7 February 2019
EMA/632473/2018

Good practice guidance for communication on medicines' availability issues

Recommendations to 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 problems with availability, measures aimed at improving communication of availability issues 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 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 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 including 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 which include unavailability issues due the revocations or cessations of marketing authorisations. The document is intended for guidance only. Implementation should be done taking into account available resources.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20
Send a question via our website www.ema.europa.eu/contact

It aims to promote good practice by:

- Enhancing current communication practices and ensuring a multidisciplinary approach within regulatory authorities;
- Aligning criteria for publication across the EU network;
- Increasing visibility and accessibility of information on 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.

The guidance addresses the following areas:

- *Who* should communicate
- *Who* is the target audience
- *Which* format or tools
- *What* information to be published
- Timing of publication
- *How* to involve stakeholders in the preparation and dissemination of information
- *Internal* collaboration
- *Examples* of communication 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.

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 EU recommendations are made at EU-wide level.

Potential negative effects that could follow communication such as panic and 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 to information on revocations and cessations of marketing authorisations to make the distinction between the permanent and temporary supply disruption. 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	**National competent authorities** should communicate on: • **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 nationwide shortages. In some instances, this communication may complement information issued centrally by EMA	
Criteria for EMA to make information publicly available	EMA communicates on: • shortages of medicines where the shortage affects more than one member state and EMA's scientific committees have given recommendations (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.	
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 shortage	• Date of the beginning of the shortage (may be anticipated date) or availability issue • Expected end date of the shortage, if applicable

Key recommendations for shortages

		• Reason for shortage
	If applicable, advice for healthcare professionals patients, veterinarians or animal keepers.	• Potential alternative medicinal products, if applicable. • Recommendations for change in clinical practice/ change in use of medicine/ use of alternative medicine
	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 be done once the shortage has been confirmed and, if applicable, recommendations have been agreed. The exact timing may be determined at national level taking into account national requirements. However, early communication is encouraged and important to allow for adequate planning and to ensure continuity of care. • 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.	
Audience	• Primarily healthcare professionals and patients, or veterinarians and animal owners • Other regulators and industry To address this wide audience, the language used in any communication should be public friendly, concise and should use lay terms.	
Collaboration with stakeholders	• EU national competent authorities and EMA should always consider involving relevant stakeholder groups on availability issues, especially in those with higher potential impact on patient care. Involvement should aim at obtaining advice and feed-back on potential suitable alternatives and their availability as well as feedback on whether key messages are well communicated and how to ensure adequate dissemination.	
	• EU national competent authorities and EMA should explore ways to multiply their communication through	

Key recommendations for shortages

	relevant organisations' channels (patients, healthcare professionals, animal owners, veterinarians), learned societies, professional/medical journals, media (press, TV), newsletters, and potentially electronic prescribing systems.
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 (under development).
	• Ideally communication staff within the agency 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 **Criteria for EMA to make information publicly available**	**National competentauthorities** should also publish information on: • **revocations** or **suspensions** of marketing authorisations within their territory • **Cessations of marketing authorisations** in their territory. For generic 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. **EMA** should communicate on other availability issues: • **revocation** or **suspension** of centrally and nationally authorised medicines • **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 all availability issues. • For 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

Key recommendations for other availability issues

	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 alternative medicinal products, if applicable. • Recommendations for change in clinical practice/ change in use of medicine/ use of alternative medicine
Timing of publication	• For **suspensions** and **revocations** of marketing authorisations: Publication as soon as the **suspension** or **revocation** has been confirmed, and recommendations (if applicable) have been agreed. Updates to reflect any change in recommendations, if applicable.	
	• For **cessation** of marketing authorisations: Publication at time of cessation.	
Audience	• See recommendations for shortages	
Collaboration with stakeholders	• See recommendations for shortages	

Key recommendations for other availability issues

Internal collaboration within the network	• See recommendations for shortages

2. Background and survey results

In May 2018, EMA and HMA carried out a survey to map communication and metric practices on shortages and availability of human medicines[1] 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 communication practices in individual EU member States.

The questionnaire focused on 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 communication tools are used.
- Globally, a similar picture can be seen than in the EU for human medicines. In the USA, the Association of Health System Pharmacists and the Food and Drug Administration publish a web listing of medicine shortages.[7,8] 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'

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

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.

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 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.

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 for national competent authorities, or shortages of medicines affecting more than one country for the EMA. 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 where the shortage affects more than one member state and EMA's scientific committee has given recommendations (a DHPC).

  revocation or **suspension** 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 • For shortages, expected end date of the shortage

	Information to publish in the catalogue
	• 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 Timing of publication

Communication 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% 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 be once the shortage has been confirmed 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 the suspension or revocation has been confirmed and recommendations have been agreed. Updates should be issued to reflect any potential change in the recommendations.
• For **cessation** 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% targeting animal owners. Wholesalers are also very often 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 key stakeholders who require timely accurate and up-to-date information 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.

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.
• To address this wide audience the language of any communication should be public friendly, concise and using lay terms.

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

It is important to involve stakeholders in the preparation of 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 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, 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 journal 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 always consider involving relevant stakeholder groups on availability issues especially in those with higher potential impact on patient care. Involvement should aim at obtaining advice and feed-back on potential suitable alternatives as well as for ensuring that the key messages are well communicated as well as ensuring adequate dissemination.
• EU national competent authorities and EMA should explore ways to multiply their communication through relevant organisations' channels (patients/animal owners, veterinarians/ healthcare professionals or learned societies), professional/ medical journals, media (press, TV), newsletters, and potentially electronic prescribing systems.

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 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, a network of appropriate contact points at national regulatory agencies for availability issues within its territory.

3. Examples of communication and interaction with stakeholders

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

- A monthly newsletter highlighting new and relevant availability issues
- The use of 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.

4. Annex II. Information currrrently 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		