4 July 2019
EMA/632473/2018

Good practice guidance for communication to the public on medicines' availability issues

Recommendations for EU national competent authorities and EMA to ensure adequate public information

1. Introduction

Medicine shortages or problems relating to the availability of medicines are a multifactorial problem involving a wide range of stakeholders, from patients and animal owners to the pharmaceutical industry. In addition to measures to improve reporting and management of availability problems, measures aimed at improving communication of such issues to the public play an important role in minimising their potential impact. There is also a need for more systematic involvement and interaction with stakeholders, especially on issues with potential impact on patients. Timely and comprehensive information is necessary to ensure planning, rationing of existing stocks and prevention of stockpiling. Advice to healthcare professionals and patients on potential alternative medicinal products is often needed. This approach to communicating shortages would also help to maintain and improve trust in the regulatory system.

Most shortages and availability problems are managed at national level; some are managed at EU level. Processes for communication to the public are already in place at EU and national level, however communication practices vary amongst member states and there is a need to review and consolidate existing practices into a single document providing clear and harmonised guidance to EU national competent authorities and EMA, promoting good practices and improving EU coordination.

1.1. Purpose of the document

This document provides EU national competent authorities and EMA with key principles and examples of good practices for communication to the public on shortages for human and veterinary medicines as well as availability issues due to revocations or cessations of marketing authorisations. The document is intended for guidance only. Implementation should be a matter for EMA and EU national competent authorities taking into account available resources and the communication needs within their territory.

It aims to promote good practice 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.

This document is based on the results of a survey of all EU member states carried out by the HMA-EMA task force to collect information on how issues related to shortages and availability of medicines are measured and communicated to the public.

The guidance addresses the following areas:

- *Who* should communicate
- *Who* is the target audience
- *Which* format or tools
- *What* information to be published
- *When* to publish
- *How* to involve stakeholders in the preparation and dissemination of information
- *Internal* collaboration
- *Examples* of communication to the public and interaction with stakeholders

Shortages referred to in this guidance are to be understood in the context of the harmonised definition agreed by EMA-HMA in the "Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)":

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

The definition applies to all shortages that are already affecting or that are expected to affect one or more EU member states in the future.

It applies to prescription and non-prescription medicines alike.

1.2. Key recommendations for good practice on publication of information on availability issues

The below recommendations have been drawn up based on the results of the survey on existing practices in member states and take into account the outcome of the workshop held at EMA in November 2018 where stakeholders raised transparency and visibility of availability issues as crucial elements for good shortage management. The recommendations also draw on EMA's experience in publishing information, which has been well established for medicine shortages affecting more than one member state where an assessment and recommendations are made at EU-wide level.[1]

[1] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages/shortages-catalogue

Potential negative effects that could follow communication such as stockpiling need to be considered when communicating and choosing the optimal timing and level of visibility are important to minimise this risk.

It is recommended that information on shortages should be kept separate from information on revocations and cessations of marketing authorisations. This will allow distinguishing between the permanent disruption in the case of cessations and revocations of marketing authorisations and temporary supply disruptions in the case of shortages. However it is recommended that this information should be easily accessible and interlinked.

Key recommendations for shortages		
Criteria for national competent authorities to make information publicly available	• shortages of medicines within their territory (nationwide issues rather than local issues). Ideally competent authorities should not apply selection criteria for publication and should communicate on all shortages occurring nationwide. In some instances, this communication may complement information issued centrally by EMA.	
Criteria for EMA to make information publicly available	• shortages of medicines (that are centrally or nationally authorised) where the shortage affects more than one member state and EMA's scientific committees have given recommendations to healthcare professionals (a DHPC).	
Format and tools	• **EU national competent authorities and EMA** should use a **systematic listing** (usually in the form of a catalogue, one for human medicines and one for veterinary medicines) to communicate on shortages. • For shortages with a high impact on patients or animals, consideration should be given to using high-profile communication tools (i.e. press release) in addition to systematic listing in the catalogue. • Regardless of the tools used, all shortages issues should be easily accessible on a webpage of the regulatory authority. • The content of the catalogue should be easily searchable. Non-machine readable data formats (such as PDFs) are not recommended and should be avoided as far as possible. Providing colour-coded or symbol-differentiated information for shortages could help to distinguish between different shortage situations (indicating impact and status of supply situation). • The use of electronic Product Information (ePI), once this is implemented across the EU, will offer opportunities to better communicate information on shortages in a timely and targeted manner.	
Information to be published in the catalogue	Details of medicine	• Trade name • Active ingredient (INN) • Pharmaceutical form and strength • MAH

