EMA
EUROPEAN MEDICINES AGENCY

Proposed harmonised shortage root cause classification

Industry Standing Group meeting

Presented by Siofradh McMahon on 29 June 2026

Supply and Availability of Medicines and Devices,
Regulatory Science and Innovation Task Force (TRS-SAM)

Harmonisation is key to interoperability

- EMA and member states have been working to harmonise shortage-related definitions and the implementation of them, including the **root causes of shortages**
    - Aim is to ensure coherence across EU/EEA and support future interoperability plans
- Following the work of the SPOC WP and CHESSMEN Joint Action, a harmonized list of shortage root causes and corresponding descriptions has been developed
- Industry consultation launched in April 2026
- Final version targeted for endorsement by MSSG in July 2026
    - CHESSMEN work package 5 work will continue to develop this topic

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Finalisation of proposal for a harmonised shortage root cause classification

Industry stakeholder consultation

- Launched in April 2026
- Feedback sought on descriptions and examples for each category
- 16 responses including from individual MAHs and industry associations
- All feedback reviewed and relevant changes implemented

Preparation for SPOC WP and MSSG endorsement

- Review and discussion of feedback from industry consultation including assessment of impact
  - No structural changes made
  - Clarifications of descriptions and addition of examples
- Minor amendments made to ensure alignment to Annex IV in the revised general pharmaceutical legislation

Final proposal endorsed by SPOC WP; MSSG adoption expected July 2026

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Summary of changes proposed based on industry feedback and final subgroup discussions

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Industry feedback: Manufacturing issues (1/3)

Section 1.1. Manufacturing issues

a) Manufacturing issues - Key materials limited/not available: Active Pharmaceutical Ingredient (API).

Description: Inability to source one or more of the active pharmaceutical ingredients required for production, *including antigens, or other biological components required for production*.

1.1. Manufacturing issues
b) Manufacturing issues - Key materials limited/not available: Raw materials/Starting materials.

Description: Inability to source one or more starting materials, reagents, and solvents intended for use in the production of intermediates or API, *donor materials*, or similar.

Example: Shortage of a critical solvent used in API synthesis due to global supply constraints, supplier discontinues a key chemical used as a starting material in API synthesis, geopolitical conflict disrupts supply of a precursor chemical needed for API production.

1.1. Manufacturing issues

d) Manufacturing issues - Key materials limited/not available: Packaging materials, key component parts or other relevant materials.

Description: Inability to source *or to use* one or more of the components required for packaging.

Examples: Co-packaged medical device for dosing not available; package leaflet delivery issues; *lack of packaging materials*.

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Industry feedback: Manufacturing issues (2/3)

1.2. Manufacturing issues - Issues with the equipment

Description: Production delays caused by equipment malfunction or *routine maintenance where supply interruption cannot be prevented*.

Examples: Breakdown of a tablet press, production line shut down for *unplanned maintenance of equipment, routine maintenance of lines for specific products where supply interruption cannot be prevented*, *safety incident*, updates in the IT systems, IT hacking/cyber-attack.

Section 1.3. Manufacturing issues - Delay in the release of the finished product — not related to quality issues

Description: Administrative or logistical delays in releasing products, unrelated to quality concerns.

Examples: Delays in batch documentation review, delays in the quality control *due to logistical challenges, batch certification by national authorities and related testing requirements*.

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Industry feedback: Manufacturing issues (3/3)

1.6. Manufacturing issues - Capacity issues
a) Capacity issues related to personnel

Description: Shortages or unavailability of trained staff, affecting production, quality control, *or batch release*.

Examples: Staff illness or quarantine, strike, high turnover in key departments, additional time needed for training of new hired staff.

1.6. Manufacturing issues - Capacity issues
b) Capacity issues related to the manufacturing process or site

Description: Insufficient production capacity due to limitations in the manufacturing process *or site*.

Examples: Manufacturing site operating in full capacity and still not meeting the demand that has not increased unexpectedly.

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Industry feedback: Regulatory issues

3.2. Regulatory issues - Other regulatory issues, please specify
Description: Any other regulatory-related problems not covered above that affect the availability of the medicine. Please specify.

