



Improving reporting and monitoring: EU-wide shortage definition and metrics

Multi-stakeholder meeting with the HMA/EMA Task Force on availability of authorised medicines
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Thematic Working Group 2 – Supply Disruption Work Programme

Agreed actions	Timelines
<ul style="list-style-type: none"> Develop concept of reportable shortages by agreeing an EU-wide definition of medicine shortage. 	Q4 2018
<ul style="list-style-type: none"> Develop guidance for companies on reporting of shortages. 	Q4 2018
<ul style="list-style-type: none"> Facilitate management and monitoring of shortages across the EU by developing metrics to “measure” shortages. 	Q4 2018
<ul style="list-style-type: none"> Encourage best practices within industry to prevent shortages. 	Q4 2019
<ul style="list-style-type: none"> Review existing guidance documents for authorities regarding how to best manage and minimise the impact of shortages (including shortages that may arise as a result of UK withdrawal from EU). 	Q4 2018

1. Developing definition of medicine shortage

Step 1: Review previous work regarding Medicine Shortages

Work completed by EMA

- Criteria for classification of critical medicinal products
- Points to consider for assessment of shortage due to GMP/quality defect
- Closing report on assessment of a supply shortage
- Decision tree on escalation from national to European level (shortages due to GMP and quality defects)
- Communication by the European Medicines Agency on supply shortages of medicinal products
- Resources for issuing treatment recommendation during shortages

Published Reports

- Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages. AESGP, EAHP, EAEP, EFPIA, EIPG, GIRP, MfE, PGEU (2017)
- Quality and Manufacturing Driven Supply Disruptions. Industry Communication Principles to Authorities. AESGP, EFPIA, EGA, PPTA (2014)
- Risk-Based Approach for Prevention and Management of Drug Shortages. Technical Report no. 68. PDA (2014)
- ISPE Drug Shortages Prevention Plan (2014)

Step 2: Review shortage definitions currently in use

Sources: EMA Survey 2015 and 'Toward a European definition for a drug shortage: a qualitative study' De Weerd et al. 2015.

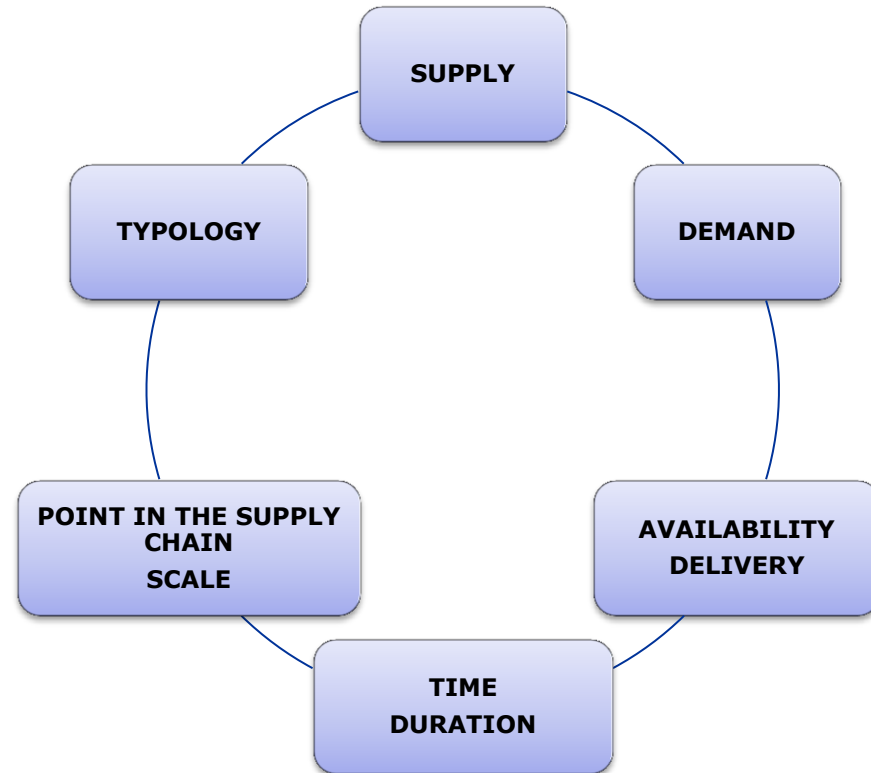
	Type	No.	Source
EMA Survey	Do you have a definition of what a shortage is in your national legislation/procedures?	No (22)	Yes (6) ES, IT, FR, PL, HU, SE
Definitions	Governmental Organisations	6	AIFA, NL, TGA, FDA, CN
	Legislation	2	FR, BL
	Professional Organisations (Pharmacy)	2	ASHP, FIP
	Professional Organisations (Industry)	3	Report, ISPE, EFPIA
	Literature	5	In references
Reporting definitions	European	5	ANSM, AEMPS, BfArM, FAMHP, Farmanco
	International	2	CN, AU

