EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of EMA in vaccine shortages

Presented by Brendan Cuddy, Head of Manufacturing and Quality Compliance,
VHPB Meeting 15th March 2018
Lisbon, Portugal

Introduction

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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.

EMA also manages individual incidents reported to it in order to prevent or minimise the impact of shortages (Case Management).

EMA involvement in medicine shortages linked to GMP

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Implementation plan 2012-2015

2012

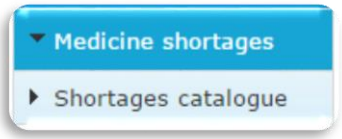
2013

22 November 2012
EMA/590745/2012
Patient Health Protection

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

- 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)

2014



08 October 2013
EMA/INS/GMP/461767/2013 Workshop on product shortages due to manufacturing and quality problems: Developing a proactive approach to prevention

What have industry associations done?

A positive response

- Formed an Inter-Association Task Force
- ISPE – ISPE Drug Shortages Prevention Plan – October 2014
- AESGP/EFPIA/EGA/PPTA – Industry Communication Principles to Authorities – Q4 2014
- PDA – Technical Report on "Risk-Based Approach for Prevention and Management of Drug Shortages" – Q4 2014

ISPE efpia PDA EGA AESG

2015

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Public Health and Risk Assessment
Pharmaceuticals

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Procedure for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public or animal health

Volume 4
EU Guidelines for
Good Manufacturing Practice for
Medicinal Products for Human and Veterinary Use

Part I
Chapter 8: Complaints, Quality Defects and Product Recalls

21 December 2015
EMA/679967/2015
Stakeholders and Communication Division

Developing a proactive approach to the prevention of medicines shortages due to manufacturing and quality problems
Report from a stakeholder meeting at the European Medicines Agency - 9 October 2015

EMA involvement in medicine shortages linked to GMP

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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
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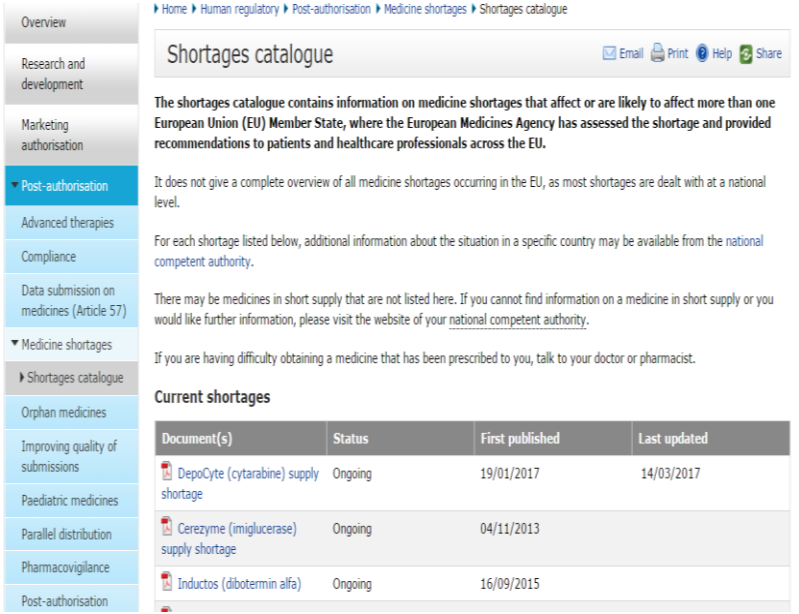
- Risk indicators for Shortages (Manufacturing and Quality)

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=WC0b01ac05807477a5

"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

Home ▸ Human regulatory ▸ Post-authorisation ▸ Medicine shortages ▸ Shortages catalogue

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 (dibotermin alfa)	Ongoing	16/09/2015	

