EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2012
EMA/708575/2012
Patient Health Protection

Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice compliance problems

Implementation plan 2012-2015

Short term actions

Action	Details	Who	Deliverable	When
Establish an internal catalogue of CAPs and non-CAPs requiring co-ordination at EU level that have experienced product shortages to facilitate future analysis of trends and communication on shortages.	The existing quality defect spreadsheet for 2012 has already been amended to introduce information on shortages. A further review will be undertaken of what information should be recorded.	EMA Secretariat	Excel spreadsheet	December 2012
Maintain a public catalogue of current shortages of CAPs and medicinal products where an EU co-ordination of assessment has been undertaken with links to all relevant Opinions, communications, etc. MAHs will be invited to report shortages caused by manufacturing/GMP compliance problems on	Revision of the quality defect web page to include more information on reporting shortages due to manufacturing problems. Development of a web page with maintained table of shortages (information to be included as of 2012). Arrangements to be put	EMA Secretariat	New/updated web pages	Q1 2013

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Action	Details	Who	Deliverable	When
a voluntary basis.	in place to allow for voluntary submission of information on shortages by MAHs.			
Develop a common understanding of the concept of “essential” medicine, develop a decision tree to assist decision-making on what shortages should be addressed at EU level, provide clarification on national input into EU advice/communication and complementary of EU and national advice/ communication.		Virtual group (EMA, France, Italy, Poland, Spain, The Netherlands, UK, CHMP working group on medicinal products shortages)	Definition of “essential” medicine, availability of decision tree, availability of process for national input into EU advice/com-munication	Q2 2013
Establish and publish an SOP for handling reports of shortages in supply of medicinal products due to quality defects and manufacturing problems and where an EU co-ordination of assessment is necessary.	Development of an SOP, whereby the interface with the European Commission, National Competent Authorities and other concerned parties processes, where applicable, are ensured.	EMA Secretariat in collaboration with the GMDP IWG	SOP	Q2 2013
Explore if “crisis” situations arising from product supply shortages can in the future also be addressed in the context of the EU Regulatory Network Incident Management Plan.	The interactions between the CHMP and the PRAC in this area also need to be considered.	Incident Review Network	Updated Incident Management Plan	July 2012 (completed)
Revise through the GMDP IWG the Community Procedure “Procedure for Handling Rapid Alerts Arising From Quality Defects”. Likewise, revise through such forum Chapter 8 of the GMP Guide “Complaints and		EMA Secretariat in collaboration with the GMDP IWPG	Proposed update to the Community Procedure Proposed update of Chapter 8 of the GMP Guide	Q4 2013

Action	Details	Who	Deliverable	When
Product Recall".			"Complaints and Product Recall"	
Develop international co-operation so that there is a sharing of information on specific shortages (with or without impact on other territories) and sharing of information on best practices on risk management and prevention strategies.	Teleconferences already initiated with FDA, HC and TGA to continue on an ad hoc basis. An extension of the scope of these teleconferences to be explored looking at aspects such as early notification of potential issues, development of criteria for notification, recalls that may cause a supply concern in another international market and specific cases.	EMA Secretariat	N/A Paper on the scope of teleconfe-rences	Ongoing Q2 2013
Raise the awareness of the impact of medicinal product shortages and stimulate industry reaction and improvements in business continuity planning guaranteeing better access for patients to essential medicines.	Industry should be invited to propose solutions to the problems encountered.	EMA Secretariat	Workshop	Q2 2013
Undertake a survey of past initiatives taken by NCAs to develop an inventory of possible tools and to share best practice.		European Commission	Launch of survey Development of inventory	Completed Completed

Medium term actions

Action	Details	Who	Deliverable	When
Facilitate risk/benefit evaluation where risk of shortage has to be balanced with potential risk due to presence of a product defect.		EMA Secretariat in collaboration with the CHMP and the PRAC	Points to consider document	Q4 2013
Promote better and proactive risk management by MAHs.	Outcome of the aforementioned Workshop to be taken into account.	EMA Secretariat in collaboration with GMDP IWG	Concept paper on proactive risk management for manufactu-rers and MAHs focusing on failsafe activities and measures that could be taken	Q1 2014
Investigate what processes could be used to measure the impact of drug shortage in patients experiencing its consequences.	Possible link to Patient Health Care Provider Report form to be developed under the new Pharmacovigilance legislation.	EMA Secretariat	Patient Health Care Provider Report form	Q4 2015