Step 2: Review shortage definitions currently in use

Themes were extracted from the current definitions

Frequently addressed themes were considered important for inclusion

Draft definition version 1.0 would attempt to include all of the themes



Step 3: Drafting the definition

- Teleconferences ,Teleconference Workshops and email allowed for full participation

Agreement was reached amongst the group that a definition should:

- Apply to both human and veterinary products
- Be concise and simple, supported by guidance
- Be sufficiently general to prevention conflict with national definitions
- Facilitate reporting of medicine shortages to NCAs as soon as possible
- Address supply of a specific medicinal product; should allow for NCA to decide on the criticality of the medicine and the availability alternatives
- Insight to the reporting systems in various member states guided the purpose of the definition; focus on the **stakeholder lead/mixed model reporting** systems to begin with.

Step 3: Drafting the definition

Version 1 December 2017

A drug shortage occurs when there are changes to either demand or supply of a drug, and demand can no longer be met. A drug shortage causes unexpected and unplanned temporary unavailability. The total stock across all levels of the national supply chain, across all geographical regions, cannot meet demand during a drug shortage.



Version 2 January 2018

A shortage of a medicinal product for **human or veterinary** use occurs when there are changes to either demand or supply of the medicine, so that **clinical need** can no longer be met. A medicine shortage causes temporary unavailability. The total stock across all levels of the national supply chain, across all geographical regions, cannot meet demand during a medicine shortage.

Step 3: Drafting the definition

Version 3 February 2018

A shortage of a medicinal product for human or veterinary use occurs when supply cannot meet clinical need. A medicine shortage causes temporary unavailability. The total stock ~~across all levels of the national supply chain, across all geographical regions,~~ across the country cannot meet demand during a medicine shortage.



Version 4 February 2018

A shortage of a medicinal product for human or veterinary use occurs when supply cannot meet clinical need at a national level. ~~A medicine shortage causes temporary unavailability.~~



Version 5 June 2018

A shortage of a medicinal product for human or veterinary use occurs when supply cannot meet ~~clinical need~~ demand at a national level.

Step 3: Drafting the definition

Version 6 August 2018

A shortage of a medicinal product for human or veterinary use occurs when supply ~~cannot~~ **will not** meet demand at a national level.



Version 7 September 2018

A shortage of a medicinal product for human or veterinary use occurs when supply ~~will not~~ **cannot** meet demand at a national level.

Medicine shortage definition

Current or anticipated.

A **shortage** of a medicinal product for human or veterinary use occurs when **supply** cannot meet **demand** at a **national level**.

The total volume of stock that is released into the supply chain by a Marketing Authorisation Holder.

Request for a medicinal product by a health care professional, veterinarian or patient in response to a clinical need.

The entire Country.

2. Developing metrics to measure shortages

Survey on metrics used for shortages

- August-September 2018

Survey to **human** and **veterinary national competent authorities** to collect information on how data related to shortages and availability of medicines is measured and communicated.

The survey consisted of two sections:

- Section One: focused on **communication** (not part of this presentation).
- Section Two: focused on **metrics of shortages used**.

