



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA/EMA Taskforce on availability of authorised medicines.

Presented by Brendan Cuddy
Head of Manufacturing and Quality Compliance



Introduction

Shortages of medicinal products can be **economic** (eg due to price competition or lack of reimbursement) or **manufacturing or quality related** (e.g non-compliance with good manufacturing practice (GMP) or due to defective medicines).

For the **manufacturing or quality reasons** for shortages, which fall within the remit of EMA, the **Agency has a long history of activity** in this area.

EMA has worked on how to best manage shortages due to **manufacturing or quality** issues since 2012, resulting in the development of a comprehensive set of documents to support regulatory authorities in addressing shortage situations due to GMP non-compliance/quality defects.

Introduction

Regulators “Tool Box”

network:

- Reflection paper on medicinal-product supply shortages caused by manufacturing / good-manufacturing-practice compliance problems
- Reflection paper on medicinal-product supply shortages caused by manufacturing/good-manufacturing-practice compliance problems - Implementation plan 2012-2015

A workshop on product shortages due to manufacturing and quality problems organised by EMA in October 2013 led to the creation of an inter-industry association taskforce with the objective of proposing solutions to prevent the root causes of shortages due to manufacturing and quality problems.

Based on the **implementation plan** and input gathered at the October 2013 workshop, EMA developed a set of **documents to support medicines regulators** involved in the EU-level coordination of shortage situations due to GMP non-compliance/quality defects:

- Criteria for classification of critical medicinal products
- Decision tree on escalation from national to European level
- Points to consider for the overall assessment of a supply shortage of a medicinal product due to GMP Non-compliance /quality defects
- Closing report on assessment of a supply shortage of a medicinal product due to manufacturing and quality problems
- Resources for issuing treatment recommendation during shortages of medicinal products
- Risk indicators for Shortages (Manufacturing and Quality)

A stakeholder meeting on 9 October 2015 reviewed the progress made since the workshop in 2013 and discussed:

- ways to evaluate the impact of measures taken to prevent shortages;

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000588.jsp&mid=WCOb01ac05807477a5

“Shortage Catalogue”

Overview

Research and development

Marketing authorisation

Post-authorisation

Advanced therapies

Compliance

Data submission on medicines (Article 57)

Medicine shortages

Shortages catalogue

Orphan medicines

Improving quality of submissions

Paediatric medicines

Parallel distribution

Pharmacovigilance

Post-authorisation

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Shortages catalogue

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The shortages catalogue contains information on medicine shortages that affect or are likely to affect more than one European Union (EU) Member State, where the European Medicines Agency has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU.

It does not give a complete overview of all medicine shortages occurring in the EU, as most shortages are dealt with at a national level.

For each shortage listed below, additional information about the situation in a specific country may be available from the national competent authority.

There may be medicines in short supply that are not listed here. If you cannot find information on a medicine in short supply or you would like further information, please visit the website of your national competent authority.

If you are having difficulty obtaining a medicine that has been prescribed to you, talk to your doctor or pharmacist.

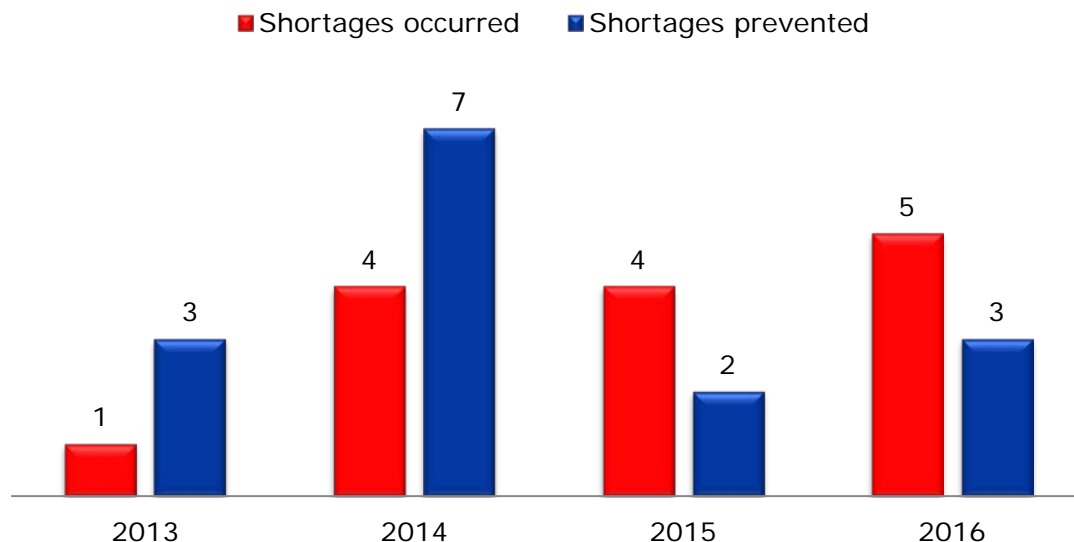
Current shortages

Document(s)	Status	First published	Last updated
DepoCyte (cytarabine) supply shortage	Ongoing	19/01/2017	14/03/2017
Cerezyme (imiglucerase) supply shortage	Ongoing	04/11/2013	
Inductos (diboterminal alfa)	Ongoing	16/09/2015	

http://www.ema.europa.eu/docs/en_GB/document_library/Supply_shortage/2016/05/WC500206823.pdf



Reporting on shortages for medicines authorised through EMA



Shortages Prevented

Stock reallocation and monitoring:

- Increased monitoring
- Permission to relabel stock agreed
- MAH increased effort replacing the defective stock
- Advice to doctors issued.

Release allowed after risk revision:

- Supervisory Authority and Rapporteur review of health hazard report and investigation report
- Defect classified as “minor” for essential products

**Where shortage occurred
Median Time to resupply:
7 MONTHS**

Next Steps

Unavailability / shortages of medicines has been recognised as a **priority topic** in the **EU Medicine Agencies Network Strategy to 2020**.

Currently, the **EMA and MS authorities have set up a joint EMA/HMA task force**:

- to assess reasons why authorised medicines are not marketed in MSs
- to establish a set of definitions and metrics to enhance shortage management
- to develop communication strategies during shortages within the network and with other actors in the healthcare system

Task force is co-chaired by Kirstin Raudsepp (Head of Estonian National Agency and Noel Wathion Deputy Executive Director EMA)

EMA also works closely with its **international partners** in this area.

Heads of Medicines Agency Task Force

3 Thematic areas

- Theme 1 Marketing of authorized medicinal products – helping to make authorised medicines available through current regulatory framework.
- Theme 2 Supply Chain Disruption – focus on prevention of supply disruptions.
- Theme 3 Communication.

Key deliverables:

- Definitions and metrics.
- Promoting best practices.
- EU information platform



Conclusion

- The Agency continues to take a proactive approach to product supply issues due to manufacturing or quality problems.
- The EMA approach will also support the new HMA task force and be a key stakeholder in aiding this work.
- The Agency is looking to develop a suitable definition of shortage / supply chain disruption and develop common communication platform.

Thank you for your attention



Further information

Brendan.cuddy@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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