



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pilot on reporting of shortages by eligible patients and healthcare professional organisations

PCWP and HCPWP Joint meeting 28 June 2023



Reporting of shortages by patient and healthcare professional organisations

Pilot to explore added value of shortage reports from eligible EU patient and healthcare professional organisations



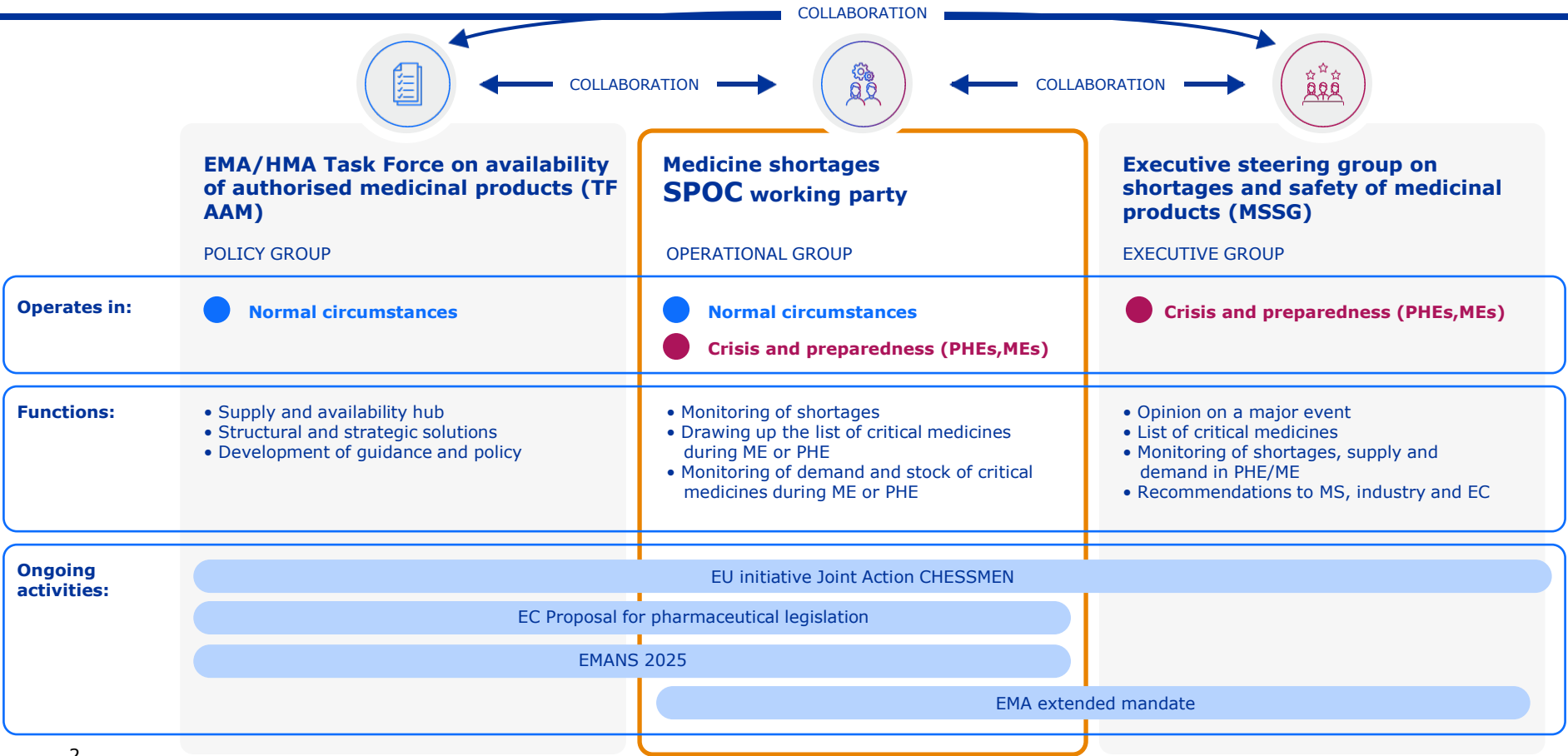
For shortages affecting one or more EU member states and where medicine in question is critical (i.e. life-saving medicine, without suitable alternative or alternative has clinical impact) or



In context of public health emergency, any information that could indicate an upcoming shortage

