



08 October 2013
EMA/INS/GMP/461767/2013

Draft agenda – Workshop on product shortages due to manufacturing and quality problems: Developing a proactive approach to prevention

14th October 2013, Room 3A

Chair: David Cockburn & Gerald Heddell

Aim: The aim of the workshop is to elicit the views of various stakeholders on what pro-active risk management steps can be taken to avoid shortages arising from manufacturing or quality problems or rapidly mitigate their impact if necessary and if further guidance is necessary and if so, what topics should be included in such a guidance. Feedback from stakeholders will help to define and analyse the extent of the challenge, and will assist the EMA to find the most appropriate solutions to address this.

Item	Agenda	Speaker	Time
	Registration, tea and coffee	09:30	
1	Welcome – setting the scene	David Cockburn	10:00
2	Introduction of Programme for the Day	David Cockburn	10:10
3	Introduction to Reflection Paper <ul style="list-style-type: none">European Medicines Agency	Brendan Cuddy	10:15



Item	Agenda	Speaker	Time
4	<p>Panel Discussion with contributions from;</p> <p>Patients And Consumers Associations</p> <ul style="list-style-type: none"> European AIDS Treatment Group <p>Healthcare Professional Representative</p> <ul style="list-style-type: none"> Dpt. of Haematology, Academic Medical Center, University of Amsterdam <p>Hospital Pharmacists</p> <ul style="list-style-type: none"> European Association of Hospital Pharmacists <p>Pharmaceutical Industry Association Representatives</p> <ul style="list-style-type: none"> International Society for Pharmaceutical Engineering <p>Pharmaceutical Industry Association Representatives</p> <ul style="list-style-type: none"> European Federation of Pharmaceutical Industries and Associations <p>Pharmaceutical Industry Association Representatives</p> <ul style="list-style-type: none"> European Generics Association <p>Pharmaceutical Industry Association Representatives</p> <ul style="list-style-type: none"> -Parenteral Drug Association 	<p>David Haerry</p> <p>Carla Hollak</p> <p>Aida Batista</p> <p>John Berridge</p> <p>Richard Bergström</p> <p>Julie Maréchal-Jamil</p> <p>Stephan Rönninger</p>	10:30
5	Questions to the Panel	12:15	
	LUNCH BREAK	13:00	
6	<p>Presentation on Regulatory Measures with contributions from;</p> <p>European Commission</p> <ul style="list-style-type: none"> Regulatory instruments already available to Member States <p>European Medicines Agency</p> <ul style="list-style-type: none"> Implementation Plan – Progress to date 	<p>Patrizia Tosetti</p> <p>Andrea Taft</p>	14:00

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7	Discussion on solutions with contributions from; Pharmaceutical Industry Association Representatives <ul style="list-style-type: none"> Plasma Protein Therapeutics Association 	John T. Delacourt	14:30
	Healthcare Professionals, Patients and Consumers <ul style="list-style-type: none"> Joint Healthcare Professionals Working Party / Patients And Consumers Working Party 	Francois Houyez	14:45
	COFFEE BREAK	15:00	
7	Discussion on solutions with contributions from; <ul style="list-style-type: none"> Joint Industry associations 	John Berridge / Richard Bergström / Julie Maréchal-Jamil / Stephan Rönninger	15:15
8	Discussion on Next Steps	All	16:00
9	Conclusions from the meeting	David Cockburn / Gerald Heddell	16:30
10	Closing Statement & Goodbye	David Cockburn / Guido Rasi	16:55
	MEETING ENDS		17:00