide guidance on practical steps for implementation of the key new GDP requirements including Computer Validation and Quality Risk Management (QRM). In addition to these technical aspects the session will also highlight the importance of technical agreements in ensuring future compliance with regulatory requirements. Attendees will participate in workshop style exercises and will be given practical guidance on approaches to implementation of the new requirements.*	
	Speaker	***Title of Presentation***
	Alfred Hunt	*Computerised Systems*
	Catherine Neary	*Maintaining Compliance with Regulatory Requirements for Outsourced Activities*
	Kevin O'Donnell	*Quality Risk Management Exercise*
	Panel Discussion	
13:00	**Lunch**	

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14:00	**Session 3**	***Session Coordinator:*** *Mike Morris*
	Protecting the Supply Chain: Considerations for Medicinal Product Compliance *The session will include discussion on the complexities relating to classification of medicinal products. Discussion will include recommendations for compliance based on findings from the inspection programme and key challenges for wholesalers in this area including classification of Traditional Herbal Medicinal Products (THMPs), borderlines with medicines and other products, food, cosmetics, biocides etc. Discussions will include practical tips and best practice examples in relation to ensuring compliance.*	
	Speaker	***Title of Presentation***
	Deirdre O'Brien	*The importance of Product Classification*
	Pat Walsh	*Practical Guide to Traditional Herbal Medicinal Products*
	Nicola Hickie	*Product Classification – borderlines between medicines, cosmetics & biocidal products*
	Panel Discussion	
15:15	**Session 4**	***Session Coordinator:*** *Hugo Bonar*
	Protecting the Supply Chain: Considerations for Security and Maintaining Integrity *The session will discuss security aspects relating to the supply chain and will include an overview of developments in relation to anti-counterfeit initiatives at both EU and global levels. Case study of falsified medicines infiltrating the legitimate supply chain will also be given.*	
	Speaker	***Title of Presentation***
	Tony Orme (MHRA)	*Falsified Medicines in the UK*
	Lorraine Nolan	*Falsified Medicines Case Studies: Impact of FMD & New GDPs*
	Niall McCarthy	*Global anti-counterfeit initiatives*
	Panel Discussion	
16:30	**General Audience Feedback on the day :**	
	At the conclusion of sessions the chairpersons will put some general questions to the audience for feedback on the event. The feedback will be recorded anonymously via the voting pads.	
17:00	**Close of Meeting**	