Key recommendations for shortages		
		• For veterinary medicines the species
	Details on shortage	• Date of the beginning of the shortage (may be anticipated date) or availability issue • Expected end date of the shortage, if applicable • Reason for shortage and actions taken to mitigate shortage
	If applicable, advice for healthcare professionals patients, veterinarians or animal keepers	• Potential alternative medicinal products, if applicable, which may include imported medicines • Recommendations for change in clinical practice/ change in use of medicine/ use of a suitable alternative
	Updates to current status of shortage	• Updates should be issued to reflect resolution or any change in recommendations, if applicable
Timing of publication	• Publication should occur once the shortage has been confirmed by the marketing authorisation holder for the affected medicine and, if applicable, recommendations have been agreed. The exact timing may be determined at national level taking into account national requirements. However, early communication to the public is encouraged and important to allow for adequate planning and to ensure continuity of care. • Updates should be issued to reflect any relevant change in the situation including recommendations. For supply situations that have been resolved, this should be reflected as soon as the notification from the marketing authorisation holder has been received that the shortage is resolved. Once a shortage is declared as resolved, there may be a delay before supplies are fully re-established and it is recommended that a disclaimer is included to explain this in shortages communications. • A record of supply problems that have been resolved should be kept for a set period of time, i.e. at least 6 months.	
Audience	• Primarily healthcare professionals and patients, or veterinarians and animal owners. • Other regulators and industry (including wholesale distributors). To address this wide audience, the language used in any communication should be public friendly, concise and should use lay terms.	

Key recommendations for shortages	
Collaboration with stakeholders	• EU national competent authorities and EMA should consider involving relevant stakeholder groups (in particular patients', consumer and healthcare professional organisations) on availability issues, especially in those with higher potential impact on patient care. Wholesale distributors may also be involved for questions on sourcing of medicines. Involvement should aim at obtaining advice and feed-back on potential suitable alternatives and recommendations, if applicable, as well as feedback on whether key messages are well communicated and how to ensure adequate dissemination. • EU national competent authorities and EMA should consider sharing the final communication with marketing authorisation holders for information. • EU national competent authorities and EMA should explore ways to multiply their communication through relevant organisations' channels (patients, healthcare professionals, consumer organisations, animal owners, veterinarians), learned societies, professional/medical journals, media (press, TV), newsletters, and potentially electronic prescribing systems (enabling the electronic generation, transmission, and filling of a medical prescription). To increase visibility and knowledge about shortage catalogues, communication campaigns may be considered at national level.
Internal collaboration within the network	• For the assessment and communication of shortages, advice and consultation may be sought where needed from the Single Point of Contact (SPOC) network.[2] • Ideally, communication staff within EU national competent authorities or EMA should be involved in the drafting of relevant communication.

Key recommendations for other availability issues	
Criteria for national competent authorities to make information publicly available	• **revocations** or **suspensions** of marketing authorisations within their territory. • **relevant cessations of marketing authorisations** in their territory. For medicines, where the cessation of marketing authorisation is due to commercial reasons and other generic options remain on the market, the inclusion into the catalogue is optional.
Criteria for EMA to make information publicly available	• **revocation** or **suspension** of centrally and nationally authorised medicines.

[2] Single Point of Contacts (SPOC) are contact points at each human and veterinary medicines regulatory agency in the EU/EEA responsible for sharing information with other SPOCs and coordinating subsequent actions in relation to shortages and availability of authorised medicines. They have been nominated by the Task Force on Medicines Availability with the aim to facilitate better prevention, identification, management and communication of shortages and availability issues.

