



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reporting of shortages by EU patient and healthcare professional organisations

PCWP/HCPWP annual meeting with all eligible organisations

Presented by Inga Abed on 15 November 2022
Stakeholders and Communication

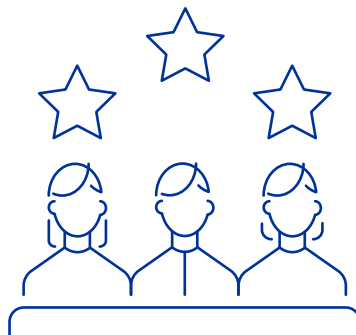
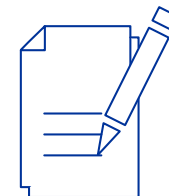
An agency of the European Union





Background

- Direct reporting not foreseen by legislation
- Mechanisms are in place at national level to collect this information from national associations
- Central mechanism may add benefit and valuable feedback, also in view of EMA's new mandate





- Patients and healthcare professionals hold crucial information on shortages, such as impact on clinical practice
- At EMA, ad-hoc reporting during Ukraine war
- Experience during COVID-19 with increase in demand for paracetamol



Details of proposal

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

Who?

- all EMA eligible organisations

What?

- For shortages affecting **one or more EU member states** and where medicine in question is critical or
- in context of public health emergency, any information that could indicate an upcoming shortage

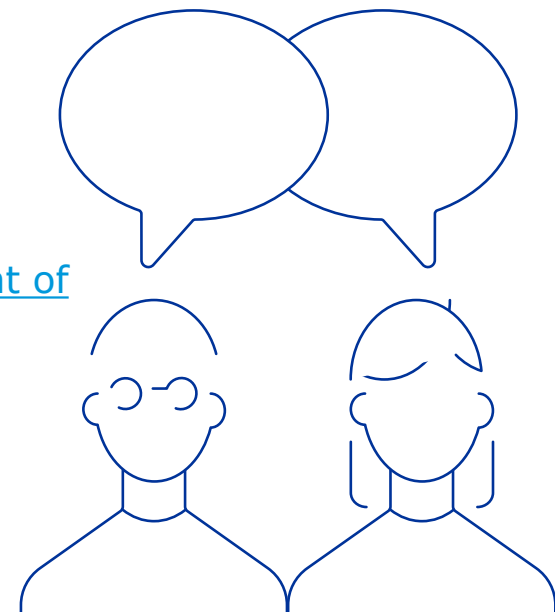


How?

- Email report using dedicated template to hcpsecretariat@ema.europa.eu
- Any reports will be internally assessed and triaged
- Involvement and assessment by [Medicines Shortages Single Point of Contact \(SPOC\) Working Party](#) as necessary

When?

- Pilot for one year starting January 2023
- With review after 6 months





Template for reporting

| Shortage assessment | | |
|-----------------------------------|--|--|
| Product details | Product name | |
| | Active substance(s) | |
| | Pharmaceutical form | |
| | Strength | |
| | Route(s) of administration | |
| | Pack size(s) | |
| Details on shortage | Date of the beginning of shortage (may be anticipated date) | |
| | Impacted countries (if known) | |
| | How are you aware of the shortage? | |
| Impact assessment | Anticipated clinical impact for patients (i.e. are alternatives available) | |
| | Are there any risks for patients with using the alternative medicine? | |
| Details of notifying organisation | Name of organisation | |
| | Name of the person completing the form and date | |
| | E-mail of contact person* | |
| | Telephone number contact person | |



Any questions?

Further information

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