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Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use

1. Introduction

Medicine shortages as well as availability issues due to revocations or cessations of marketing authorisations are recognised as a growing issue across the EU and globally, and the COVID-19 pandemic has further increased their impact. They affect medicines of all classes and are increasingly affecting European countries. This may have a significant impact on patient care as they can lead to medicine rationing and delay of critical treatments and can require patients to use alternatives which may be less efficacious or may increase the risk of medication errors due to unfamiliarity with the new regimen. The use of alternatives may also lead to adverse events caused by unexpected drug-drug interactions and to suboptimal treatment outcomes, which can lead to additional healthcare costs. Availability issues with shortages in particular are recognised as a major area to tackle in the European Medicines Agencies Network Strategy to 2025[1] as well as in the European Commission's roadmap for its Pharmaceutical Strategy - Timely patient access to affordable medicines.[2] The European Commission's roadmap for its Pharmaceutical Strategy and the legal mandate to reinforce the role of EMA in supply shortages in times of crisis will also provide further opportunities to pursue full transparency for shortage information, especially during times of crises.

Supply chains are complex and involve many different stakeholders, from patients and healthcare professionals to the pharmaceutical industry. The causes of shortages are multifactorial, and can include manufacturing problems causing delays or interruption in the production, shortages of raw materials, increased demand of medicines, distribution problems, labour disruptions and natural disasters. Close involvement of stakeholders is a prerequisite for avoiding and handling shortages. In addition, a successful response to medicine shortages requires a multi-layered approach that includes detection, prevention and response strategies.

This paper focuses on proactive mechanisms to prevent shortages of medicines for human use. As patients and healthcare professionals are the main actors at the end of the supply chain, their activities in preventing shortages are usually limited to demand management strategies. This paper goes beyond standard demand management strategies and also looks at measures that help to improve preparedness, planning and rationed use for medicines that are either in short supply or expected to

[1] https://www.ema.europa.eu/en/news/launch-public-consultation-joint-network-strategy-2025
[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines

be so in the near future. Such actions may not prevent a shortage at hand but may help to manage the impact of future shortages. Measures include improved communication and information flow, as well as measures to better handle the use of alternative medicines.

This guidance refers to medicines for human use only. 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 both prescription and non-prescription medicines.

Availability issues are wider than shortages and concern supply issues linked to revocations or cessations of marketing authorisations.

Most shortages and availability issues are managed at national level; some are managed at EU level. Processes for prevention of shortages and availability issues vary among member states and this document intends to review and consolidate existing practices into a single document, providing clear and harmonised guidance to stakeholders, promoting good practices and improving EU coordination.

1.1. Purpose of the document

This document provides patients and healthcare professionals with key principles and examples of good practices (included as an annex) for shortage prevention and management. It is intended for guidance only. Implementation needs to consider national healthcare settings and regulatory frameworks in place at national level.

This document has been developed in the context of the HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use, which was set up in December 2016 to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and to ensure their continued availability. The document does not address commercial activities such as pricing of medicines because this is outside the remit of the Task Force.

The recommendations given in this document have been developed following a review of current practices across the EU, in consultation with representatives of healthcare professionals' and patients' organisations, taking into account other published frameworks for the management and prevention of medicine shortages. These practices are presented in more detail in the annex (section 2).

The document aims to promote good practice by:

- Enhancing and exploring current practices for prevention;
- Increasing visibility and accessibility of information on existing practices for prevention;
- Fostering interaction and improving information exchange between the different stakeholders.

1.2. Key recommendations for good practice for patient and healthcare professional organisations

The recommendations below have been drawn up based on consultation with member organisations of the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP). They are based on existing practices and initiatives in individual countries or organisations where the recommendations have been implemented often in isolation. The recommendations include general principles for patient and healthcare professional organisations and should be considered as a

general guidance to be adapted to national circumstances. For all recommendations, collaboration with health authorities and subsequent impact assessment is key.

