



Best practice guidance for EU authorities on public communication

Multi-stakeholder meeting with the HMA/EMA Task Force on availability of authorised medicines
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Objectives what do we want to achieve?

“
Increase visibility and
accessibility of information on
availability on medicines
”

“
Allow timely access to
up-to-date information
”

“
Align criteria for
publication across EU
network
”

“
More interaction with
stakeholders
”

“
Enhance current communication
practices by ensuring a
multi-disciplinary approach
within regulatory body
”



Tools



- All availability issues accessible on a single webpage
- Includes systematic listing for shortages, withdrawals and suspensions

Involvement of stakeholders



- Early involvement is key

Timing of publication



- Important to allow for planning and continuity of care

Target audience



- Patients, HCPs, regulators and industry
- Public friendly language

Dissemination



- Organisations' channels
- professional/ medical journals
- media (incl social media)
- newsletters
- electronic prescribing systems



Proposed criteria for systematic listing



Topic

Details



Details of medicine

- Trade name
- active ingredient (INN)
- Pharmaceutical form & strength
- Pharmaceutical company

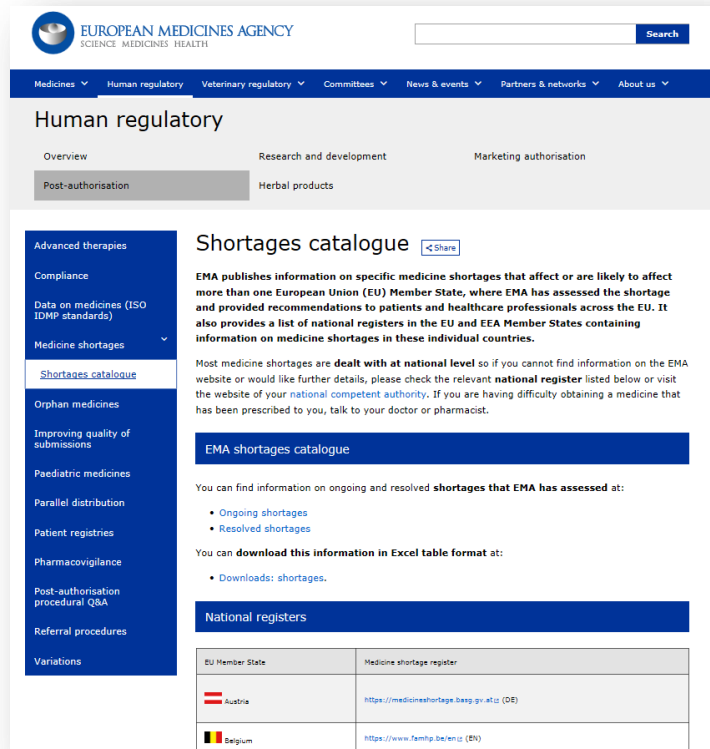
Details on availability issue/shortage

- Date of beginning of shortage (or anticipated date)
- Expected end date of the shortage, if applicable
- Reason for availability issue or shortage

Advice for healthcare professionals/ patients, if applicable

- Potential alternative medicinal products (INN), if applicable
- Recommendations for change in clinical practice/ change in use of medicine/ use of alternative medicine (INN), if applicable

Interlinking EMA catalogue to information at national level



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EMA publishes information on specific medicine shortages that affect or are likely to affect more than one European Union (EU) Member State, where EMA has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU. It also provides a list of national registers in the EU and EEA Member States containing information on medicine shortages in these individual countries.

Most medicine shortages are **dealt with at national level** so if you cannot find information on the EMA website or would like further details, please check the relevant **national register** listed below or visit the website of your **national competent authority**. If you are having difficulty obtaining a medicine that has been prescribed to you, talk to your doctor or pharmacist.

EMA shortages catalogue

You can find information on ongoing and resolved **shortages that EMA has assessed at**:

- Ongoing shortages
- Resolved shortages

You can **download this information in Excel table format at**:

- Downloads: shortages.

National registers

EU Member State	Medicine shortage register
Austria	https://medicineshortage.basg.gv.at/ (DE)
Belgium	https://www.famhp.be/en/ (EN)

National registers	
EU Member State	Medicine shortage register
Austria	https://medicineshortage.basg.gv.at/ (DE)
Belgium	https://www.famhp.be/en/ (EN)
Bulgaria	http://www.bda.bg/bg/ (BG)
Croatia	http://www.halmed.hr/en/ (EN)
Cyprus	No online register available
Czech Republic	http://www.sukl.cz/ (CZ)
Denmark	https://laegemiddelstyrelsen.dk/ (DK)
Estonia	http://www.ravimiamet.ee/ (ET)
Finland	http://www.fimea.fi/ (FI)
France	https://ansm.sante.fr/ (FR)
Germany	https://www.bfarm.de/ (DE) www.pei.de (DE)
Greece	http://www.esf.gr/ (GR)
Hungary	https://www.ogyel.gov.hu/ (HU)
Ireland	https://www.hpra.ie/ (EN)
Italy	http://www.agenziafarmaco.gov.it/ (IT)
Latvia	https://www.zva.gov.lv/ (LV)
Lithuania	http://vkt.lt/ (LT)
Luxembourg	No online register available
Malta	No online register available

Improving information sharing within the EU network

- Building upon existing mechanisms
- Pooling together information sharing for both centrally and non-centrally authorised medicines
- Virtual dedicated network: streamlining and avoiding duplication
- **Objective:**
 - To optimise cooperation, coordination and improve responsiveness of the EU network
 - To allow better monitoring, prevention, management and communication on shortages in the EU

EU Regulator's manual to consolidate the output of the Task Force on availability

- To become reference material for all EU regulators
- Easier access, publically available - facilitates implementation
- Compiles output from the Task Force and previous work on shortages from the EU network:

Reporting

Assessment

Management

Communication

- Will be available on EMA's website as well as on HMA's website

Any questions?

Further information

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