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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 multifactorial and involve 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 play an important role in minimising their potential impact. There is also a need for more systematic involvement and interaction with stakeholders. 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 treatment alternatives is often needed. Proactive communication on medicine shortages and availability issues also maintains and increases trust in the regulatory system.

Most medicine shortages and availability problems have until recently been managed at national level; only selected shortages of medicines, often linked to quality defects, were managed at EU level with EMA involvement. For shortages of human medicines, EMA's role has gradually increased over recent years. The HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TFAAM)² (was set up in 2016 to address the issue of availability of medicines and improve continuity of supply of medicines for human and veterinary use in the EU. As a result of the COVID-19 outbreak, EMA initiated several activities to better monitor and coordinate actions on shortages within the EU network. Under its new mandate ([Regulation on EMA's Reinforced Role \(Regulation \(EU\) 2022/123\)](#)), EMA has additional responsibilities to monitor critical shortages that might lead to a crisis situation. In addition, EMA coordinates EU countries' responses to shortages of critical medicines during a crisis (public health emergency or major event). The **Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)** has been set up to ensure a robust response to medicine supply issues caused by major events or public health emergencies. The **Medicines Shortages Single Point of Contact (SPOC) Working Party** is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. It provides recommendations to

¹ The guidance was initially published on 4 July 2019 and subsequently updated to reflect the role of media.

² <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages>

the MSSG on all matters related to the monitoring and management of medicine shortages and other medicine availability issues affecting human and veterinary medicines.

This guidance was initially drawn up in 2018 to consolidate existing practices of communication into a single document providing guidance to EU national competent authorities and EMA. The guidance was updated in 2024.

The document also takes into account the work of CHESSMEN, Coordination and Harmonization of the Existing Systems against Shortages of Medicines - European Network.³

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 patients and healthcare professionals and the media.

This document is based on the results of surveys of all EU Member States carried out by [TFAAM](#) in 2018 and in 2022. It also takes into account the survey carried out by CHESSMEN in 2024.

The guidance addresses the following areas:

- *Who* should communicate
- *Who* is the target audience
- *Which* format or tools
- *What* information to publish
- *When* to publish
- *How* to involve stakeholders in the preparation and dissemination of information
- *How* to engage with media
- *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)":

³ [Mission and objectives \(ja-chessmen.eu\)](#)

'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.

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 (see

Table 1 and Table 2) build on existing practices in EU Member States as reflected in the results of the surveys carried out in 2018 and 2022. The recommendations also take into account the outcome of the [workshop](#) held at EMA in November 2018 where stakeholders raised the need to increase 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 level.⁴

The key recommendation of the guidance focuses on the use of systematic listings, such as shortage catalogues, to communicate shortages to the public in a balanced way.

Although the use of shortage catalogues as a communication tool by regulatory authorities has increased since the publication of the first version of this guidance, stakeholders participating in EMA's multistakeholder workshop in 2023 ([Moving together towards better prevention of medicine shortages in the EU \(europa.eu\)](#)) highlighted the need for further improvements in communication and transparency. In particular, media, traditional as well as social media, was highlighted as an important group that should also be addressed in the guidance. Media plays an important role in influencing people's behaviour and authorities should take measures to ensure information in the media is appropriately framed to address buying behaviour (the need to limit quantity of packs of medicines provided at one time) and reduce likelihood of stockpiling.

Although stockpiling could be an unintended consequence of proactive communication about availability issues, this should not prevent authorities from communicating. Choosing the optimal timing to communicate and optimal communication tools is important to minimise the risk of stockpiling. For example, shortage catalogues are product-specific and target patients and healthcare professionals who are affected by the shortage and are actively looking for information (including healthcare professionals who dispense or prescribe the medicine, as well as industry).

Regulatory authorities should also issue guidance to healthcare professionals on the need to limit quantities of medicine packs prescribed and dispensed, where applicable, to limit stockpiling behaviour. However, it is crucial that there is trust between stakeholders for these measures to be effective. Authorities should therefore communicate regularly and openly through their public databases or websites about what they are doing, to provide reassurance and build trust.

While open communication is important, it may not always be enough to change behaviour, and in exceptional cases regulatory measures (e.g. restricting the sale of OTC medicines) to control stockpiling behaviour may also need to be considered.

