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Public information on shortages in the EU/EEA: improvements made between 2018 and 2020

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ABSTRACT

Background In July 2019, the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) Task Force on Availability of Authorised Medicines for Human and Veterinary Use (TFAAM) published good practice guidance which provides key principles for European Union (EU) regulatory authorities for communication on shortages and availability issues. The use of a shortage catalogue was a key recommendation.

Objectives To assess how EU/European Economic Area (EEA) national competent authorities have implemented the recommendations of the good practice guidance.

Methods A survey was run in 2020 among EU/EEA national competent authorities to assess communication practices. The results were compared with those of a similar survey carried out 2 years earlier, before publication of the guidance. The survey covered human medicines only and was sent to 31 authorities: one per EU/EEA member state (and two to Germany's two medicines regulatory authorities).

Results In 2020, 81% of authorities (25/31) had a dedicated public shortage catalogue on their website. This was an increase from 74% (23/31) in 2018, when a similar survey was run. In future this is expected to increase to 87% with two more member states making plans to implement catalogues. Although many member states publish information on shortages there is still selection in terms of the details that are being published, and there is further scope to extend the information currently provided.

Conclusion Since publication of the EMA/HMA good practice guide in 2019, transparency has increased across the EU/EEA, and public catalogues of shortages are now a routine tool used by many medicines agencies. Further opportunities to improve transparency on supply issues lie ahead with the EMA network strategy to 2025, the revised EU pharmaceutical legislation and the new legal mandate reinforcing the role of the EMA.

INTRODUCTION

Medicine shortages have long been a concern across the European Union (EU) and globally, and the COVID-19 pandemic has further increased their impact. Shortages significantly impact patient care as they can lead to a delay of critical treatments, and require switching to alternatives which can be less effective or may increase the risk of medication errors and adverse events.¹ Healthcare professionals deal with shortages on a daily basis, and an important part of their work involves sourcing alternatives and advising patients on how to use them.

In addition to the impact on patients, the impact on the work of healthcare professionals, especially

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Medicine shortages are an increasing concern across the European Union (EU) and globally. Professional and patient organisations have repeatedly called for better information.

WHAT THIS STUDY ADDS

⇒ This study has shown that information on shortages has become more accessible across the EU/European Economic Area (EEA) in recent years. Public catalogues of shortages are a routine tool used by many EU/EEA national medicines agencies to provide information to the public. However, the study also highlights the need for further improvements to achieve full transparency.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study yields new data on transparency in the field of shortages, which has not been widely studied before. It also helps to promote the good practice guidance for communication to the public on medicine availability issues, and helps to increase awareness among pharmacists of shortage catalogues.

pharmacists and prescribers, is significant, and has been repeatedly highlighted in recent years. Pharmacists are spending a significant amount of time dealing with shortages, including sourcing alternatives, while prescribers' workload also increases as patients are sent back to their doctor when a medicine is out of stock at the pharmacy. It is often the case that the prescriber learns about a medicine shortage when a patient returns to them after being unable to collect their prescription at the pharmacy.²

A survey carried out in 2018 among hospital pharmacists showed that 91.8% were dealing with shortages in their hospital pharmacy, compared with 86.2% in 2014.³ In 2021, community pharmacists reported spending an average of 5.1 hours per week dealing with shortages, including sourcing alternatives.⁴

To manage shortages, healthcare professionals need timely information to help them plan, ration existing stocks, source alternatives and implement necessary changes to clinical practice linked to the use of alternatives. Timely information is essential so that patients can be switched to an alternative if needed and given necessary training to avoid treatment interruption.

European healthcare professional and patient organisations have long called on national



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governments and the European Commission to improve communication on medicines shortages and asked for a communication strategy on shortages targeting all EU member states.³ Research confirms that national medicine shortage catalogues are valuable in providing the necessary information to healthcare professionals and patients to address shortages quickly and efficiently.⁵ At an European Medicines Agency (EMA) workshop in 2015, stakeholders (industry, national competent authorities and patient and healthcare professional organisations) called for an improvement of communication channels for exchanging information on shortages.⁶

An open and transparent approach to communication between regulators, healthcare professionals and patients not only improves preparedness and lessens the impact of shortages but also helps to maintain and improve trust in the regulatory system. Ensuring that healthcare professionals are better prepared will also increase the trust patients have in them.