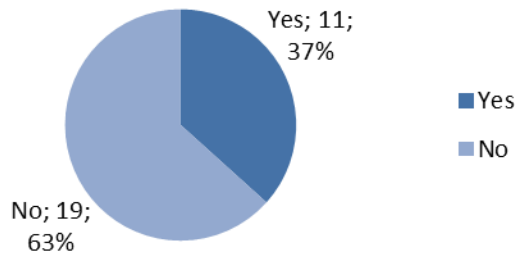
- From the analysis of the results **key information** required to evaluate shortages was extracted.
- Further work is needed to create a “**unit of shortage**” enabling **measurement of shortages** and **supply chain’s performance**.



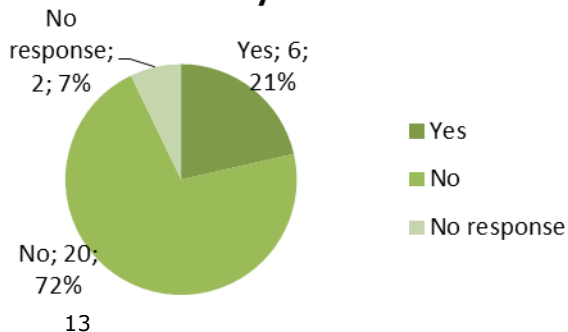
Survey on metrics used for shortages: analysis of results

Do you have a metric (measurement) of shortages?

Human authorities Metrics are used by only 37% of Human authorities and 21% of Veterinary authorities.



Veterinary authorities



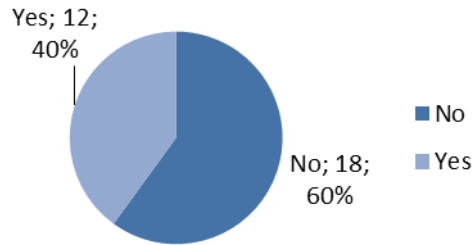
Information recorded	Human authorities	Veterinary authorities
Data on length of time/duration of medicine unavailability	10	2
Medicines criticality	7	3
Data on market share	6	1
Supply volume	8	2
Actions required by competent authority to manage and mitigate shortage	5	1
Data on demand	5	1
Other: drug consumption/sale	4	3

Survey on metrics used for shortages: analysis of results

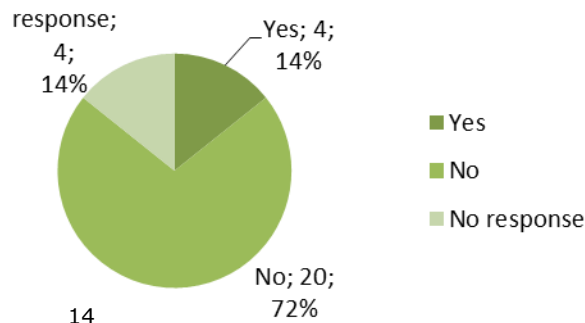
Do you analyse trends within data gathered on shortages?

- Trend analysis is performed by 40% of Human authorities and 14% of Veterinary authorities.

Human authorities



Veterinary authorities



Typology of trend recorded	Human authorities	Veterinary authorities
Reason for shortage	10	3
Number of shortage notification received	11	3
Pharmacological class of medicine	7	2
Duration of shortage	9	2
Criticality of medicine	8	2
Regional distribution of shortage	1	-
Animal species concerned	Not applicable	1
Other	3	-

Metrics for shortages: analysis of the results

- The survey shows that there is no harmonised set of data in use, although some competent authorities do collect and evaluate information on shortages.
- The survey was useful to identify the useful key information needed to adequately describe shortages. These could be collected through the “template for shortage notification”.
- Further work is required to identify a universal metric (**unit of shortage**) applicable to all EU and easy to apply.



Metrics for shortages: analysis of the results

- The “unit of shortage” can represent a powerful metric enabling characterisation of the supply chain’s performance.

Key characteristics of the unit of shortage:

- applicable to all marketing authorisation holders and manufacturers;
- linked to the definition of shortages (data on supply and demand);
- takes into account the geographical distribution;
- easy to calculate and record (use of readily available data).



Metrics for shortages: points for discussion

- What kind of metric can represent a unit of shortage?
- How can this unit be applied across the Countries?
- Are you already using similar metrics?



Any questions?

Further information

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See websites for contact details

European Medicines Agency www.ema.europa.eu

Heads of Medicines Agencies www.hma.eu

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