	Key recommendations	Comments
Communication and transparency	Organisations should develop shortage observatories or seek links with already established shortage observatories (in collaboration with national medicine authorities and health authorities). Shortage observatories are organisations that: – collect and analyse information from patients and healthcare professionals on shortages and the consequences on patients' outcomes/safety/adherence to inform/raise the awareness of the health authorities so that they can take action; – collect information from healthcare professionals on changes in clinical practice that may lead to changes in demand for medicines; – collect information on early signals of potential shortages (feedback to regulator/health authority and use as trigger for mitigation practices), especially where no direct reporting mechanisms are in place. This is particularly important for local shortages; – obtain feedback from patients and healthcare professionals on risks of replacement/substitution therapies (including reducing the dose of medicines) as well as other risks (such as risk of buying medicines online from illegal channels).	These can be national, but also EU, level in order to lead to EU harmonised criteria for collection of information
Communication and awareness raising	• Develop key messages to promote information on causes of shortages and develop education campaigns on how to ensure safe use of alternatives and how to make the best use of available supplies (also addressing risks of stockpiling, risks of buying medicines online) in liaison with the national medicine agencies and/or health authorities. • Develop key messages for education campaigns (e.g. campaigns to increase blood and plasma donations to help increase the production of plasma-derived medicinal products).	• This can be done at EU or at national level • Could be general or specific for disease areas
Identification of medicines at risk	• Collaborate with national authorities and healthcare professionals to define criteria and methodology for	

	Key recommendations	Comments
of shortages and distribution measures	developing registries of essential and critical medicines, taking into account ongoing initiatives (the EC "structured dialogue" to address vulnerabilities in the supply of medicines in the EU). • Collaborate with relevant national authorities to ensure fair distribution of essential medicines among regions and according to demands.	

1.3. Key recommendations for good practice for patient organisations

	Key recommendations	Comments and examples
Communication and transparency	At EU and national level, organisations (in collaboration with patient professionals and national medicine agencies/health authorities) to draft and disseminate guidance for patients on: – how to deal with supply tensions or shortages to avoid worsening of the situation (this should include information on causes of shortages related to patient actions such as stockpiling); – where to find information about specific shortages (i.e., national medicine agencies' catalogue, patient organisations' websites); – how organisations and individuals can 'report' information on potential, new or ongoing shortages. Any guidance should be informative without causing unnecessary alarm, as this could cause stockpiling, exacerbating any supply situations.	Based on experience from International Patient Organisation for Primary Immunodeficiencies (IPOPI)

1.4. *Key recommendations for good practice for healthcare professional organisations*

	Key recommendations	Comments
Communication and transparency	• Organisations to liaise with health authorities/medicines agencies to ensure that: – electronic systems in place are used to automate detection and reporting of supply issues by healthcare professionals, to minimise workload; – any electronic alerts on medicine shortages are integrated into the electronic prescribing and dispensing systems. These messages should also include options for alternatives as recommended by health authorities. • Promote awareness on how healthcare professionals (in particular prescribers and pharmacists) can notify medicine shortages and encourage engagement in the notification process. • Organisations to liaise with health authorities to ensure more timely, transparent and accessible data on medicine shortages is made available to healthcare professionals and patients. This is at both national and EU level. • Any risk of stockpiling which may come with increased transparency should be monitored and addressed through communication and awareness campaigns.	See pharmacy reporting systems in the annex.
Fair distribution/ measures to control distribution	• Organisations should help establish appropriate and transparent communication tools within the supply chain to enable pharmacists to source a medicine in short supply from alternative authorised sources (e.g. other pharmacies where legally allowed or sourcing directly from manufacturers in case of contingency plans). • Organisations should collaborate with health authorities to implement measures to avoid stockpiling of medicines by signalling to authorities sudden unexpected increases in demand of medicines (e.g., based on clustered dispensing data from pharmacies or online information form for healthcare professionals), helping to put restrictions for dispensing and/or prescribing in place where recommended and ensuring effective dissemination to healthcare providers on these measures (e.g. restrictions on paracetamol dispensing during COVID-19 pandemic).	See annex for examples

