The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the EMA Survey on implementation of 'Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use'

On 12 September 2024, the CPME Board adopted the 'CPME response to the EMA Survey on implementation of 'Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use'' (CPME 2024/117).

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

Fields marked with * are mandatory.

EUROPEAN MEDICINES AGENCY

The good practice guide was first published in 2022. Awareness of the guidance has been low and a subgroup with representatives of patients and healthcare professionals was therefore set up to discuss how to raise awareness of the guidance, as well as measures to increase its implementation and the general need to update it.

EMA is carrying out this survey to better understand the current landscape and any initiatives on prevention organisations may have been involved in. Any relevant initiatives identified could then also support a potential webinar as discussed at EMA's recent meeting of PCWP and HCPWP on 2-3 July 2024. The aim of the webinar would be to further support organisations in the implementation of the guidance.

We would appreciate your input by **9 September 2024**.

1. Profile

* Name and Surname:

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* Are you a member/observer of the PCWP or HCPWP?

- ( ) Yes, PCWP
- (•) Yes, HCPWP

* Representing:

HCPWP - CPME

2. Survey questions

The questions focus on the recommendations of the good practice guide to identify any measures that your organisation may have taken or that you are aware of linked to the implementation of the recommendation. Please provide as much information as possible including links

1. “Organisations should develop shortage observatories or seek links with already established shortage observatories (organisation that collects and analyses information from patients and healthcare professionals on shortages and the consequences on patients’ outcomes)”.
Are you aware of shortage observatories or is your organisation interacting with any such organisation?

- (•) Yes
- ( ) No

If Yes, please provide details (such as name of organisation, country and activities)

The Netherlands and Germany have registries for drug shortages. The Dutch website (https://www.cbg-meb.nl/onderwerpen/medicijninformatie-medicijntekorten) presents not only the product on shortage, but also the available alternatives. Germany has a similar system of centrally collecting the information on shortages and the alternatives (https://anwendungen.pharmnet-bund.de/lieferengpassmeldungen/faces/public/meldungen.xhtml). EMA should have a similar system to all EU countries.

The Royal Dutch Pharmacists Association has reporting system for medicines shortages. The data is published on a website. In 2004 the Royal Dutch Pharmacists Association (KNMP) launched the website KNMP Farmanco: www.farmanco.knmp.nl. It provides pharmacists with up to date information on medicine shortages in The Netherlands. On the website a medicine shortage can be reported by industry or pharmacists. Based on the report, the manufacturer is contacted for an analysis of the problem such as reason for the shortage. Within 24 hours of the report, information is provided on the website about the cause and the duration of the shortage and possibilities for solutions. An advice on a pharmaceutical alternative, import or pharmacy preparation is usually published afterwards. This way, medicine shortages are reported quickly, which allows pharmacists to take proper action. Possibilities for solutions are only visible after logging in.
https://farmanco.knmp.nl/about-knmp-farmanco

https://www.knmp.nl/over-de-knmp/vereniging-knmp/about-knmp

2. “Organisations should 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”.
Are you aware of or is your organisation providing any such information material?

- (●) Yes
- ( ) No

If Yes, please describe and include link

> In Spain there is a system for reporting /detecting medicines shortage with an automated method.
>
> The General Council of Pharmacists of Spain (CGCOF) has developed two digital tools that aim to prevent and mitigate medicine shortages, a global burden that deeply affects patients and community pharmacists: CisMED, a communication system that generates real-time information on supply incidents at pharmacy level, and FarmaHelp, which allows community pharmacies to communicate with other pharmacies in the surrounding area when a patient's request for a medicine cannot be fulfilled at the first instance.

3. “Organisations should collaborate with relevant national authorities to ensure fair distribution of essential medicines among regions and according to demands.”
Are you aware of or is your organisation involved in such initiatives?

- (●) Yes
- ( ) No

If yes please provide details

> The KNMP, together with the Royal Dutch Medical Association (KNMG), is involved in such collaboration in The Netherlands.

4. "At EU and national level, organisations (in collaboration with patient professionals and national medicine agencies/health authorities) are recommended to develop and use 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."

Are you aware of, or has your organisation developed, any such information material?

- ( ) Yes
- (●) No

5. "Organisations should 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."

Are you aware of or is your organisation involved in any work in this area?

- ○ Yes
- ◉ No

6. "Organisations should promote awareness on how healthcare professionals (in particular prescribers and pharmacists) can notify medicine shortages and encourage engagement in the notification process"
Are you aware of or is your organisation involved in any awareness raising activities in this area?

- ◉ Yes
- ○ No

If Yes, please provide details

> CPME shared EMA calls for shortages reporting with its members last winter.

7. "Organisations should liaise with health authorities to ensure that 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."
Are you aware of or is your organisation involved in any relevant initiatives?

- ◉ Yes
- ○ No

If yes please provide details

> Besides the dissemination of EMA calls for reporting with CPME members last winter, we also prepared a lobbying package with our members in the context of the revision of the general pharmaceutical legislation. Such package could be used at the national level to lobby governments and complement our lobby efforts at the EU level.

8. "Any risk of stockpiling which may come with increased transparency should be monitored and addressed through communication and awareness campaigns."
Are you aware of or has your organisation developed any information on stockpiling?

- ◉ Yes
- ○ No

If yes, please provide details

> In The Netherlands the government has decided to organize stockpiling. The KNMP has only published the information from the government: https://www.knmp.nl/actueel/nieuws/aanleg-ijzeren-voorraad-geneesmiddelen-verplicht-1-januari-2023

9."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)."
Are you aware of or is your organisation involved in any relevant initiatives?

- ○ Yes
- ◉ No

10. "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)."
Are you aware of or is your organisation involved in any relevant initiatives?

- ◉ Yes
- ○ No

If yes, please provide details

CPME recommends that any guidelines on restrictions on prescribing would have to be made with doctors.

11. "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."
Are you aware of or is your organisation involved in any initiatives in this area?

- ◉ Yes
- ○ No

If yes, please provide details

Any guidelines on restrictions on prescribing need to be made with doctors.

12. "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."
Are you aware of or is your organisation involved in any relevant initiatives?

- ○ Yes
- ◉ No

13. Are you aware of a template for these types of risk assessments?

- ○ Yes
- ◉ No

14. Are there any other activities (not listed below) that you are aware of or engaging in that are linked to the prevention or management of shortages?

- ○ Yes
- ◉

No

15. At the PCWP/HCPWP meeting of 2-3 July, the possibility of a webinar was raised. The webinar would focus on the guidance and how the recommendations could be further applied by organisations. Would you be interested in attending such a webinar?

- (●) Yes
- ( ) No
- ( ) Maybe

Please provide further details

16. Would you be interested in presenting your initiatives?

- ( ) Yes
- (●) No
- ( ) Maybe

Please provide further details

17. Do you have any other suggestions for content of the webinar?

- (●) Yes
- ( ) No
- ( ) Maybe

Please provide further details

It would be valuable having presentations from healthcare professionals and patients on how they are applying the “EMA/HMA Good practice guidance for patients and healthcare professionals on the prevention of shortages. It could also be good to bring national competent authorities and industry to the table so that they could present their views on the guidelines. Furthermore, the webinar should be properly disseminated to reach as many healthcare professionals and patients as possible.

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