⁴ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/medicine-shortages/shortages-catalogue>

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

Table 1 Key recommendations for shortages

Key recommendations for shortages		
Criteria for national competent authorities to make information publicly available	<ul style="list-style-type: none"> • Shortages of medicines within their territory (nationwide issues rather than local issues). Ideally competent authorities should not communicate selectively but on all shortages occurring nationwide. In some instances, this communication may complement information issued at EU level by EMA. 	
Criteria for EMA to make information publicly available	<ul style="list-style-type: none"> • Shortages of medicines (either centrally or nationally authorised) where the shortage affects more than one Member State and EMA's scientific committees have given recommendations to healthcare professionals (in the form of a DHPC (direct healthcare professional communication) or MSC (medicine shortage communication)). EMA also publishes information on critical shortages of medicines that are raised to the SPOC Working Party and are subject to regular monitoring by the working party. 	
Format and tools	<ul style="list-style-type: none"> • 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. They should be clearly dated. • 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 shortage 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) should be avoided as they are not picked up by search engines. Providing colour-coded or symbol-differentiated information for shortages could help to distinguish between different shortage situations (indicating impact and status of supply situation). 	
Information to be published in the catalogue	Details of the medicine	<ul style="list-style-type: none"> • Trade name • Active ingredient (INN) • Pharmaceutical form and strength • MAH

Key recommendations for shortages

		<ul style="list-style-type: none"> Target species (for veterinary medicines)
	Details on shortage	<ul style="list-style-type: none"> 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 the shortage. Information on reimbursement and price differences of treatment alternatives, where applicable⁵.
	Details on the mitigating measures	<ul style="list-style-type: none"> Information on actions taken by the relevant regulatory authority. Information about cooperation within the EU Network and initiatives at European level, if relevant.
	If applicable, advice for healthcare professionals (including pharmacists and prescribers), patients, veterinarians or animal keepers	<ul style="list-style-type: none"> Available treatment alternatives, if applicable, which may include imported medicines. Recommendations for change in clinical practice / change in use of medicine / use of a suitable therapeutic alternative. Recommendations for healthcare professionals, including pharmacists (hospital and/or community) not to order more medicines than usual, if stockpiling is a concern. Link to any published DHPC or MSC.
	Updates to current status of shortage	<ul style="list-style-type: none"> Updates should be issued to reflect resolution or any change in recommendations, as applicable.
Timing of publication		<ul style="list-style-type: none"> Once a shortage has been confirmed by the MAH for the affected medicine and, if applicable, recommendations have been agreed by the regulatory authority, the exact timing of publication may be determined at national level taking into account the national situation. However, early communication to the public is encouraged

⁵ As recommended by CHESSMEN work package 6 on Identification of best practices to address medicines shortages

Key recommendations for shortages

	<p>and important to allow for adequate planning and to ensure continuity of care.</p> <ul style="list-style-type: none"> • Updates should be issued to reflect any relevant change in the situation, including new recommendations. For supply situations that have been resolved, this should be reflected following receipt of the MAH notification. Once a shortage is declared as resolved, there may be a delay before supplies are fully re-established (also depending on how a resolution of shortage is defined) and it is recommended that a disclaimer is included in shortages communications to explain this. • It is recommended that a record of any resolved supply problems is kept for a defined period of time. While current practices vary from several weeks to up to 10 years, it is considered good practice to keep these records for extended periods (e.g. 5 years) for transparency purposes.
Audience	<ul style="list-style-type: none"> • Primarily healthcare professionals and patients, or veterinarians and animal owners, in the relevant Member State. • Other regulators and industry (including wholesale distributors). <p>To address this wide audience, the language used in any communication should be public-friendly, concise and using lay terms.</p>
Collaboration with stakeholders	<ul style="list-style-type: none"> • EU national competent authorities and EMA should carry out stakeholder listening activities to pick up concerns and false narratives on shortages that need to be addressed, including social media monitoring, identifying trends and key opinion leaders. • EU national competent authorities and EMA should consider involving relevant stakeholder groups (in particular patient, consumer and healthcare professional organisations) early in availability issues, especially for those with an expected higher impact on patient care. Involvement should aim at obtaining advice and feedback on potential suitable alternatives and recommendations, if applicable, as well as feedback on clarity of messages and how to ensure adequate dissemination. For serious shortage situations, competent authorities should always consider sharing press releases with relevant healthcare professionals and patient organisations, before publication. • Wholesale distributors and MAHs may also be involved for questions on sourcing of treatment alternatives. Involvement should aim at obtaining advice and feedback on potential suitable alternatives and recommendations, if applicable, and how to ensure adequate dissemination. • Legacy media outlets (newspapers, TV, radio) as well as social media are important channels for reaching the general public and should be