Key recommendations for other availability issues		
	• **cessations of marketing authorisations for** centrally authorised medicines.	
Format and tools	• **EU national competent authorities and EMA** should use a **systematic listing** (usually in the form of a catalogue, one for human medicines and one for veterinary medicines) to communicate on other availability issues. • For other availability issues with a high impact on patients or animals, consideration should be given to using high-profile communication tools (i.e. press release) in addition to systematic listing in the catalogue.	
Information to be published in the catalogue	Details of medicine	• Trade name • Active ingredient (INN) • Pharmaceutical form and strength • MAH • For veterinary medicines the species
	Details on availability issue	• Date of the beginning of the cessation or revocation • Reason for availability issue
	If applicable, advice for healthcare professionals patients, veterinarians or animal keepers	• Potential suitable alternatives, if applicable • Recommendations for change in clinical practice/ change in use of medicine/ use of suitable alternatives
Timing of publication	• For **suspensions** and **revocations** of marketing authorisations: – Publication as soon as the **suspension** or **revocation** has been recommended, and recommendations (if applicable) have been agreed. – Updates to reflect any change in recommendations, if applicable. • For relevant **cessations** of marketing authorisations: publication at time of cessation. • It is good practice to keep a public record for at least 6 months.	
Audience	See recommendations for shortages	
Collaboration with stakeholders	See recommendations for shortages	
Internal collaboration within the network	See recommendations for shortages	

2. Annex I. Full analysis

In May 2018, EMA and HMA carried out a survey to map public communication on shortages and availability of human medicines[3] by EU regulators. The purpose was to assess, qualitatively and quantitatively, how EU regulators communicate to the public on shortages and supply issues.

The results of the survey build on existing knowledge on communication practices gained from previous work which led to the development of EMA's public catalogue on shortages.

The survey comprised a questionnaire with 7 questions on the public communication practices in individual EU member States.

The questionnaire focused on public communication activities to the general public, mainly in relation to shortages.

The survey was sent to the Single Point of Contact (SPOC) nominated for human and veterinary medicines at the relevant regulatory authority for each Member state.

For human medicines, the survey was sent to 33 SPOCs (28 EU Member states, including 2 SPOCs for Germany to cover the two regulatory agencies (BfArM and PEI), including EMA and 3 for EEA). Of these, 30 responded. The response rate was 90%.

For veterinary medicines, the survey was sent to 30 SPOCs and 27 responded. The response rate was 90%.

The survey found the following results:

- For human medicines a majority (87%) of EU regulatory authorities (national competent authorities and EMA) already publish information on shortages on their website.
- Amongst the authorities that publish information, a majority (69%) do not have set criteria for publication and publish on any shortage that is reported. Only selected member states have criteria for publication based on the duration of the shortage and the criticality of the medicine.
- Most authorities also communicate on other issues such as revocation or suspension of medicines (50%) or withdrawals of medicines due to commercial reasons (70%). However this information is not necessarily reflected in the listing of shortages and various other communication tools may be used (such as press releases for individual availability issues).
- Globally, a similar picture for human medicines can be seen as in the EU. In the USA, the Association of Health System Pharmacists and the Food and Drug Administration publish a web listing of medicine shortages.[4,5] Both listings include information on current and resolved shortages as well as other information for patients and consumers. The websites contain concise information on products affected by the shortage, the reason for the shortage, suitable alternatives and the expected resolution date. The information on the FDA website covers 'medically necessary' medicines as well as those considered non-medically necessary for which the FDA has received multiple requests for information. However it does not include information on shortages of brief duration.
- For veterinary medicines, the picture is similar with fewer EU regulatory authorities publishing information with only 52% publishing information on shortages on their website.

[3] This guidance applies only to human medicines at present, however a similar approach will be taken to address veterinary medicines.