Examples: Delay due to the inability to meet new regulatory requirements, *unexpected* delay in regulatory procedures.

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NPL requirements for root cause reporting – Annex IV

(e) Reason for shortage~~;~~ ***providing information on:***

(i) Manufacturing issues including, but not limited to:

- ***Unavailability of active pharmaceutical ingredient***
- ***Unavailability of excipients***
- ***Unavailability of other raw materials***
- ***Issues with the equipment,***
- ***Delay in the release of the finished product,***
- ***GMP non–compliance,***
- ***Manufacturing site transfer***
- ***Capacities issues***
- ***Other manufacturing issues***

Unavailability of packaging materials, key component parts or other relevant materials

Related personnel; Related to the manufacturing process or site

(ii) Quality issues;

(iii) Distribution issues, including but not limited to:

- ***Export restrictions/bans***
- ***Import/export delays***
- ***Transport issues***
- ***GDP non-compliance***
- ***Other distribution issues***

(iv) Unexpected increase in demand, including but not limited to:

- ***Changes in prescribing behaviour***
- ***Unavailability from other MAHs***
- ***Other issues related to increased demand***

(v) Commercial reasons; including but not limited to:

- ***Change of the MAH Business strategy***
- ***Insolvency proceedings of the manufacturer or MAH***
- ***Other commercial reasons***

(vi) Regulatory issues; including but not limited to: Pending variation to the terms of the marketing authorisation Other regulatory issues

(vii) any other reasons.

Link to NPL (Regulation) text (p. 402)

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Proposed harmonised shortage root cause classification: list of categories and subcategories

Category	Shortage root cause sub-categories

Manufacturing issues	• Unavailability of:
	  ○ API
	  ○ Excipients
	  ○ Raw materials, starting materials
	  ○ Packaging materials, key component parts or other relevant materials
	• Issues with the equipment
	• Delay in the release of the finished product – not related to quality issues
	• GMP non–compliance
	• Manufacturing site transfer
	• Capacity issues:
	  ○ Related to personnel
	  ○ Related to the manufacturing process or site
	• Other manufacturing issues

Quality issues	Quality issues
Regulatory issues	• Pending variation to the terms of the marketing authorisation • Other regulatory issues

Category	Shortage root cause sub-categories
Unexpected increased demand	• Unavailability from other MAHs • Changes in prescribing behaviour • Other issues related to increased demand
Distribution issues	• Export restrictions/bans • Import/export delays • Transport issues • GDP non-compliance • Other distribution issues
Commercial reasons	• Change of the MAH • Business strategy • Insolvency proceedings of the manufacturer or MAH • Other commercial reasons

List of categories with descriptions and examples included in presentation annex

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Annex to 4.1

Proposed harmonised shortage root cause classification including descriptions and examples – **DRAFT (not yet adopted by MSSG)**

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1. Manufacturing issues

Description: Unforeseen disruptions within the manufacturing process due to one of the following reasons

a) Manufacturing issues – Unavailability of:

a.1) Manufacturing issues – Unavailability of: Active Pharmaceutical Ingredient (API)

Description: Inability to source one or more of the active pharmaceutical ingredients required for production, including antigens, or other biological components required for production.

a.2) Manufacturing issues – Unavailability of: Raw materials/Starting materials.

Description: Inability to source one or more starting materials, reagents, and solvents intended for use in the production of intermediates or API, donor materials, or similar.

Example: Shortage of a critical solvent used in API synthesis due to global supply constraints, supplier discontinues a key chemical used as a starting material in API synthesis, geopolitical conflict disrupts supply of a precursor chemical needed for API production.

a.3) Manufacturing issues – Unavailability of: Excipients.

Description: Inability to source one or more of the excipients required for production.

Example: Supplier discontinues a stabiliser used in injectable formulations.

a.4) Manufacturing issues – Unavailability of: Packaging materials, key component parts or other relevant materials.

Description: Inability to source or to use one or more of the components required for packaging.

Examples: Co-packaged medical device for dosing not available; package leaflet delivery issues; lack of packaging materials.

b) Manufacturing issues - Issues with the equipment

Description: Production delays caused by equipment malfunction or routine maintenance where supply interruption cannot be prevented.