Information on shortages for the public has gradually increased in the past years. Literature reports suggest that in 2014 only seven EU member states had a national medicine shortage catalogue.⁵ Reports show that in 2017 this number had increased to 12.

In 2016, EMA established its public catalogue for shortages. In December 2016, the EMA and the Heads of Medicines Agencies (HMA) set up an HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use (TFAAM) to provide strategic support and advice to tackle disruptions in the supply of human and veterinary medicines and ensure their continued availability. One of the key priorities of the task force include enhancing communication of supply problems to EU/European Economic Area (EEA) citizens by improving timely access to up-to-date information for all actors within the network.⁷ A key objective was to develop good practice guidance for communication to the public on medicines' availability issues, advising EU/EEA authorities on the minimum set of information as well as criteria for public communication on medicine shortages and availability issues. The guidance was published in July 2019⁸ following a survey in 2018 to map communication practices at member state level to understand the EU/EEA landscape of public information on shortages. It lays the foundations for an improved and harmonised approach in the EU/EEA to communicating on medicine shortages.

The guidance aims to promote good practice of public communication on shortages and availability issues by:

- ▶ Enhancing current communication to the public and ensuring a multidisciplinary approach within regulatory authorities.
- ▶ Aligning criteria for publication across the EU network.
- ▶ Increasing visibility and accessibility of information on the availability on medicines.
- ▶ Fostering interaction with stakeholders.

In 2020, the task force carried out another survey to assess how publication practices on shortages have changed.

METHODS

Design of the study

In 2020 a survey was sent by email to the EU single points of contact (SPOC) network, which is a network of experts dealing with supply issues at national medicines agencies in EU/EEA member states.⁹ The survey covered human medicines only and was sent to all 31 SPOCs: one SPOC per EU/EEA member state (two for Germany as it has two medicines regulatory authorities). After the UK's withdrawal from the EU, the UK was not surveyed. The survey was sent on 22 October 2020 with a call for

action by 5 November 2020. On 4 November 2020 a reminder with an extension of deadline of 1 December 2020 was sent to six SPOCs who had not yet responded. On 1 December 2020 a final reminder was sent asking for feedback within a week, after which two responses were missing.

Data analysis

The 2020 survey consisted of several questions as detailed in the online supplemental annex.

The authors analysed the results and compared them with the results of the 2018 survey. Any changes in publication practices were confirmed by checking catalogues online. Where answers were unclear this was followed up with SPOCs directly and answers were amended accordingly.

RESULTS

The response rate to the survey was 94% (29/31). For the two missing member states the websites were checked to assess whether they have a public catalogue. Overall, 81% of EU/EEA authorities (25/31) published a public catalogue with information on shortages of individual medicines (see online supplemental table 1.).

In terms of improvements made since 2018, seven authorities answered that they had implemented changes to their publication practices affecting either the criteria for publication or the type of information published in their shortage catalogue. Two agencies implemented a catalogue for the first time. In addition, Ireland implemented a shortages catalogue in 2018; however, this was not highlighted in the survey. The two member states that did not respond to the survey do not currently have a catalogue, and their plans for implementing a catalogue are therefore unknown. Nine authorities indicated that they had plans for future improvement whereas twelve member states stated that they did not have any plans for changes (this includes one member state that does not have a catalogue in place). Planned changes included the implementation of a catalogue for three