	Key recommendations	Comments
Extemporaneous preparations	Organisations (in cooperation with pharmacists and national authorities) should liaise with health authorities to issue guidance on safe extemporaneous preparations of medicines which are in short in supply and when there are no remaining alternatives left in the market and to help develop protocols where needed.	This is also raised in the European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html)
Good prescribing practices	Organisations (in cooperation with pharmacists and national authorities) should liaise with health authorities to issue guidance on dose-sparing measures (does reduction, interruption or restrictions in target patient groups), where applicable, to manage existing stocks.	
Risk assessments	Organisations (in cooperation with national authorities) should encourage healthcare professionals to carry out (retrospective or prospective) risk assessments for medicines with high clinical impact. Risk assessments are used to record trends and patterns of shortages and to determine risks related to substitutions ultimately improving preparedness for handling any shortage and associated risks.	https://www.frontiersin.org/articles/10.3389/fphar.2020.00357/full

1.5. Other actions

Although pricing issues are not within the scope of this paper, the important role of marketing strategies in contributing to shortages is acknowledged. For example, excessive pricing by dominant firms has been a key focus of awareness campaigns by patient, consumer and healthcare professional organisations.[3]

Patient, consumer and healthcare professional organisations also play an important advocacy role to other stakeholders. These include advocating for:

- strengthening the supply obligations of producers and distributors of medicines to help prevent shortages;
- better information for patients, especially on the causes and duration of shortages;

[3] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1347

- better staffing levels to account for pharmacists' and other healthcare professionals' time required to deal with shortages;
- early notification of shortages;
- equitable stock distribution across the EU.

The actions above have been reflected in various position papers and policy recommendations of relevant organisations and can be found in the annex.

2. Annex

Section 2.1 comprises the review of current practices across the EU, which was compiled with representatives of healthcare professionals' organisations and patients' organisations, taking into account other published frameworks for the management and prevention of medicine shortages.

Section 2.2. presents the view of representatives of healthcare professionals' organisations and patients' organisations on policy recommendations to prevent shortages.

The outcome of this consultation formed the basis for this good practice guidance.

2.1. Existing practices

2.1.1. Prevention and notification of shortages

Action	Description	Organisa-tion	Concerned MS	References and notes
Reporting/early notification of signals by healthcare professionals, which are clustered and assessed by national competent authorities	In **Ireland**, pharmacists/wholesalers worked with the national medicines agency (HPRA) to set up a **Medicine Shortages Framework** to help avert potential shortages from occurring and to reduce the impact of shortages on patients by coordinating the management of potential or actual shortages as they arise.	PGEU (Pharmaceutical Group of the European Union)	Ireland	https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0020-medicines-shortages-framework-v2.pdf?sfvrsn=4 https://www.hpra.ie/homepage/medicines/medicines-information/medicines-shortages
	In **Spain**, the Information Centre on Supply of Medicines (**CISMED**) established by the Spanish General Pharmaceutical Council manages information sent directly by pharmacies to the regional pharmaceutical councils.	PGEU	Spain	https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf
	In the **Netherlands**, **Farmanco**, established by KNMP (the Royal Dutch Pharmacists Association) is open to reports from manufacturers, wholesalers, pharmacists, other healthcare professionals and patients, and allows public access to the information.	PGEU	The Netherlands	https://farmanco.knmp.nl/about-knmp-farmanco https://www.knmp.nl/dossiers/geneesmiddelentekorten/cijfers-geneesmiddelentekorten https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf

Action	Description	Organisa-tion	Concerned MS	References and notes
	In **Portugal**, the **National Association of Pharmacies** (ANF) set up a system that automatically registers information on medicines not delivered to pharmacies by wholesalers. The information is used by CEFAR (centre for health research and evaluation) to produce a report quarterly and shared with the national agency (Infarmed). This system is voluntary and complementary to the shortages reporting system set up and managed by Infarmed.	PGEU	Portugal	https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf
	In **France**, supply chain actors (manufacturers, wholesalers, community) can notify shortages to the 'DP-Ruptures' system.	PGEU	France	http://www.ordre.pharmacien.fr/Le-Dossier-Pharmaceutique/Ruptures-d-approvisionnement-et-DP-Ruptures
Reporting/early notification of signals by patients/ consumers	In **Italy**, an ad hoc national forum of stakeholders dealing with pharmaceutical shortages was set up in 2015, under the coordination of the national medicines agency (AIFA): all supply chain actors and administration cooperate in setting up activities against any distribution distortion which is generating shortages at national or local level (e.g. non authorised export). A specific regulation allowing AIFA and the Ministry of Health to limit the export of some critical medicines was also issued in 2019.	N/A	Italy	https://www.aifa.gov.it/documents/20142/1177582/Tackling_distribution_related_shortages_of_medicines.pdf
	A twinning project of four PGEU member organisations has been conducted with the aim of presenting CISMED as an innovative initiative and to explore the feasibility and usefulness of exchanging comparable information on shortages generated by pharmacies across borders.	Consejo General de Colegios Oficiales de farmacêuticos (GCCOF-España), Associação Nacional da	Spain Portugal France Italy	https://digitalhealtheurope.eu/news/pharmacy-based-system-for-medicine-shortage-detection-system-cismed-sets-up-mechanism-to-exchange-information-

Action	Description	Organisa-tion	Concerned MS	References and notes
	The results of the pilot have demonstrated that this exchange based on common standards is possible and useful to do at a supranational level based on existing pharmacy reporting systems in place. Moreover, it showed that (automated) pharmacy reporting systems are key to anticipating the occurrence of a supply problem through real-time monitoring of signals at the point of demand by patients. Now that the project has been completed, the aim of the participating countries is to continue working together to facilitate the technical implementation of a mechanism for the exchange of information on shortages at EU level.	Farmácias (ANF-Portugal), Ordre National des Pharmaciens (CNOP-France) and Federazione Nazionale Unitaria Titilari di Farmacia (Federfarma- Italia)		on-medicine-shortages-among-four-countries/
Prevention/management during COVID-19 pandemic	Various member states have set up 'medicines shortages coordination groups'. 1. In the Netherlands, for example, the National Coordination Centre for Medicines (LCG) has been set up to establish a national list of COVID-19-related medicines; monitoring stocks; the possible central procurement of raw materials and medicines; coordinating compounding of medicines and raw materials; and acting as a central contact point for the existing Medicines Shortages and Defects Notification Centre and the Ministry of Health, Welfare and Sport. 2. In the Netherlands, pharmacists were temporarily allowed to	EAHP (European Association of Hospital Pharmacists)	The Netherlands, France, Italy, Portugal	Best practices received via e-mail https://www.igj.nl/zorgsectoren/geneesmiddelen/nieuws/2020/04/02/coronavirus-meer-ruimte-voor-apotheken-bij-leveringsproblemen-van-geneesmiddelen

Action	Description	Organisa-tion	Concerned MS	References and notes
	exchange their supplies of medicines if necessary to solve shortages due to supply problems during the COVID-19 pandemic. • In **Italy**, the military pharmaceutical industry has started to produce certain drugs needed to treat COVID-19 patients. In addition the ad hoc national forum was strengthened, involving all regional authorities in a coordination network centralising the requests for critical medicines (e.g. ICU products), measuring the local needs and optimising the supply, through a direct cooperation with the marketing authorization holder (MAH) associations. • **Portugal** established a national contingency stock. It is divided by the hospitals chosen by the government to be on the front line of the fight against COVID-19. It covers approximately 10-20% of the normal consumption. • Veterinary products, like propofol, have been temporarily allowed for human use in some countries. • In some countries proactive contacts with the manufacturer regarding the supply of hydroxychloroquine have been set up, as well as a contact number for pharmacists by which they can receive direct supply from manufacturer when distributors/wholesalers cannot deliver. • In some countries EMA			