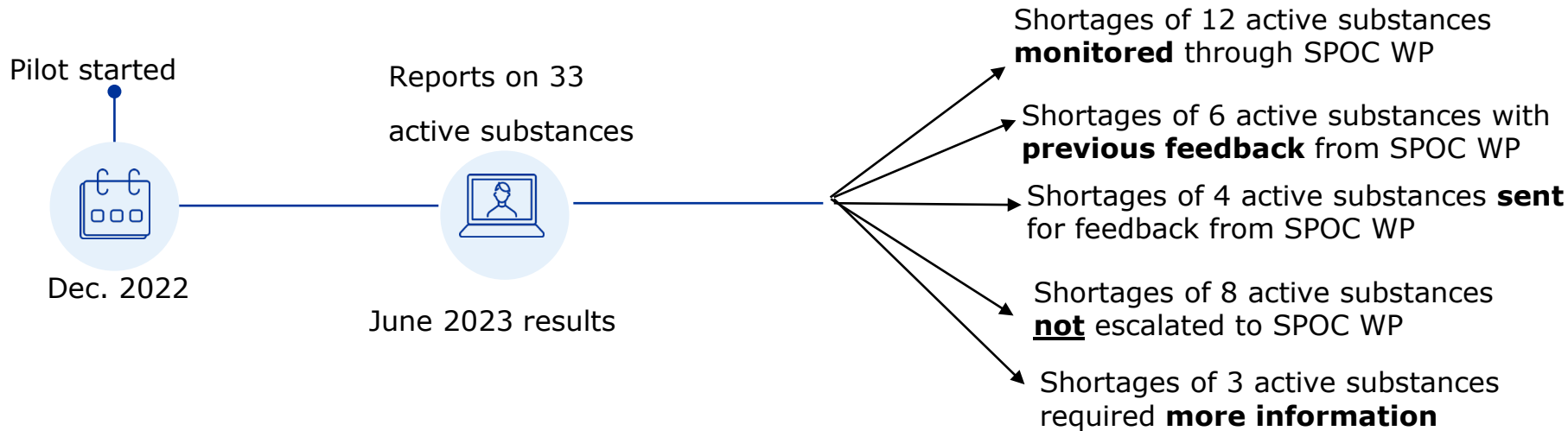
Shortages that meet criteria and not yet raised at SPOC WP are forwarded to them for review and input.

What does the SPOC WP do?



How does SPOC WP monitor shortages?

- Raise critical shortages in their territory
- Establish extent and impact of critical shortage across EU
- Decide if there is a need for EU coordinated action and decide what further actions are needed (e.g. engagement with marketing authorisation holders and manufacturers of alternatives)



Shortages monitored through SPOC WP

Active substance affected

Alteplase

Amoxicillin +/- clavulanic acid,
azithromycin, cefuroxime,

Clonazepam

Ibuprofen paediatric formulations

Human immunoglobulins

Paclitaxel

Paracetamol

Active substance affected

Ranitidine

Tenecteplase (Metalyse)

Radiopharmaceuticals I-131 and Tc-99m/Mo99

Shortages send for feedback to SPOC WP

Active substance affected	Follow-up
Adenosine solution for injection (Adenocor)	Feed-back Feb 2023: 4 NCAs (ES, PL, SI, SK) confirmed that there is a shortage, however shortage either not critical, or already resolved (Slovakia). No coordinating actions were considered necessary at the time.
Albumin – solution for infusion	Request for info sent to SPOC WP from Feb 2023: 6 NCAs (HR, HU, IT, RO, SI, SK) confirmed shortage, however not critical alternatives exist. This shortage is handled at national level and no coordinating actions were considered necessary at the time.
Protamine	SPOC WP was consulted in Feb 2023: 5NCAs (DE, ES, HU, LI, NL) confirmed ongoing shortage. DE, ES, HU consider not critical as alternatives or importation of product from abroad. based on feedback from SPOC WP this shortage is handled at national level and no further coordinating actions were considered necessary at the time.
Sumatriptan subcutaneous	<p>SPOC WP was consulted in Feb 2023:</p> <ul style="list-style-type: none"> •12 NCAs informed us that sumatriptan sc is either not marketed •5 NCAs confirmed availability issues <p>Regarding duration: for most of them the shortage lasted 1-2 months In 2 countries the supply issue is already resolved based on feedback from SPOC WP this shortage is handled at national level and no further coordinating actions were considered necessary at the time</p>