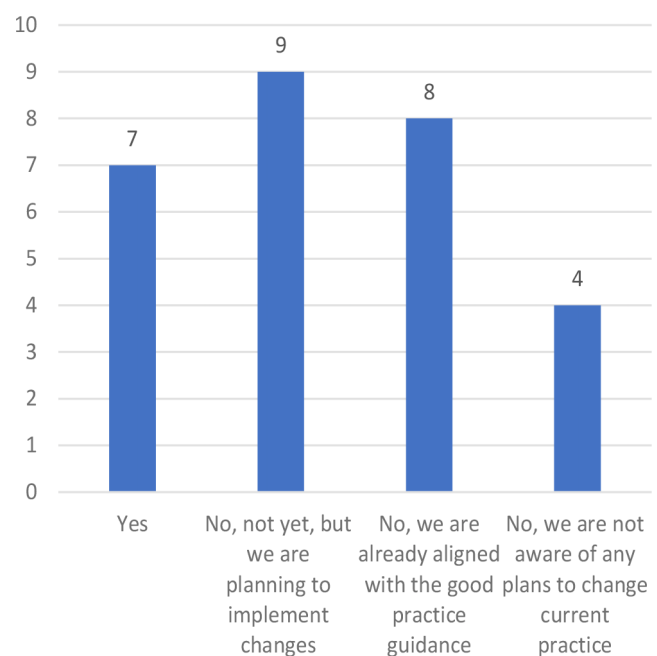


Figure 1 Number of competent authorities that made direct changes to their publication practices on shortages and availability issues since publication of the communication practices.

authorities and improvements in the information published in the catalogue for three authorities (for further details see illustration in figure 1, with details in online supplemental tables 4 and 5).

Online supplemental table 2 lists the details provided in the catalogues in 2020. In addition to the planned improvements highlighted it becomes clear that there are further improvements that can be made to increase the information available. In addition to the basic information on the medicine in shortage (such as name, pharmaceutical form and manufacturer) information such as the start date of shortage and expected duration as well as information on alternatives is very relevant for planning and mitigating purposes, but is not always included. Only one authority specifically indicated that they wanted to make improvements in this respect, and only 18 of the 25 regulatory authorities with a shortage catalogue actually publish information on alternatives. In four cases the information on alternatives is very generic, and only states that alternatives are available without specifying what they are.

In terms of the type of shortages that are published 39% (9/23 responses) of regulatory authorities indicated that they have criteria for publication whereas 61% (14/23 responses) indicated that they have no criteria for publication and published all shortages (online supplemental table 3). This picture was similar to the results seen in 2018. For regulatory authorities that do not publish all shortages, selection was based on the impact of the shortage on the patient (the two main criteria are availability of therapeutic alternatives and expected patient impact) and the expected duration of the shortages (communication for shortages with an expected duration of more than 2 weeks).

There are therefore further improvements that can be made to provide more information on alternatives and to increase the information on shortages that are included in catalogues. There are many different steps in managing supply problems including gathering information, distribution tasks, searching for alternatives and administration tasks. A recent study in a hospital showed that 25% of the time that is spent on dealing with shortages is spent on gathering information about supply disruptions, with 10% of time being spent on searching for alternative medicines; both of which are tasks that can be made easier by referring to a catalogue with the relevant information.¹⁰

DISCUSSION

Main findings

Since publication of the EMA/HMA good practice guide on communication in 2019, transparency has increased across the EU/EEA, with several member states planning further increases in the level of information they publish.

Although some member states implemented changes or a new catalogue since publication of the guidance, it is unclear whether these changes would not have happened without the publication of the guide. The COVID-19 pandemic may also have been another factor that influenced the increase in transparency on shortages, as has been the case for the EMA, with increased transparency seen for COVID-19-related communication. The response to the question about future plans also reflects an intention which may or may not become reality.

In addition to the areas for improvement highlighted by national agencies there are other improvements that can be made to align with the recommendations of the guidance, but these are not in the planning. It is therefore important to continue promoting the guidance and to monitor how publication practices change over time, whether the plans highlighted are indeed

implemented or further changes are envisaged. In addition, it will be important to assess the value of this information and how these catalogues are used by patients and healthcare professionals, and to promote their use in this stakeholder group. This is particularly important in light of a recent survey carried out with members of eligible organisations (see: <https://www.ema.europa.eu/en/partners-networks/healthcare-professionals/eligible-healthcare-professionals-organisations>) in the context of the EMA's annual meeting on 15 November 2022. The results showed a lack of awareness among patients and healthcare professionals, with 72% of surveyed healthcare professional representatives being unaware of either EMA or national shortages catalogues and 63% of patient representatives being unaware of the catalogues.¹¹ In this context, the good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use was published in 2022, which reiterates the need for information for patients and healthcare professionals and the need to promote the use of the catalogues.¹² It further highlights the important role healthcare professionals and patients play in the identification, detection and reporting of shortages which should be further expanded.