[4] http://www.ashp.org/menu/DrugShortages/CurrentShortages.aspx

[5] https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

Based on the analysis of the survey results the following key areas for communication on availability have been identified:

Key recommendations

Public communication should be considered for

- **any shortage** of a medicine that affects the whole country (nationwide issues rather than local issues).
- **revocations** or **suspensions** of medicines.
- **cessations** of marketing authorisations. For cessation of marketing authorisations due to commercial reasons, information may be less relevant for stakeholders as these medicines can usually be substituted.

2.1. Which format and tools?

The survey found the following results for the formats and tools used by regulatory authorities:

- For human medicines, 88% of authorities who already publish information on availability issues, usually do this in the form of a systematic listing, i.e. a catalogue format. The majority of authorities (69%) do not have set criteria for publication and publish all reported shortages. Only selected member states have criteria for publication related to the duration of the shortage and the criticality of the medicine.
- In addition to the shortage catalogue EU regulatory authorities (national competent authorities and EMA) use a variety of communication tools to inform on availability issues: Press releases (57%), newsletters (30%) and social media (23%).
- For veterinary medicines, the proportion of authorities that use a catalogue listing is 64%. Most of those (64%) do not use any selection criteria when publishing information. Communication tools used by veterinary regulatory authorities are press releases professional organisations and professional journals.

A catalogue listing is ideal for providing information on shortages as it allows quick one-stop referencing and is ideal for stakeholders looking for specific information. Presentation of information can be in summarised in bullet-point format and colour coded to highlight new and more relevant shortages.

It is envisaged that in the future a single portal will give access to all information on availability issues from EU regulatory authorities. While the single portal is being built, as an interim solution, both the HMA webpage (https://www.hma.eu/598.html) and the EMA Webpage (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages/shortages-catalogue) provide a listing of links to national shortage catalogues.

Key recommendations
EU national competent authorities should use a **systematic listing** in a catalogue to communicate on the following issues: • **shortages** of medicines affecting the country. In some instances this communication complements information issued centrally by EMA. Ideally regulatory authorities should not apply selection criteria for publication and should communicate on any nationwide shortage (as per the agreed EMA-HMA definition). • **revocations** or **suspensions** of medicines within their territory. • **cessations** of marketing authorisations in their territory. For cessation of marketing authorisations due to commercial reasons, this should be decided at national level depending on the relevance to stakeholders (especially for generics where there may be many other generic alternatives). **EMA** should use a **systematic listing** in a catalogue to communicate on the following issues: • **shortages** of medicines (centrally or nationally authorised) where the shortage affects more than one member state and EMA's scientific committee has given recommendations (a DHPC). • **revocations** or **suspensions** of centrally and nationally authorised medicines. • **cessations** of marketing authorisations for centrally authorised medicines.
• For availability issues with a high impact on patients or animals, EU national competent authorities and EMA should consider using additional communication tools (press releases, newsletter or social media) and reflect the information on the homepage. High-patient impact is usually associated with safety-related issues or unavailability of a critical medicine.
• Regardless of the tools used, all availability issues should be accessible on a single webpage.

2.2. What information to publish

When the decision to publish a shortage in a catalogue has been made, the information to publish should be brief, concise but sufficient for healthcare professionals and patients or veterinarians and animal owners to identify the medicine involved and take the required actions. The information is based on information published by those member states who already publish (see annex I) and is summarised in the table below:

Table 1: Recommendations for publishing information on medicine's availability issues

	Information to publish in the catalogue
Details of medicine	• Trade name • Active ingredient (INN) • Pharmaceutical form and strength • MAH • For veterinary medicines the species should be specified
Details on availability issue/shortage	• Date of the beginning of the shortage (may be anticipated date) or availability issue

	Information to publish in the catalogue
	• For shortages, expected end date of the shortage • Reason for availability issue or shortage
Advice for healthcare professionals/ patients, if applicable	• Potential alternative medicinal products, if applicable • Recommendations for change in clinical practice/ change in use of medicine, if applicable
Updates to current status of availability issue/shortage	• Updates to reflect resolution or any change in recommendations, if applicable

2.3. When to publish

Communication to the public needs to be timely and up-to-date to ensure effective planning. The survey found that:

- EU national competent authorities and EMA always update their published information on shortages, as new information becomes available and when the shortage is resolved.
- In addition, some member states (35%) review their information at set time intervals (ranging from daily to monthly).
- Once a shortage is resolved, most authorities remove the information (62%) and only 38% keep this information on their website.
- For veterinary medicines, 71% of EU regulatory authorities also update their information as new information becomes available. 27% review the information at set time intervals. Once a shortage is resolved 57% of authorities remove the information from the website.