Key recommendations for shortages	
	<p>considered as an important group for regulators to engage with (see dedicated section).</p> <ul style="list-style-type: none"> • EU national competent authorities and EMA should explore ways to disseminate 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 shortages, communication campaigns may be considered at national level.
Internal collaboration within the EU Network	<ul style="list-style-type: none"> • The assessment of shortages and the drafting of related communications requires a multidisciplinary approach. Shortages of specific medicines that could lead to raised media attention should be identified early, and the assessment team should work with internal communication team to ensure proactive communication. • For the assessment and communication of shortages, EMA/ NCAs can seek advice and consultation where needed from the SPOC Working Party.⁶ • Communication experts should work together with shortage experts on high-impact availability issues and when there is need for guidance to healthcare professionals and patients. • For shortages affecting more than one Member State, national competent authorities should also consider the communication from EMA and published DHPC or MSC.

Table 2 Key recommendations for other availability issues

Key recommendations for other availability issues	
Criteria for national competent authorities to make information publicly available	<ul style="list-style-type: none"> • revocation or suspension of marketing authorisations within their territory. • relevant cessation 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 shortage catalogue is optional.
Criteria for EMA to make information publicly available	<ul style="list-style-type: none"> • revocation or suspension of centrally and nationally authorised medicines.

⁶<https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party> .

Key recommendations for other availability issues

	<ul style="list-style-type: none"> • cessation of marketing authorisations for centrally authorised medicines. 	
Format and tools	<ul style="list-style-type: none"> • 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 these 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	<ul style="list-style-type: none"> • Trade name • Active ingredient (INN) • Pharmaceutical form and strength • MAH • Target species (For veterinary medicines)
	Details on availability issue	<ul style="list-style-type: none"> • Date of the beginning of the cessation or revocation. • Reason for cessation or revocation.
	If applicable, advice for healthcare professionals patients, veterinarians or animal keepers	<ul style="list-style-type: none"> • Potential suitable alternatives, if applicable. • Recommendations for change in clinical practice / change in use of medicine / use of suitable alternatives. • Links to any published DHPC or MSC.
Timing of publication	<ul style="list-style-type: none"> • For suspension and revocation of marketing authorisations: <ul style="list-style-type: none"> – Publication as soon as the suspension or revocation has been recommended, and recommendations (if applicable) have been agreed. Early publication is key to allow healthcare professionals and patients to prepare for use of alternatives. – Updates to reflect any change in recommendations, if applicable. • For cessation of marketing authorisations: as soon as possible to ensure switch to available alternatives. • It is good practice to keep a public record for at least 5 years. 	
Audience	See table 1	

Key recommendations for other availability issues

Collaboration with stakeholders	See table 1
Internal collaboration within the network	See table 1

1.3 The role of media

Media outlets play an important role in the reporting of medicines shortages, which can impact public opinion and behaviour.

The research on the reporting of medicines shortages by media and its impact on consumer behaviour is limited; more information in the context of crises has been described in the literature⁷. In relation to food shortages for example, media messaging has been shown to promote either reassurance or anxiety with resulting outcomes ranging from no change in behaviour, to better preparation for challenges ahead or panic buying.

It is important that regulators engage proactively with the media and support reporting to debunk common misconceptions about shortages and promote understanding of shortage management in the EU. This applies in particular to critical shortages of medicines with a significant impact on clinical practice that are being monitored by EMA's SPOC Working Party. The below checklist is intended to help identify shortages with the potential for high media attention.

Checklist of questions (also frequently asked by journalists) to help define the level of media attention:

- What is the situation in the country?
 - How many patients use the medicine in question? Does the shortage affect large patient groups?
- How serious is the disease?
 - Does the shortage affect a vulnerable patient group, e.g. children, people with epilepsy, people with diabetes?
- What is the cause of the shortage and what are the consequences for patients (and healthcare professionals)?
 - What is the reason for the shortage?
 - What should healthcare professionals and patients do?
 - What is the regulator doing?
 - Are there available alternatives?
 - Does the patient have to return to the doctor to get a new prescription, switch to a different treatment?