Action	Description	Organisa-tion	Concerned MS	References and notes
	recommendations on on-label use of hydroxychloroquine were disseminated to limit tensions on supply in the context of COVID-19, with further dissemination to medical professions and parts of the wider public. • In some countries, the health authorities set up a quota system for critical medicines used in ICU. The 'crisis health hub' was set up (under the authority of the ministry of health) to communicate with the regional health authorities and an ad hoc group focused on ICU.			
Extemporaneous preparations/production of medicines	Patient groups requested AGEPS, the French Agency of Hospital Pharmacies, to manufacture a product (mexiletine) after its marketing authorisation was withdrawn for commercial reasons. Although the medicine was not widely used for its authorised indication it was widely used for an off-label indication. AFM-Telethon co-funded a phase III clinical trial to demonstrate efficacy for this indication (NIH NCT02336477)	EURORDIS and AFM (the French Muscular Dystrophy Associ-ation)	France	https://www.afm-telethon.fr/essai-myomex-dans-myotonies-non-dystrophiques-112256
Essential medicines list	Creation of a national registry for essential medicines for which there are no alternatives: • creation of alliance with other patient organisations dependent on plasma-derived medicinal products (PLUS, the Platform of Plasma Protein Users); • actions to increase blood donations; • Fair distribution among regions, according to needs; • good prescribing practices to	IPOPI		

Action	Description	Organisa-tion	Concerned MS	References and notes
	calculate the amount needed.			
Other	Patients' organisation and network advocates for a national HIV programme, for people living with HIV to receive the treatment they need (budget and strategies to prevent the re-export of HIV drugs)	via EATG (European AIDS Treatment Group)	Romania	
	In the **Netherlands**, an initiative set up by Dutch pharmacists called 'PharmaSwap' was set up as a tool to combat the waste of expensive medicines. Similar approaches may be used to exchange medicines to solve shortages. https://www.pharmaswap.com/home-en.html		Netherlands	https://www.pw.nl/nieuws/2021/pharmaswap-krijgt-toestemming-igj-voor-opschalen https://www.knmp.nl/over-de-knmp/dit-doet-de-knmp/alle-ideeen-voor-de-knmp-zorginnovatieprijs
Prevention of supply tensions	In **Italy**, every patient with a chronic disease has a therapeutic plan, with provisions to ensure enough supply of all prescribed medicines for 3 months. Costs are managed at regional level (negotiating price with suppliers) and needs are defined according to the therapeutic plan. The hospital pharmacy manages stocks and delays with the collaboration of patients. For example, the pharmacist may only reduce the quantity dispensed to help other patients on the medicine, when there are tensions or late deliveries.	N/A	Italy	

Action	Description	Organisa-tion	Concerned MS	References and notes
Prospective risk assessments	In some countries healthcare professionals carry out risk assessments of medicines at risk of shortage, in order to prevent harm to patients and develop protocols for therapeutic substitution.	EAHP	All	https://www.frontiersin.org/articles/10.3389/fphar.2020.00357/full

2.1.2. Management measures on shortages

Action	Description	Organisation	Concerned MS	References and notes
Management (at prescribing level)	Emergency guidance on ART forced treatment interruptions due to drug unavailability	EATG	International	
Management (at pharmacy level)	Depending on national rules, the most common solutions offered by community pharmacists are the following: • Sourcing the same medicine from alternative sources (e.g. other pharmacies where legally allowed (NL in the case of COVID-19) or directly from manufacturers in case of contingency plans); • Changing to the same medicine with a different strength when still available, and adjusting therapy posology accordingly; • Generic substitution; • Therapeutic substitution; • Preparing a compounded formulation; • Importing the medicine from a country where it is available. Hospital pharmacies use similar management strategies depending on national rules.	PGEU EAHP	all EU Member States	https://www.igj.nl/zorgsectoren/geneesmiddelen/nieuws/2020/04/02/coronavirus-meer-ruimte-voor-apotheken-bij-leveringsproblemen-van-geneesmiddelen https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf knmp.nl/dossiers/geneesmiddelentekorten/cijfers-geneesmiddelentekorten
Pricing	Complaint by the national consumer organisation Altroconsumo to the antitrust authority about the shortages of three cancer drugs linked to a price increase strategy (abuse of dominant position). Letter from BEUC to the European Commission asking for an EU-wide investigation. Subsequently accepted as an	via BEUC (the European Consumer Organisation)	Italy/EU	https://www.altroconsumo.it/organizzazione/international/press-releases/2016/anticancer-drugs-antitrust-authority-fines-aspen-pharma-for-5mio-euros https://www.beuc.eu/publications/beuc-x-2016-

