



7 October 2015

EMA/INS/GMP/665392/2015

Inspection and Human Pharmacovigilance

Agenda - Stakeholder meeting on Product Shortages due to manufacturing and quality problems: developing a proactive approach to prevention

9 October 2015 09:00 – 17:00 Room 2F

Chair: Gerald Heddell (MHRA), David Cockburn (EMA)

Aim: The aim of the workshop is to report back on the progress made by the participants of the October 2013 workshop and to identify the following:

What have the participants done since October 2013 to develop measures that may contribute to the prevention of shortages?

What are the future approaches that they may develop and implement?

What is needed for the prevention measures that have been developed to ensure they are implemented?

How can we measure the success of shortage prevention tools that have been developed?

Item	Description	Speaker	Time
	Registration, tea and coffee		08:30
SESSION 1 RECORDED	CLOSED SESSION National competent authority discussion		
	Introduction		09:00
(a)	<ul style="list-style-type: none">Welcome to the meetingOutline the objectives of the meeting	Gerald Heddell David Cockburn	5'
(b)	<ul style="list-style-type: none">Discussion of issues raised by Industry Association TaskforceCommunication	Brendan Cuddy Brendan Cuddy	20'



Item	Description	Speaker	Time
	<ul style="list-style-type: none"> Supply chain inspection Results of shortage survey 	Brendan Cuddy Maria-Jesus Alcaraz	5'
(c)	Development of the EMA implementation plan	Brendan Cuddy	15'
	Open discussion		30'
	COFFEE	10:30 – 11:00	
SESSION 2 RECORD & BROADCAST	OPEN SESSION Prevention & Communication of Shortages		11:00
(a) European Medicines Agency	<ul style="list-style-type: none"> Opening statement Welcome Progress since last meeting GMP update (incl ICH Q12) Results of shortage survey 	Guido Rasi Brendan Cuddy David Cockburn Maria-Jesus Alcaraz	5' 10' 5' 5'
(b) Industry	<ul style="list-style-type: none"> Integrated presentation from Inter-Association Taskforce Introduction (John Berridge) EFPIA/AESGP/EGA/PPTA on communications PDA on risk-based model ISPE on shortages prevention plan 	Pharmaceutical Industry Association Representatives	60'
(c) Patient and healthcare representatives	<ul style="list-style-type: none"> Presentation from representatives of Patients' and Consumers' Working Party ESMO group presentation 	Eurordis & EAHP Nathan Cherny	20'
(d) National Competent Authorities	Large competent authority	France	10'
	Small competent authority	Ireland	10'
	LUNCH BREAK	13:00 – 14:00	
SESSION 3 NO RECORDING	OPEN SESSION Workshop		14:00
(a) All Stakeholders	<ul style="list-style-type: none"> Workshop to discuss next steps focussed on implementation, shortage measurement and communication Introduction from EMA <p>Four groups: 12-15 participants Min 1 rep from patients' group Min 1 rep from EMA</p>	Brendan Cuddy Each group given 30 mins	30' 40'

Item	Description	Speaker	Time
	Min 1 rep from NCA Divide industry representatives amongst groups	10' presentation	
	Group 1 - Implementation <ul style="list-style-type: none"> Industry implementation of tools NCA usage - Inspector review when on site Does usage lead to identification of critical medicines? 	Moderator: John Berridge	30'
	Group 2 - Measurable <ul style="list-style-type: none"> How shall we measure a shortage, can we define a shortage? How do we report shortages? Measurable (are tools having an impact?) 	Moderator: Patrick Costello	30'
	Group 3 - Communication <ul style="list-style-type: none"> Communication of shortages Industry to regulator Communication through the entire supply chain Communication to the public 	Moderator: Belen Escribano	30'
	Group 4 - Other issues that cause disruption <ul style="list-style-type: none"> Application of the principles / practices to other parts of the supply chain GDP issues, etc Business continuity planning 	Moderator: Brendan Cuddy	30'
(b)	Discussion on groups outputs and next steps		
(c)	External stakeholders evaluation form		5'
	COFFEE	15:45 – 16:00	
SESSION 4 RECORDED	CLOSED SESSION National competent authority discussion		16:00
(a)	Reflections on the meeting and agreement on next steps		30'
(b)	Internal stakeholders evaluation form		5'
	Closed session ends	16:30 – 17:00	