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

Availability of Authorised Medicines

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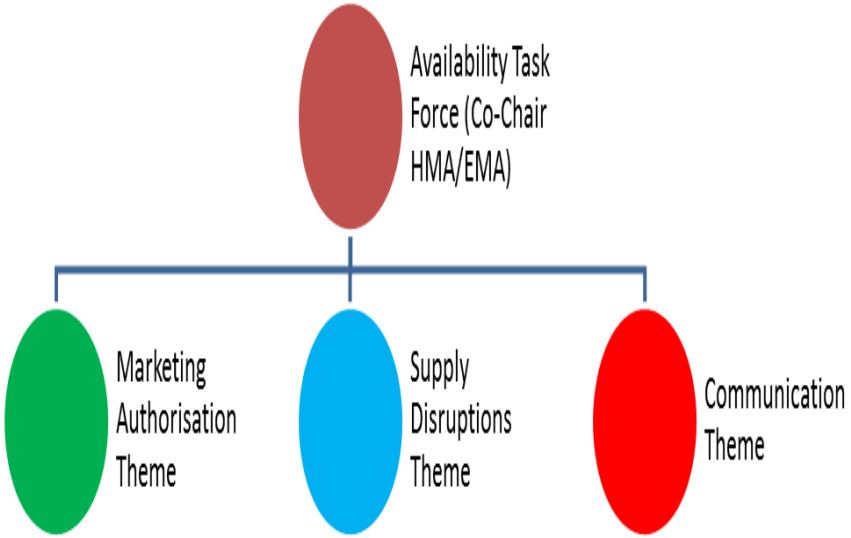
Unavailability / shortages of medicines has been recognised as a **priority topic** in the **EU Medicine Agencies Network Strategy to 2020**.

Availability of Authorised Medicines Task Force (TFAAM).

Co-chaired by Kristen Raudsepp (HMA Estonia) and Noel Wathion (EMA).

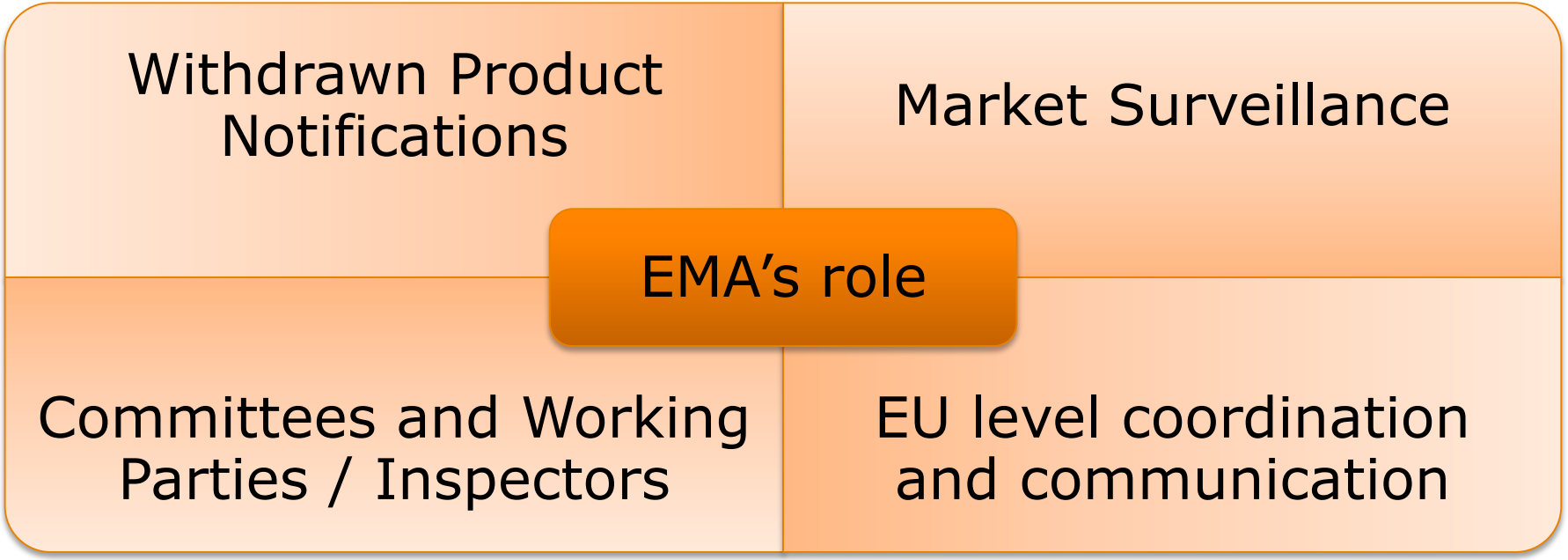
3 thematic areas.