CONCLUSION

Information on shortages has become more accessible over the last 10 years and public catalogues of shortages are increasingly being used by national medicines agencies to provide information to their stakeholders, including patients and healthcare professionals. The results of the latest survey are encouraging and show that transparency of information on shortages has come a long way. However, levels of transparency remain variable across member states and further improvements are needed to meet the demands and needs by patients and healthcare professionals. This includes information on alternatives or duration of shortages, which is very valuable information for healthcare professionals and patients.¹³

Overall, the EU picture remains fragmented, without a catalogue providing an EU-wide picture. Whereas the EMA only provides information on medicine shortages affecting more than one member state and does not get involved in the day-to-day managing of every shortage, its catalogue cannot provide a full overview of shortages occurring in the EU/EEA. To deal with this, the EMA catalogue provides links to national shortage catalogues. This allows users to complement EMA information with that provided at national level. Although this is helpful and allows users to complement EMA information, it is not optimal.

The future will bring further opportunities to provide better information to patients and healthcare professionals with the EMA network strategy to 2025,¹⁴ the revision of the EU pharmaceutical legislation¹⁵ and the new legal mandate reinforcing the role of EMA in supply shortages in times of crisis.¹⁶

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Annex

Details of questionnaire sent to SPOCs

<ul style="list-style-type: none">• Has your agency made direct changes to its publication practices on shortages and availability issues since the publication in July 2019 of the Good practice guidance for communication to the public on medicines' availability issues (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf)<ul style="list-style-type: none">– Yes (please provide details below)– No, not yet, but we are planning to implement the following changes (please specify below)– No, we are already aligned with the good practice guidance– No, we are not aware of any plans to change current practice (please add any comments below)
<ul style="list-style-type: none">• Does your agency have a dedicated area on its public website providing information on shortages of individual medicines (e.g. a catalogue)?<ul style="list-style-type: none">– Y/N
<ul style="list-style-type: none">• Which elements does your agency publish for shortages of individual medicines? (Select all that apply)<ul style="list-style-type: none">– Trade name– Active ingredient (INN)– Pharmaceutical form– Strength– Marketing authorisation holder– Cause of shortage– Start date of shortage– Estimated end date of shortage– Availability of alternative medicines (without specifying details of the alternative medicines, e.g: name, strength, pharmaceutical form)– Alternative medicines available (including details of the alternative medicines, e.g: name, strength, pharmaceutical form)– Others

Supplemental table 1: Details of authorities that publish a catalogue of shortages

EU/EEA authority	Type of information in 2020	Type of information in 2018
Austria	Catalogue	Catalogue
Belgium	Catalogue	Catalogue
Bulgaria	Catalogue	Catalogue
Croatia	Catalogue	Catalogue
Cyprus	No catalogue available	No catalogue available
Czechia	Catalogue	Catalogue
Denmark	Catalogue	Catalogue
Estonia	Catalogue	Catalogue
Finland	Catalogue	Catalogue
France	Catalogue	Catalogue
Germany (Paul Ehrlich Institut)	Catalogue	Catalogue
Germany (Bundesinstitut fuer Arzneimittel und Medizinprodukte)	Catalogue	Catalogue
Greece	Catalogue	Catalogue
Hungary	Catalogue	Catalogue
Ireland	Catalogue	No catalogue available
Iceland	Catalogue	Catalogue
Italy	Catalogue	Catalogue
Latvia	Catalogue	Catalogue
Liechtenstein	No catalogue available	No catalogue available
Luxembourg	No catalogue available	No catalogue available
Lithuania	Catalogue	Catalogue