Key recommendations
• For **shortages**: publication should occur once the shortage has been confirmed by the MAH and recommendations have been agreed (if applicable). The exact timing may be determined at national level taking into account national requirements. Updates should be issued to reflect any potential change in the recommendations. For supply situations that have been resolved this needs to be reflected as soon as notification is received that the shortage is resolved. This could be by updating the catalogue listing to mark the medicine as available again. It is good practice to keep a record of supply problems that have been resolved for a set period of time, i.e. at least 6 months.
• For **suspensions** and **revocations** of marketing authorisations: publication should be as soon as a recommendation for suspension or revocation has been given. Updates should be issued to reflect any potential change in the recommendations.
• For relevant **cessations** of marketing authorisations: publication should be at time of cessation.

2.4. Who is the target audience

- For human medicines most EU national competent authorities and EMA mainly target healthcare professionals (100%) and patients (92%) in communication. Industry and other regulators are also targeted in 60% of the cases.

- For veterinary medicines 93% target veterinarians and 64% are targeting animal owners. Wholesalers are also targeted in 57% of the cases, industry and regulators less frequently (in 36% and 43% of the cases).
- Healthcare professionals and patients, veterinarians and animal owners are the key audience who require timely accurate and up-to-date information from public health authorities on availability issues. This is particularly important as information from other sources on availability issues is sparse and early knowledge is important to allow for early planning and adjustment of clinical practice. Other regulators and industry (including wholesale distributors) are less often targeted but would also benefit from early information.

Key recommendations

- Public communication by EU national competent authorities and EMA should primarily target patients and healthcare professionals for human medicines and veterinarians and animal owners for veterinary medicines.
- Other regulators and industry (including wholesale distributors) should also be targeted.
- To address this wide audience the language of any communication should be public friendly, concise and using lay terms.

2.5. Other communication tools used and how to involve stakeholders in the preparation and dissemination of information

It is important to involve stakeholders in the preparation of public communication documents to address their concerns and information needs.

The survey found that:

- For human medicines 54% of authorities who communicate on availability issues overall also engage with their target audience in their communication. For veterinary medicines it is only 26% who engage with their target audience. In both cases, it is not clear whether this is seeking active advice or rather for dissemination only.
- EU national competent authorities and EMA use a variety of communication tools to disseminate information on availability issues: Communication through relevant organisations' channels (patients, consumers, healthcare professionals or learned societies) (63% for human medicines and 48 % for veterinary medicines), press releases (57% and 48% for veterinary medicines), professional/medical journals (57% for human medicines and 48% for veterinary medicines), media (press, TV) (33% for human medicines and 30% for veterinary medicines), newsletters (30% for human medicines and 20% for veterinary medicines), social media (23% for human medicines and 26% for veterinary medicines).

  Some EU authorities feed information about shortages into the national electronic patient health systems (EMR) and electronic prescribing systems (7% for human medicines and 11% for veterinary medicines). Thus, healthcare professionals and veterinarians will get instant alerts about shortages when prescribing or dispensing the medicine in question.

Key recommendations

- EU national competent authorities and EMA should consider involving relevant stakeholder groups (patients, consumers and healthcare professional organisations) on availability issues especially in those with higher potential impact on patient care.
- Wholesale distributors may also be involved for questions on sourcing of medicines. Involvement should aim at obtaining advice and feed-back on potential suitable alternatives and recommendations when applicable as well as for ensuring that the key messages are well communicated and ensuring adequate dissemination.
- EU national competent authorities and EMA should consider sharing the final public communication for information with marketing authorisation holders for information.
- EU national competent authorities and EMA should explore ways to multiply their communication through relevant organisations' channels (patients, consumers, animal owners, veterinarians, healthcare professionals or learned societies), professional/medical journals, media (press, TV), newsletters, and potentially electronic prescribing systems. Other means to explore to interlink shortage information could be electronic product information.