- 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.



Stakeholder Workshop: November 2018.

What is/can be the role of EMA in vaccine shortages?



Incident Management – Shortages 2014 - 2017

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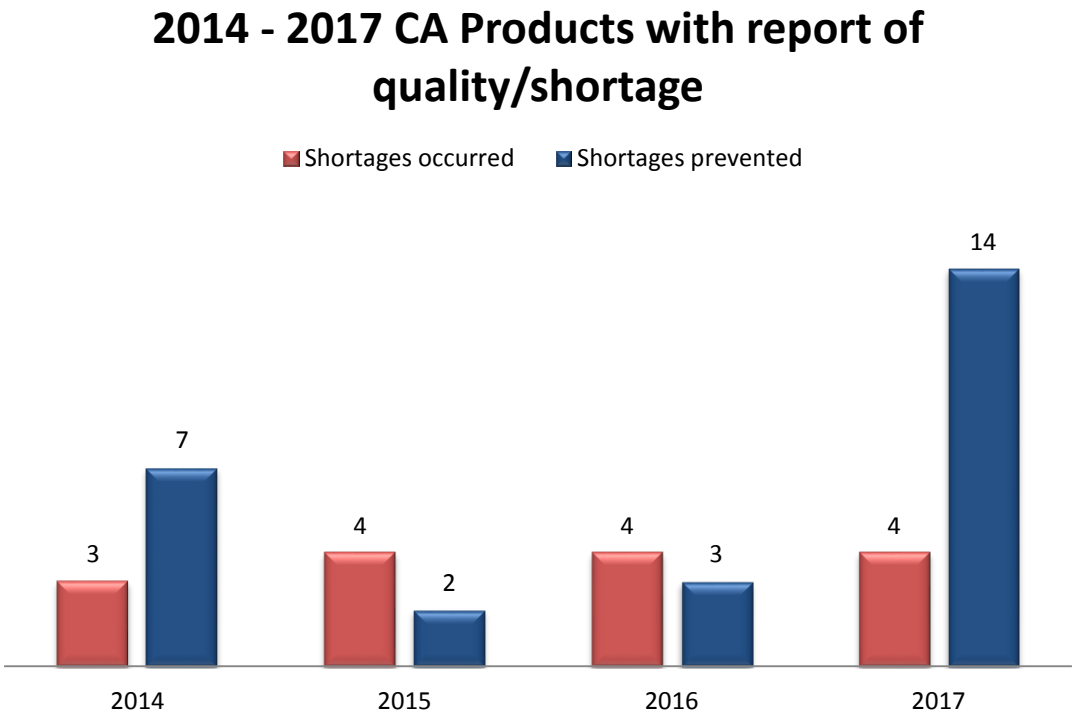

Shortages Prevented
Stock reallocation and monitoring:
- Increased monitoring
- Permission to relabel stock agreed
- MAH increased effort replacing the defective stock
- Advice to doctors issued.

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

Conclusion

- The Agency continues to take a proactive approach to product supply disruption due to manufacturing or quality problems.
- A proactive approach by regulators and industry can prevent or minimise risk of shortage.

Any questions?

Further information

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