EU/EEA authority	Type of information in 2020	Type of information in 2018
Malta	No catalogue available	No catalogue available
Netherlands	No catalogue available	No catalogue available
Norway	Catalogue	Catalogue
Poland	No catalogue available	No catalogue available
Portugal	Catalogue	No catalogue available
Romania	Catalogue	Catalogue
Slovak Rep.	Catalogue	Catalogue
Slovenia	Catalogue	Catalogue
Spain	Catalogue	Catalogue
Sweden	Catalogue	Catalogue

Supplemental table 2: Details of information provided in the public shortage catalogue

EU Authority	Trade	Active	Pharmaceutical form	Strength	Marketing authorisation holder	Cause	Start Date	Estimated end date	Alternatives without details	Alternatives with details	Other
Austria	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓
Belgium	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗
Bulgaria	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗	✓
Croatia	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗
Czech Rep.	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗	✗
Denmark	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓
Estonia	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗	✗
Finland	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗	✓
France	✓	✓	✓	✓	✓	✗	✓	✗	✓	✗	✗
Germany (PEI)	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗
Germany (BfArM)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Greece	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗
Hungary	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Ireland	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗	✓
Iceland	✓	✗	✓	✓	✗	✓	✓	✓	✓	✗	✗
Italy	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗
Latvia	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗
Lithuania	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓
Norway	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Portugal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Romania	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Slovak Rep.	✓	✗	✓	✓	✓	✗	✓	✗	✓	✗	✓
Slovenia	✓	✗	✓	✓	✓	✗	✓	✓	✓	✗	✗
Spain	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗

EU Authority	Trade	Active	Pharmaceutical form	Strength	Marketing authorisation holder	Cause	Start Date	Estimated end date	Alternatives without details	Alternatives with details	Other
Sweden	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗

Supplemental table 3: Selection criteria for publishing in the shortage catalogue

EU Authority	Criteria for publication
Austria	X
Belgium	✓
Bulgaria	No information provided
Croatia	X
Czech Rep.	X
Denmark	✓
Estonia	X
Finland	X
France	✓
Germany (PEI)	X
Germany (BfArM)	✓
Greece	✓
Hungary	X
Ireland	✓
Iceland	No information provided
Italy	X
Latvia	X
Lithuania	X
Norway	✓
Portugal	✓
Romania	X
Slovak Rep.	X
Slovenia	X

EU Authority	Criteria for publication
Spain	✓
Sweden	✗

Supplemental table 4: Type of changes made by competent authorities to their publication practices on shortages and availability issues since publication of the communication practices

Country	Change
Austria	Catalogue updated with information on medicines with a parallel export ban.
Belgium	Publication for all availability issues, publication 2 weeks before expected start date of shortage, information on availabilities and set-up of taskforce for critical medicines
Denmark	Introduction of catalogue for “serious” and “critical” shortages including information about expected duration (start/end dates) and cause of shortage.
Iceland	Total overview of reported shortages (updated weekly) Dedicated news guidance to HCP/patients Shortage reporting from MAHs and consumers/HCPs
Italy	Updated information on webpage (actions taken during COVID-19)
Latvia	Information is uploaded 2 hours after notification Improved communication on medicines in foreign packaging material Information on stocks
Portugal	Implementation of catalogue

Supplemental table 5: Details of future changes planned by competent authorities

Country	Plans for implementation
Croatia	Change from pdf to machine readable format
Czech Republic	English version of the catalogue in addition to the national language version (implemented at the time of report writing) Possibility to view reports made by marketing authorisation holders updated daily
Cyprus	No catalogue yet but plans to communicate on critical shortages
France	Improvements to catalogue (reduce criteria for publication, make information more public friendly)
Lithuania	Improvements to catalogue (e.g. interlinking information on revocation/cessation, use of high-profile communication tools, colour-coded information, keeping records on solved situations)
Luxembourg	Implementation of catalogue (within the framework of the future National Medicines and Health Products Agency (the Luxembourg Agency for Medicines and Health Products - ALMPS))
The Netherlands	Implementation of catalogue
Romania	Information about alternative medicines Dedicated section of communication in relation to medicines' availability issues Inclusion of key recommendations for shortages and for other availability issues.
Slovenia	Proposed changes are at conceptional level and concrete actions are not defined yet.