2.6. Internal collaboration

The survey found that most communication materials are prepared by the departments involved in the assessment of the availability issue (i.e. inspection) but often also involve communication colleagues (57% for human medicines, 30% for veterinary medicines).

As an outcome of this review it is recommended to systematically consider involvement of communication staff in the drafting of relevant communication to ensure that it fulfils the needs of the target audience.

In addition during the assessment and communication of a shortage member states should seek advice and consultation where needed using the the Single Point of Contact (SPOC) network.

2.7. Examples of public communication and interaction with stakeholders

Based on the survey feedback, the following initiatives were identified in selected EU member states as examples of public communication and collaboration which could potentially be implemented in other member states:

- A monthly newsletter highlighting new and relevant availability issues
- Involving stakeholders i.e. in disseminating information on shortages
- Alerts (pop-ups) on shortages in electronic patient records and electronic prescription systems to alert doctors and pharmacists at the point of prescribing or dispensing the medicine in question.
- Collaboration with the most commonly used sources of medicinal product information among healthcare professionals (i.e. electronic pharmaceutical compendiums). In some countries compendiums publish real-time alerts on important safety issues, shortage situations etc., providing instant information for the patient or physician.

2.8. Review

It is proposed that public communication practices in EU member states on availability issues will be reviewed regularly and this guidance will be updated accordingly and as needed.

3. Annex II. Information currently provided in shortage catalogues

Table 1: Information provided in shortage catalogues for human medicines by individual EU authorities

EU authority	Trade name	Active ingredient (INN)	Pharmaceutical form	Strength	MAH	Cause of shortage	Start date of shortage	Estimated end date of shortage	Alternatives available, without details	Alternatives available, with details	Other
Austria	X	X	X	X	X	X	X	X			X
Belgium	X	X	X	X	X	X	X	X			
Bulgaria	X	X	X	X	X		X				X
Croatia	X	X	X	X	X	X	X	X			X
Czech Republic	X		X	X			X			X	
Denmark	X	X	X	X			X			X	X
Estonia	X	X	X	X	X			X			
Finland	X	X	X	X	X		X	X			
Germany (PEI)	X	X	X	X	X		X	X		X	X
Germany (BfArM)	X	X	X	X	X	X	X	X	X	X	X
Greece	X	X	X	X	X		X	X	X		
Hungary	X	X	X	X	X	X	X	X	X		
Iceland	X	X	X	X					X	X	
Italy	X	X	X	X	X	X	X	X	X		X
Latvia	X	X	X	X			X	X	X		
Lithuania	X	X	X	X	X	X	X	X	X	X	
Netherlands											X
Norway	X	X	X	X	X	X	X	X	X	X	
Romania	X	X	X	X	X	X	X	X			
Slovak Republic	X		X	X	X		X	X			X
Slovenia	X		X	X			X	X			
Spain	X	X	X	X			X	X	X		X
Sweden	X	X	X	X	X		X	X		X	X
EMA	X	X	X	X		X	X	X			X

Table 2: Information provided in shortage catalogues for veterinary medicines by individual EU authorities

EU authority	Trade name	Active ingredient (INN)	Pharmaceutical form	Strength	Species	MAH	Cause of shortage	Start date of shortage	Estimated end date of shortage	Alternatives available, without details	Alternatives available, with details	Other
Austria	X	X	X	X			X		X			X
Belgium	X	X	X	X	X		X	X	X		X	
Denmark	X	X	X	X				X			X	X
Estonia	X	X	X	X				X	X			
Finland	X	X	X	X				X	X			
Germany (PEI)	X	X						X			X	
Greece	X	X	X	X	X	X	X					
Liechtenstein		X						X				X
Norway	X	X	X	X		X	X	X	X	X	X	
Slovenia	X		X	X				X	X			
Spain		X			X							
Sweden	X	X	X	X	X				X		X	
UK	X	X	X	X					X	X		