Action	Description	Organisation	Concerned MS	References and notes
	interested third party in the opened formal investigation.			101_aspen_pharmas_anticompetitive_practices.pdf https://www.beuc.eu/press-media/news-events/beuc-be-involved-eu-investigation-aspen-pharma

2.1.3. Communication

Action	Description	Organisation	Concerned MS	References and notes
Awareness raising	Education campaign for policy makers, health authorities and payers to better understand the characteristics of immunoglobulin replacement therapies and to make the best use of available supplies. Advocacy for the need to have in place national demand management plans, such as the UK Clinical Guidelines for Immunoglobulin Use (2011)	IPOPI	EU	
Awareness raising	Promotion of existing information tools for healthcare professionals, such as registry of shortages, or the procedure for reporting supply issues. Set-up of "shortage alerts" in the software used for medicines prescription/dispensing (at prescriber/pharmacy level)	through the ad hoc national forum of stakeholders dealing with pharmaceutical shortages	Italy	
Prescribing practice	Central cascade system where GP practices are advised of current drug shortages (through electronic prescribing systems). In the UK, there is also a pharmacist-based system where alternative medications are advised.	UEMO (European Union of General Practitioners)	Norway, Sweden, UK	best practices
Raising awareness	Shortages observatories to gather feedback on patient experiences with shortages and feedback to authorities to trigger public action (crisis management & better regulation)	TRT-5 (groupe inter-associatif traitements & recherche thérapeutique), Epilepsie France, SOS-Hépatites, France Assos Santé	France	https://www.france-assos-sante.org/publication_document/penuries-de-medicaments-et-de-vaccins-resultats-de-lenquete-realisee-en-decembre-2018-par-linstitut-bva-pour-france-assos-sante/

Action	Description	Organisation	Concerned MS	References and notes
	La Ligue Contre le Cancer carried out an exploratory study about consequences of shortages among patients and health professionals in November 2019. In September 2020, awareness campaign on the consequences of shortages for cancer patients and the launch of a website to gather testimonies from patients affected by medicines shortages. In parallel, la Ligue is working with health authorities to aim for better regulation and better patient information.	La Ligue Contre le Cancer		https://www.ligue-cancer.net/article/57712_cher-patient-pour-votre-medicament-merci-de-patienter
Raising awareness and assistance for patients and consumers	Examples of awareness raising activities conducted by national consumer organisations: Receiving notifications from consumers and informing them about regulatory measures. Proactive dissemination of recommendations from regulatory authorities on drug shortages. Publishing articles in consumer magazines about specific cases of medicines shortages, shedding light to root causes, solutions. Conducting consumer surveys about drug shortages and their impact.	BEUC- via member organisations Altroconsuo (Italy), Deco (Portugal), Forbrukerrådet (Norway), Forbrugerrådet Tænk (Denmark), Organización de Consumidores y Usuarios (Spain), Test-Achats/Test-Aankoop (Belgium), UFC-Que Choisir (France)		
Encouraging healthcare professionals to carry out risk assessments	To foster more proactive shortage management, awareness among healthcare professionals should be raised on the need to perform risk assessments. Risk assessments can help healthcare professionals to prepare protocols for mitigating shortages	EAHP	All	https://www.frontiersin.org/articles/10.3389/fphar.2020.00357/full