⁷ <https://www.mdpi.com/1911-8074/13/8/166>

In order to obtain balanced reporting, the following points should be made when communicating to journalists about availability issues:

- Prevention and mitigation of shortages is a shared responsibility involving all stakeholders.
- MAHs are obliged to notify the authorities in advance, when they suspect there will be a disruption of supply.
- When considering figures related to medicine shortages, it is important to view them in the appropriate context. Not all shortages have the same impact on patients, with some being more severe than others in terms of health, quality of life, or financial impact. For instance, shortages of specific dosages or formulations may not be as problematic if alternatives are available and substitution by pharmacists is permitted by national legislation. Rather than focusing solely on the absolute number of package notifications, it may be more helpful to highlight shortages with greater impact on patients, such as those with no available alternatives.
- The number of cases (in percentage) where specific measures from healthcare professionals are necessary could be highlighted, e.g. when doctors are advised to consider treatment alternatives or when it is necessary to dispense imported packages of the medicine.
- When presenting figures related to medicine shortages (i.e. numbers of notifications), it is important to also share the number of approved medicines overall. This helps to put the numbers in perspective.
- To provide further context, shortages that have been prevented or resolved should also be highlighted.
- Resources where patients and healthcare professionals can find accurate and up-to-date advice should be highlighted.
- Stockpiling can make a shortage worse and negatively affect patients. Patients should not buy or request more medicines than needed and healthcare professionals should not prescribe or dispense more medicines than required.

Below are some examples of good practice to improve communication practice based on experiences from EU Member States:

- EU Member States have implemented several good practices for communicating with the media and other stakeholders on regulatory issues. These include webinars for journalists to provide information on the EU regulatory system and address common misconceptions. For shortages some Member States have also conducted master classes, which have included healthcare professional and patient organizations as well as other health authorities. Webinars on other topics could be used as an example for setting up webinars on medicine shortages. For example, EMA has hosted webinars on COVID-19 vaccine safety issues, such as COVID-19 safety monitoring in the EU and how to search and interpret data on EudraVigilance, which can also be applied to shortages.
- To ensure effective communication, media enquiries should be coordinated by the communication department and common key messages for media interviews should be established.
- In addition, it is helpful to inform healthcare professionals of relevant shortage communications before sending them to the media. Where possible, publishing an informative press release

summarizing the current shortage situation with expert quotations can address recurring media enquiries.

- Finally, regulators are encouraged to monitor and evaluate the performance and impact of any communication material continuously, ensuring that optimal results are achieved.

1.4 Social media and potential influence on consumer health behaviour

Social media also plays an important role by stimulating trends on medication usage which can go viral and result in medicine shortages, as recently seen in areas such as weight loss. A recent study⁸ has highlighted the potential of the platform TikTok for reaching large numbers of people promoting the use of medicines. The study highlighted the power of social media platforms in driving consumer health behaviour and generating demand for medicines through videos largely uploaded by non-professionals.

It is therefore important for regulators to actively carry out social media listening as part of their stakeholder listening activities to pick up concerns and false narratives that need to be addressed. In addition, regulators should consider social media platforms as part of their mix of communication channels.

The following recommendations should be applied for any communication from regulators through social media:

- The messages for the audiences should be simple, clear and practical. Adjusting tone for individual platforms, avoiding jargons and using simple and clear language is key.
- Combining efforts both at national and EU level, as well as using multiple social media channels, multiple formats (videos, carousels, live engagement) and in collaboration with key stakeholder organisations to ensure a wide spread of messages in multiple languages.
- Regulators may not have access to or be able to engage on all social media platforms (such as TikTok), but collaboration with carefully selected social media influencers (someone who has a significant following on one or more social media platforms and can impact the purchasing decisions or behaviour of their followers with their recommendations and endorsements) may help to raise awareness and provide information.

Messaging on social media should be based on common material across the EU Network, and awareness about ongoing campaigns or initiatives at national or European level is important to try and tackle the large number of voices on social media platforms.

Regulators are encouraged to continuously monitor and evaluate the performance and impact of any communication material to ensure optimal results.

2. Annex I. Full analysis

This guidance was build based on the results of a survey carried out in May 2018 by EMA and HMA with the Single Point of Contact (SPOC) for human and veterinary medicines at the relevant regulatory authority for each Member State, to map existing practices of public communication on shortages and

⁸ Descriptive analysis of TikTok videos posted under the hashtag #Ozempic Corey H. Basch a, Sandhya Narayanan a , Hao Tang b , Joseph Fera c , Charles E. Basch d. Journal of Medicine, Surgery, and Public Health Volume 1, 2023, 100013

availability of human medicines⁹ by EU regulators. The purpose of the survey was to assess, qualitatively and quantitatively, how EU regulators communicate to the public on shortages and supply issues.

