

Annex

Details of questionnaire sent to SPOCs

<ul style="list-style-type: none">• Has your agency made direct changes to its publication practices on shortages and availability issues since the publication in July 2019 of the Good practice guidance for communication to the public on medicines' availability issues (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf)<ul style="list-style-type: none">– Yes (please provide details below)– No, not yet, but we are planning to implement the following changes (please specify below)– No, we are already aligned with the good practice guidance– No, we are not aware of any plans to change current practice (please add any comments below)
<ul style="list-style-type: none">• Does your agency have a dedicated area on its public website providing information on shortages of individual medicines (e.g. a catalogue)?<ul style="list-style-type: none">– Y/N
<ul style="list-style-type: none">• Which elements does your agency publish for shortages of individual medicines? (Select all that apply)<ul style="list-style-type: none">– Trade name– Active ingredient (INN)– Pharmaceutical form– Strength– Marketing authorisation holder– Cause of shortage– Start date of shortage– Estimated end date of shortage– Availability of alternative medicines (without specifying details of the alternative medicines, e.g: name, strength, pharmaceutical form)– Alternative medicines available (including details of the alternative medicines, e.g: name, strength, pharmaceutical form)– Others

Supplemental table 1: Details of authorities that publish a catalogue of shortages

EU/EEA authority	Type of information in 2020	Type of information in 2018
Austria	Catalogue	Catalogue
Belgium	Catalogue	Catalogue
Bulgaria	Catalogue	Catalogue
Croatia	Catalogue	Catalogue
Cyprus	No catalogue available	No catalogue available
Czechia	Catalogue	Catalogue
Denmark	Catalogue	Catalogue
Estonia	Catalogue	Catalogue
Finland	Catalogue	Catalogue
France	Catalogue	Catalogue
Germany (Paul Ehrlich Institut)	Catalogue	Catalogue
Germany (Bundesinstitut fuer Arzneimittel und Medizinprodukte)	Catalogue	Catalogue
Greece	Catalogue	Catalogue
Hungary	Catalogue	Catalogue
Ireland	Catalogue	No catalogue available
Iceland	Catalogue	Catalogue
Italy	Catalogue	Catalogue
Latvia	Catalogue	Catalogue
Liechtenstein	No catalogue available	No catalogue available
Luxembourg	No catalogue available	No catalogue available
Lithuania	Catalogue	Catalogue

EU/EEA authority	Type of information in 2020	Type of information in 2018
Malta	No catalogue available	No catalogue available
Netherlands	No catalogue available	No catalogue available
Norway	Catalogue	Catalogue
Poland	No catalogue available	No catalogue available
Portugal	Catalogue	No catalogue available
Romania	Catalogue	Catalogue
Slovak Rep.	Catalogue	Catalogue
Slovenia	Catalogue	Catalogue
Spain	Catalogue	Catalogue
Sweden	Catalogue	Catalogue

Supplemental table 2: Details of information provided in the public shortage catalogue

EU Authority	Trade	Active	Pharmaceutical form	Strength	Marketing authorisation holder	Cause	Start Date	Estimated end date	Alternatives without details	Alternatives with details	Other
Austria	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓
Belgium	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗
Bulgaria	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗	✓
Croatia	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗
Czech Rep.	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗	✗
Denmark	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓
Estonia	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗	✗
Finland	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗	✓
France	✓	✓	✓	✓	✓	✗	✓	✗	✓	✗	✗
Germany (PEI)	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗
Germany (BfArM)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
Greece	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗
Hungary	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Ireland	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗	✓
Iceland	✓	✗	✓	✓	✗	✓	✓	✓	✓	✗	✗
Italy	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗
Latvia	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗
Lithuania	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓
Norway	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Portugal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Romania	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
Slovak Rep.	✓	✗	✓	✓	✓	✗	✓	✗	✓	✗	✓
Slovenia	✓	✗	✓	✓	✓	✗	✓	✓	✓	✗	✗
Spain	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗

EU Authority	Trade	Active	Pharmaceutical form	Strength	Marketing authorisation holder	Cause	Start Date	Estimated end date	Alternatives without details	Alternatives with details	Other
Sweden	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗

Supplemental table 3: Selection criteria for publishing in the shortage catalogue

EU Authority	Criteria for publication
Austria	X
Belgium	✓
Bulgaria	No information provided
Croatia	X
Czech Rep.	X
Denmark	✓
Estonia	X
Finland	X
France	✓
Germany (PEI)	X
Germany (BfArM)	✓
Greece	✓
Hungary	X
Ireland	✓
Iceland	No information provided
Italy	X
Latvia	X
Lithuania	X
Norway	✓
Portugal	✓
Romania	X
Slovak Rep.	X
Slovenia	X

EU Authority	Criteria for publication
Spain	✓
Sweden	✗

Supplemental table 4: Type of changes made by competent authorities to their publication practices on shortages and availability issues since publication of the communication practices

Country	Change
Austria	Catalogue updated with information on medicines with a parallel export ban.
Belgium	Publication for all availability issues, publication 2 weeks before expected start date of shortage, information on availabilities and set-up of taskforce for critical medicines
Denmark	Introduction of catalogue for “serious” and “critical” shortages including information about expected duration (start/end dates) and cause of shortage.
Iceland	Total overview of reported shortages (updated weekly) Dedicated news guidance to HCP/patients Shortage reporting from MAHs and consumers/HCPs
Italy	Updated information on webpage (actions taken during COVID-19)
Latvia	Information is uploaded 2 hours after notification Improved communication on medicines in foreign packaging material Information on stocks
Portugal	Implementation of catalogue

Supplemental table 5: Details of future changes planned by competent authorities

Country	Plans for implementation
Croatia	Change from pdf to machine readable format
Czech Republic	English version of the catalogue in addition to the national language version (implemented at the time of report writing) Possibility to view reports made by marketing authorisation holders updated daily
Cyprus	No catalogue yet but plans to communicate on critical shortages
France	Improvements to catalogue (reduce criteria for publication, make information more public friendly)
Lithuania	Improvements to catalogue (e.g. interlinking information on revocation/cessation, use of high-profile communication tools, colour-coded information, keeping records on solved situations)
Luxembourg	Implementation of catalogue (within the framework of the future National Medicines and Health Products Agency (the Luxembourg Agency for Medicines and Health Products - ALMPS))
The Netherlands	Implementation of catalogue
Romania	Information about alternative medicines Dedicated section of communication in relation to medicines' availability issues Inclusion of key recommendations for shortages and for other availability issues.
Slovenia	Proposed changes are at conceptional level and concrete actions are not defined yet.