



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-HMA collaboration on shortages and availability of medicines

Stakeholder input

PCWP and HCPWP joint meeting
18 April 2018

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Background



Shortages of medicines: **global** problem



Causes are **varied**: economical (marketing / reimbursement decisions), manufacturing or quality related (GMP)



Significant impact on users and healthcare systems due to:

- ▶ medicines rationing
- ▶ delay of critical treatments
- ▶ use of alternatives that may be less efficacious or increase risk of medication errors and adverse events



Previous EMA involvement in shortages

 Long history of activity but limited to manufacturing and quality issues

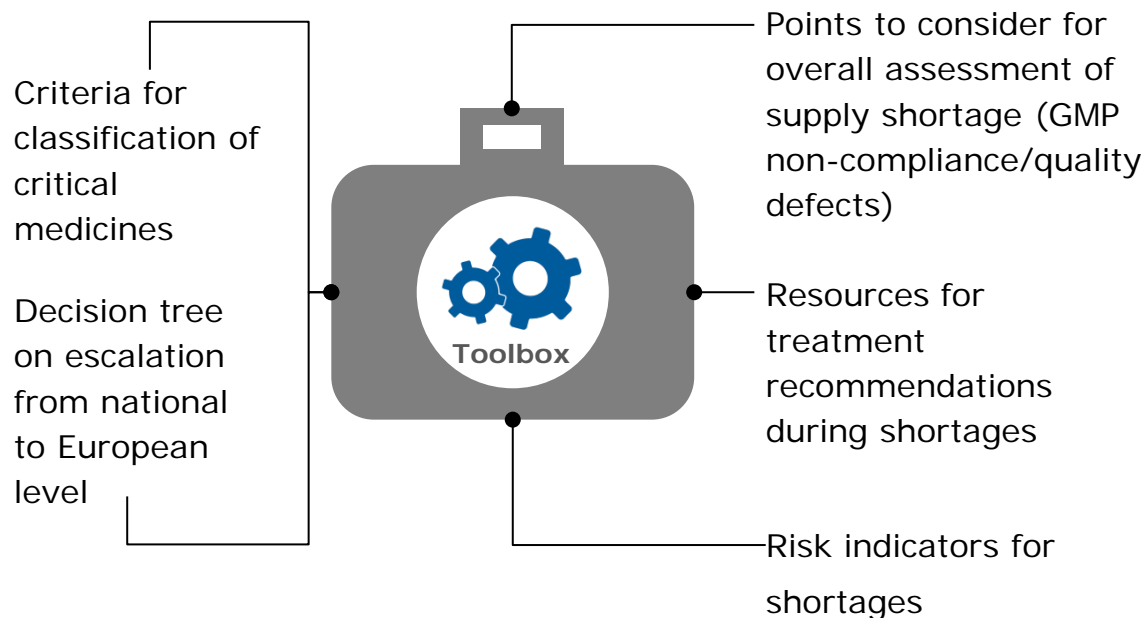
 Since 2012 work at EU level to coordinate and develop:

- ▶ assessment of shortages
- ▶ risk-minimisation measures
- ▶ measures to alleviate impact on patients
- ▶ measures communicate within the EU regulatory network

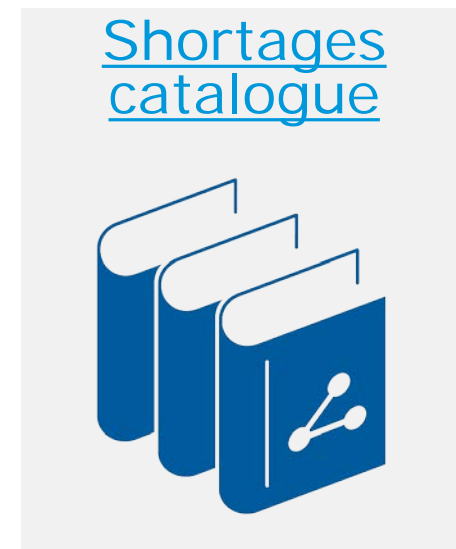




Regulator toolbox for supporting assessments



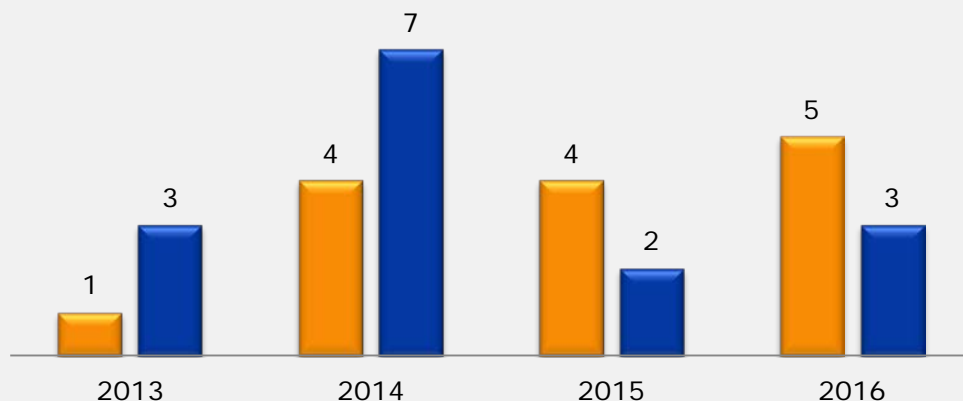
Communication to stakeholders



EMA activities – manufacturing related shortages

Reporting on shortages of Centrally Authorised Medicines

■ Shortages occurred ■ Shortages prevented



Actions to prevent shortages:

- ▶ Liaising with manufacturers and rapporteurs to ensure essential medicines continue to reach the market
- ▶ Additional monitoring for essential products affected by a 'minor' defect
- ▶ Advice to doctor and pharmacists issued
- ▶ Permission to relabel imported stock when national supply in shortage
- ▶ Increased production and resilience planning post medicine recall





Where shortage occurred
Median Time to resupply:
7 MONTHS


Joint EMA/HMA Task Force

 Availability issues recognised as **priority topic** in **EU Medicines Network Strategy to 2020**

 **Joint EMA/HMA task force** with aim to:

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

 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



Brexit



EMA together with EU network is working on regulatory preparedness for Brexit



This will also include a detailed assessment of the risk of shortages of medicines and ways to mitigate these



Theme 1: Marketing of authorized medicinal products




Co-chaired by **CMDh** and **CMDv**

TWG1 2018 work plan focus topics

- ▶ Make approval process for generics/biosimilars easier
- ▶ Fast-track variations needed during shortages (i.e. change of manufacturing site)
- ▶ Investigate proposals for continuing marketing of old non-innovative but critical medicines
- ▶ Review procedure for withdrawal applications to assess the possibilities of covering the market with marketed alternatives
- ▶ Support to the European Observatory on the supply of medical radioisotopes



Work progress

Work plan objective	Status
 Facilitate access to generics and biosimilars	ASMF worksharing; EMA Action Plan on Biosimilars (e.g. Information Guide for HCPs)
 Fast-track variations	EU regulatory authorities have facilitated approval of relevant variations and extended the ASMF worksharing to radiopharmaceuticals
 Withdrawal applications	CMDh continues to debate and exchange essential information in relation to the identification and management of these shortages

Theme 2: Supply Chain Disruption




Co-chaired by **EMA** and **DKMA**

TWG2 2018 work plan focus topics

- ▶ Development of a **definition** of medicine shortage
- ▶ Develop concept of reportable shortage and agree on common set of **reporting requirements**
- ▶ Development of **metrics** that could be used to measure a shortage
- ▶ Encourage **best practices within the industry to prevent** shortages
- ▶ Meetings of the Work Stream 2 will be held every two months throughout 2018. Sub-groups may be formed to work on specific areas between meetings



Work progress

Work plan objective	status
 Shortage Definition	Draft definition agreed by group
 Shortage Reporting	Medicine shortage notification guidelines. A first draft to MAH's have been commented and discussed by the group
 Shortage Co-Ordination	Existing guidance documents have been compiled and are being assessed by the working group. The working groups will assess if any update/further work is necessary.

Theme 3: Communication

Co-chaired by **EMA** and **Norway**

Work plan objectives

- ▶ Improve internal communication and coordination within the EU network
- ▶ Improve external communication to the public and transparency
- ▶ Enhance interaction with stakeholders for better management and communication of availability issues



Improve internal communication and coordination within the EU network



Best practice toolkit on when, how and what information should be shared within network



Common information system and a process for internal coordination



Best practice toolkit on when, how and what information should be shared with industry



Improve external communication to the public and transparency



Map and analyse current public communication practices on medicines availability and shortages, as well as existing resources across the EU



Best practice guidance for EU authorities advising on the minimum set of information as well as criteria for public communication



Platform for EU citizens to access the information on medicine availability





Enhance interaction with stakeholders for better management and communication of supply problems







Multi-stakeholder workshop to get stakeholders' perspectives and input for Task Force deliverables





Progress of work

Work plan objective	status
 Checklist of basic information to share within network	Ongoing with TWG2
 Best practice toolkit on when, how and what info to share with industry	Ongoing with TWG2
 Mapping of communication practices	Survey drafted by group
 Dedicated webpage	mock-up

Next steps

June 2018 Meeting

- ▶ First face to face meeting of task force
- ▶ One day intensive plenary session
- ▶ Discussion and co-ordination of taskforce, EMA and national Brexit preparedness initiatives
- ▶ Presentation of draft documents for discussion, comment and finalisation
- ▶ Preparation for November's Stakeholders meeting

November 2018 workshop

- ▶ With task force and external stakeholders to start dialogue and input into deliverables of task force
- ▶ Presentation and discussion of Brexit preparedness initiatives
- ▶ Presentation of documents (e.g. definition, reporting) for feedback
- ▶ Presentation of communication tools and platforms (e.g. website) for feedback



Thank you for your attention

Further information

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