Shortages with feedback from SPOC WP

Active substance affected	Follow-up
Amphotericin B infusion (Abelcet)	Shortage report dates Jan 2022. Listed in national shortage catalogues. Following feedback from SPOC WP national management was considered sufficient. Since then, no additional requests were received from SPOC WP.
Co-trimoxazole	Based on feedback from SPOC WP this shortage is handled at national level.
Levofloxacin	In Feb 2023 an increase of notifications for levofloxacin in ES, this shortage is handled at national level and no coordinating actions were considered necessary at the time.
Nadroparin	SPOC WP was consulted in Sep 2022 following notification in NL of shortage of Nadroparin. Based on feedback from SPOC WP this shortage is handled at national level and no coordinating actions were considered necessary at the time.
Vigabatrin	SPOC feedback collected in November 2022 highlighted shortage in 4 Member States. based on feedback from SPOC WP this shortage is handled at national level and no further coordinating actions were considered necessary at the time
Zonegran (zonisamide)	SPOC feedback collected in November 2022 highlighted shortage in 4 Member States. Based on feedback from SPOC WP this shortage is handled at national level and no further coordinating actions were considered necessary at the time. Follow-up with MAH

Shortages reported not escalated to SPOC WP

Active substance affected	Follow-up and comments
Ambroxol (Ambrobene)	Not currently monitored by SPOC WP, previously not considered critical in France. For Spain, brandname does not exist.
Betamethasone injection	Shortage report states that alternatives are available. Therefore EMA considered that the shortage is not critical and no escalation to the SPOC WP was necessary, national management was considered sufficient
Bupivacaine injection (Marcaine)	Shortage report states that alternatives are available. Therefore EMA considered that the shortage is not critical and no escalation to the SPOC WP was necessary, national management was considered sufficient
Midazolam oral solution	EMA considered that no escalation to the SPOC WP was necessary and national management was considered sufficient
Omeprazole	Shortage report refers to one manufacturer only and states that alternatives are available. Therefore EMA considered that the shortage is not critical and no escalation to the SPOC WP was necessary, national management was considered sufficient
Oxybutynin transdermal (Kentera)	Shortage reported by MAH to EMA (temporary cessation), follow-up with MAH who confirmed that shortage is now resolved.

Shortages reported not escalated to SPOC WP

Active substance affected	Follow-up and comments
Primidone	EMA considered that no escalation to the SPOC WP was necessary and national management was considered sufficient
Quinapril	Shortage report specified shortage affecting several Member States but alternatives were available. Therefore EMA considered that no escalation to the SPOC WP was necessary and national management was considered sufficient

Reports which required further information

Active substance affected	Problem	comments
Prednisolone paediatric formulations	<ul style="list-style-type: none"> • report from Estonia, based on one hospital only. • Missing information (name of formulations affected) • No start date included 	Further information was requested
Cefadroxil	report from patient organisation in Belgium (unclear if nationwide issue). Date of report unclear. Online pharmacies in Belgium seem to have cefadroxil in stock.	Further information was requested
Ganciclovir (Cymvene)	report from patient organisation in Belgium (unclear if nationwide issue). Date of report unclear.	Further information was requested

Assessment

- Most shortages are known and reports are confirmatory, information on medication errors adverse events.
- The reports mostly concern NAPs, only 3 CAPs.
- Some differences in criticality assessment (i.e. oxybutynin, sumatriptan)
- Problems highlighted:
 - Not enough information about shortage, or medicine (i.e. formulation)
 - Reports of long-standing well known shortages (i.e. reflected in catalogues)
 - Inconsistent criticality assessment or different criticality assessment
- Pilot support increase in communication on SPOC WP monitoring activities (SPOC WP minutes publication and expansion of EMA shortage catalogue)

- Plan to continue the pilot
- Adjust criteria for reporting:
 - For shortages affecting ~~one or~~ **two or more** EU member states and where medicine in question is critical (i.e. **diseases with serious implications for health, life-saving medicine, without suitable alternative or alternative has clinical impact**) **and where the shortage is not already listed in shortage catalogues**
 - In context of public health emergency, any information that could indicate an upcoming shortage

To summarise

- Use template to report
- Consider following questions:
 - If a national organisation reports a shortage, are other organisations reporting similar shortages?
 - Are the shortages reflected in respective national catalogues?
- Only report if:
 - Shortage affects 2 or more Member States
 - Shortage is current and started recently (not yet reflected in national catalogue)
- Remember – reporting the shortage to EMA is for the purpose of additional coordinating actions through SPOC WP in addition to actions by national agencies

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

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