2.2. Policy recommendations

2.2.1. Prevention

Action	Description	Organisation	Concerned MS	References
Reporting/early notification	Develop catalogues of shortages. All European countries should develop a national system for reporting medicines shortages based on a minimum set of data requirements. European regulatory authorities (Heads of Medicines Agency (HMA)/EMA) could: • coordinate the development of a harmonised procedure for reporting of shortages, based on a shared definition; • develop a platform/database to collate the reports from the national systems. All stakeholders, including patients and physicians, should have access to a user-friendly, web-based system to report shortages.	ESMO (European Society for Medical Oncology)	All EU Member States	https://www.esmo.org/policy/shortages-of-inexpensive-essential-cancer-medicines
Reporting/early notification	Enhancement and enforcement of current obligations of pharma companies: clarification of Art 81 and 23a of the Community Code Directive and strengthening of the directive by providing for sanctions.	CPME (Standing Committee of European Doctors) BEUC	All EU Member States	https://ec.europa.eu/health/system/files/2018-10/ev_20180525_rd01_en_0.pdf
Reporting/early notification	• Introduce legislation for early notification requirements for medicines shortages. • National legislation for early notification from manufacturers should be implemented in all European countries, as stipulated in Directive 2001/83/EC. The legislation should include a requirement for manufacturers to provide information about the reasons for discontinuation of supply.	ESMO	All EU Member States	

Action	Description	Organisation	Concerned MS	References
Contingency plans	Advocates for national contingency plans to ensure that the plasma-derived medicinal products developed on the basis of EU plasma remain in the EU after manufacturing in times of tensions.	IPOPI	International	
Contingency plans	• Establish strategic plans for medicines shortages • Countries should establish a task force to develop a national strategic plan for medicines shortages, underpinned by national legislation and funding. • This initiative could be proposed at a European level, with countries having an option to implement it on a national level.	ESMO	All EU Member States	https://www.esmo.org/policy/shortages-of-inexpensive-essential-cancer-medicines
Procurement	Establish procurement models designed to prevent medicines shortages: • Good procurement practices addressing predictability and profitability for medicines manufacturers should be identified. These could include using tender criteria that include price as well as other factors, e.g. quality track record of manufacturers. • Tender cycle harmonisation could be considered within and across countries. • National procurement for medicines experiencing shortages could be considered.	ESMO	All EU Member States	https://www.esmo.org/policy/shortages-of-inexpensive-essential-cancer-medicines & https://www.esmo.org/content/download/199478/3584846/1
Procurement	Prudent procurement practices as one of the best practices to prevent shortages. Procurement practices focusing solely on the price have resulted in	EAHP	All EU Member States	http://www.eahp.eu/sites/default/files/eahp_position_paper_on_procur

Action	Description	Organisation	Concerned MS	References
	manufacturers pulling out of national markets, leading to market consolidation and consequently increasing the risk of medicines shortages. Allowing more than one winner for tenders of pharmaceutical products would lower the risk of single supplier dependence.			ement_0.pdf
• **Procurement** • **stockpiling** • **export bans** • **reducing dependency third countries**	Increasing diversification of supply sources; reducing Europe's overreliance on external manufacturing; changing procurement practices to allow for more winners of tenders and apply other criteria than price; stockpiling of medicines at EU level. Avoiding national stockpiling beyond limited, justified stockpile of essential medicines for emergency use; allowing Member States to temporarily ban parallel export if justified, reasonable and proportionate.	CPME	ALL EU Member States	https://www.cpme.eu/api/documents/adopted/2020/4/cpme.2020-005.FINAL_.CPME_.Policy.on_.Medicine.Shortages.pdf https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf
	Explore possibilities for expanding the scope of the Joint Procurement Agreement (JPA), so it can be used beyond situations of serious cross-border health threat (e.g. to ensure availability and affordability of new innovative medicines).	BEUC		
Fair stock distribution	During crisis situations (e.g. COVID-19 pandemic), the rescEU stockpiling mechanism should be favoured over national stockpiling approaches to ensure equitable access. Transparency should be increased around the functioning of this mechanism and the criteria to distribute stocks. In addition, the Commission should develop guidelines and a monitoring	BEUC	EU institutions/ Member States	https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf

Action	Description	Organisation	Concerned MS	References
	system to ensure that national initiatives on stockpiling are proportionate to their needs and do not create unintended consequences in other countries.			
Essential medicines lists	Develop essential medicines lists and assess the risk for shortages. Countries should develop national essential medicines lists based on the WHO Model List of Essential Medicines (EML). The EMA Risk Indicators for Shortages (manufacturing and quality) should be used to identify high-risk products.	ESMO	All EU Member States	https://www.esmo.org/content/download/199478/3584846/1/Cancer-Medicines-Shortages-in-Europe.pdf
Contingency plans	Pharmaceutical companies should be required to submit shortage prevention plans to competent authorities when they market a medicine. Such plans can help identify risks early on and promote mitigation measures (e.g. diversify the supply of active pharmaceutical ingredients, improve good manufacturing practices). Based on these prevention plans and other information, competent authorities should proactively monitor the supply of those medicines that are at risk of shortage, particularly if they are essential (e.g. based on clinical need, added therapeutic value, reasonable price, narrow-therapeutic index). The criteria to define 'priority monitoring lists' of medicines should be transparent.	BEUC	All EU Member States	https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf

Action	Description	Organisation	Concerned MS	References
Monitoring system	Create early warning systems on medicine shortage at both national and European level. Some Member States have established early warning systems which facilitate the anticipation and the prevention of potential shortages, for instance monitoring the stocks of medicines. In Romania, such a monitoring system provides information to the government on existing stock levels. The adoption of similar systems in other EU countries or at EU level should be supported to allow health systems to take prevention/mitigation measures as early as possible.	EPHA (European Public Health Alliance)	All EU Member States	https://epha.org/position-medicine-shortages/
	The Single Point of Contact network (SPOC) established by EMA/HMA should become an established monitoring system on drug shortages.	BEUC		https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf
EU Joint Action	EU Joint Action focusing on the prevention of medicine shortages to further support the exchange of best practices among Member States and to help develop common prevention measures.	EPHA	All EU Member States involved in the Joint Action	https://epha.org/position-medicine-shortages/

2.2.2. Management

Action	Description	Organisation	Concerned Member States	References
Fair and equitable distribution	Sourcing the same medicine from alternative authorised sources (e.g., other pharmacies where legally allowed or sourcing directly from manufacturers in case of contingency plans)	PGEU	Selection of countries	https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf
Reducing impact on healthcare professionals	EAHP urges national governments and healthcare organisations to evoke appropriate staffing levels in order to lower the impact that medicines shortages currently have on the overall patient services provided by hospital pharmacists.	EAHP	All EU member states	https://www.eahp.eu/sites/default/files/eahp_position_paper_on_medicines_shortages_june_2019.pdf
Use of alternatives	The European Commission should conduct a study mapping alternative (public) drug manufacturing models in Europe and beyond. Scaling-up these initiatives at the national and EU level can help improve the availability of medicines that are in short supply (including old medicines for which there is no commercial interest).	BEUC	all	https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf
Extend role of pharmacists	Widen professional competence: The scope of pharmacy practice should be extended when medicines are in short supply, so pharmacists can use their skills and knowledge to better manage patient care and ensure continuity of treatment. When a medicine is not available, pharmacists should be allowed to substitute with the most appropriate alternative as part of a shared decision-making	PGEU	European - EU institutions and member states	https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf

	process with prescribers and patients or in accordance with national protocols where appropriate. Shared electronic communication tools between pharmacists and prescribers (e.g., shared electronic health records) can enable this process effectively and safely.			

2.2.3. Communication

Action	Description	Organisation	Concerned MS	References and comments
Communication	To improve communication, the following principles should be adopted by national and European competent authorities, when developing policies and communication strategies on shortages: • Ensure greater transparency and availability of medicine shortages data; • Encourage early detection and central assessment of potential shortages by connecting all medicine supply chain actors and national competent authorities at national level in consistent reporting systems; • Increase access to the information available across all parts of the supply chain.	PGEU	All	https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf
Enabling consumer reporting	Competent authorities should enable medicines users to report on drug shortages and their impact.	BEUC	All	https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf
Ensuring effective public communication	The EMA catalogue should be expanded and evolve into a comprehensive user-friendly pan-European database on shortages connected to national public databases. The electronic Product Information (ePI) should be implemented across the EU. ePIs should complement, but not replace, paper leaflets in the packages. BEUC calls for ePIs to	BEUC	All	https://www.beuc.eu/publications/beuc-x-2020-034_addressing_medicine_shortages_during_the_covid-19_pandemic.pdf

	be developed and managed by regulatory authorities, and to comply with EU's data protection and security framework.			