This guidance was also built on existing knowledge on communication practices gained from establishing [EMA's public catalogue on shortages](#).

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. Of the authorities who already publish information on availability issues, 88% do this in the form of a systematic listing, i.e. a catalogue format. In addition to the shortage catalogue, EU regulatory authorities use a variety of communication tools to inform on availability issues: press releases (57%), newsletters (30%) and social media (23%).
- Amongst the authorities that publish information for human medicines, a majority (69%) do not have selection criteria for publication and publish information on any shortage that is reported to them. Only some Member States have criteria for publication based on the duration of the shortage and the criticality of the medicine.
- Most authorities 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).
- 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, 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.
- Of all EU regulatory authorities that publish information on veterinary medicines, 71% 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.

When looking at the global situation, a similar picture for human medicines can be seen as in the EU. In the United States, the Association of Health System Pharmacists and the Food and Drug Administration publish a web listing of medicine shortages.^{10, 11} 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

¹⁰ <http://www.ashp.org/menu/DrugShortages/CurrentShortages.aspx>

¹¹ <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>

received multiple requests for information. However, it does not include information on shortages of brief duration.

2.1 Examples of public communication and interaction with stakeholders

The 2018 survey results highlighted the following initiatives 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;
- involvement of stakeholders, for example in disseminating information on shortages;
- alerts (pop-ups) about 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 doctor.

2.2 Review of communication practices and the guidance

A review of communication practices in the EU was carried out in 2022¹² which showed that transparency across the EU/EEA has increased and public catalogues of shortages are now a routine tool used by medicines agencies.

In 2024 the good practice guidance on communication was updated to reflect the role of media and the survey and recommendations by CHESSMEN. The update reflects the outcome of discussions within the multistakeholder workshop on shortages in 2023 and the TFAAM.

This guidance will be reviewed on a regular basis and changes in public communication practices in EU Member States on availability issues will be reflected.

¹² Abed I, Garcia Burgos J, Knudsen Y, [Public information on shortages in the EU/EEA: improvements made between 2018 and 2020](#). European Journal of Hospital Pharmacy. 2023 February 8, doi: 10.1136/ejhpharm-2022-003554

3. Annex II. Information provided in shortage catalogues

Table 3: Results of 2018 survey to Member States: 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 4: Results of 2018 survey to Member States: 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		

Table 5. Results of survey carried out by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) in January 2024 in the context of CHESSEMEN: information published in shortage catalogues

Data categories: ■ Medicinal product, ■ Shortage details, ■ Information for the HCPs, treatment alternatives, mitigation measures

■ Included in shortage catalogue, ■ Not included in the shortage catalogue, ■ No public shortage catalogue

Data point	SE	NO	DE	BE	PT	AT	CZ	FI	FR	HR	EE	ES	HU	IE	IT	GR	DK	LV	LT	RO	SI	BG	CY	LU	NL	PL	26
Product name	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	22
Strength	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	22
Pharmaceutical form	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	22
Active substance/INN	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	21
Expected end date of shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	21
MAH	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	20
Pack size	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	19
Actual start date of shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	17
Root cause of shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	14
Availability of alternatives	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	13
Date of notification	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	11
ATC code	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	11
Date of notification update	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	10
Expected start date of shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	9
Information to HCPs	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	7
Therapeutic alternatives listed	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	6
Shortage status*	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	5
Actual end date of the shortage	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	5
Mitigation measures	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	5
Total: 19	19	17	16	15	15	14	14	12	12	12	11	11	11	11	11	10	10	10	9	8	8	5					

4. Annex IV. List of abbreviations

CHESSMEN: Coordination and Harmonization of the Existing Systems against Shortages of Medicines - European Network

DHPC: Direct healthcare professional communication

EC: European Commission

EEA: European Economic Area

EMA: European Medicines Agency

EU: European Union

HMA: Heads of Medicines Agencies

MAH: Marketing authorisation holder

MSC: Medicine shortage communication

MSSG: Executive Steering Group on Shortages and Safety of Medicinal Products

NCA: National Competent Authority

SPOC WP: Medicines Shortages Single Point of Contact Working Party

TFAAM: Task Force on the Availability of Authorised Medicines for Human and Veterinary Use