Examples: Breakdown of a tablet press, production line shut down for unplanned maintenance of equipment, routine maintenance of lines for specific products where supply interruption cannot be prevented, safety incident, updates in the IT systems, IT hacking/cyber-attack.

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1. Manufacturing issues

Description: Unforeseen disruptions within the manufacturing process due to one of the following reasons

c) Manufacturing issues - Delay in the release of the finished product — not related to quality issues

Description: Administrative or logistical delays in releasing products, unrelated to quality concerns.

Examples: Delays in batch documentation review, delays in the quality control due to logistical challenges, batch certification by national authorities and related testing requirements.

d) Manufacturing issues - GMP non-compliance

Description: Production halted or reduced due to non-compliance with Good Manufacturing Practices at the manufacturing site. This does not include product-specific quality defects but refers to broader site level issues.

Examples: Statement of noncompliance with GMP and implementation of CAPAs.

e) Manufacturing issues - Manufacturing site transfer

Description: Temporary or prolonged disruption due to the physical relocation of manufacturing activities to a different site.

Examples: Production paused or delayed during equipment relocation or validation activities, changes of the contract manufacturers.

f) Manufacturing issues - Capacity issues

f.1) Manufacturing issues - Capacity issues related to personnel

Description: Shortages or unavailability of trained staff, affecting production, quality control, or batch release.

Examples: Staff illness or quarantine, strike, high turnover in key departments, additional time needed for training of new hired staff.

f.2) Manufacturing issues - Capacity issues related to the manufacturing process or site

Description: Insufficient production capacity due to limitations in the manufacturing process or site.

Examples: Manufacturing site operating in full capacity and still not meeting the demand that has not increased unexpectedly.

g) Manufacturing issues - Other manufacturing issues

Description: Any other manufacturing-related problems not covered in the above categories. Please specify.

Examples: Manufacturing issues caused by unpredicted major events and natural disasters.

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2. Quality issues

a) Quality issues

Description: Unforeseen quality incidents within the manufacturing process leading to medicinal products that are not of the correct quality as defined by their marketing authorisation, including cases when such cases require recalls or suspension of supply.

Please note that manufacturing authorisation holders are obliged to report to their competent authority (EMA for centrally authorised medicines) any product quality defect, including a suspected defect according to GMP requirements (Art. 13 of Commission Directive (EU) 2017/1572).

Examples: Detection of impurities above the limit or new impurities, out of specifications (OOS), suspected or confirmed defective product preventing release of batches to the market, ongoing quality investigation.

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3. Regulatory issues

Description: Issues related to the regulatory requirements or obligations of the marketing authorisation holder

a) Regulatory issues - Pending variation to the terms of the marketing authorisation

Description: Pending submission of a variation to modify the terms of the marketing authorisation.

Examples: To include a new manufacturer, add a new step in the manufacturing process**.**

b) Regulatory issues - Other regulatory issues

Description: Any other regulatory-related problems not covered above that affect the availability of the medicine. Please specify.

Examples: Delay due to the inability to meet new regulatory requirements, unexpected delay in regulatory procedures.

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4. Unexpected increased demand

Description: When sales of the medicinal product unexpectedly increases above the company forecasted levels

a) Unexpected increased demand - Changes in prescribing behaviour

Description: Shifts in clinical practice or clinical guidelines that increase demand for a specific medicine or off-label use.

Examples: Off-label use of a medicine, change in clinical guidelines, approval of a new indication leading to broader patient eligibility.

b) Unexpected increased demand - Unavailability of alternative products from other MAHs

Description: Demand surge caused by supply disruptions from other MAHs. Examples: A competitor's product is recalled, in shortage or discontinued, shifting demand to the remaining available product(s).

c) Unexpected increased demand - Other issues related to increased demand

Description: Any other factors not covered above that lead to a sudden or sustained increase in demand. Please specify.

Examples: New national stockpiling requirements, new contingency stock requirements, excessive export of the product due to parallel trade.

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5. Distribution issues

a) Distribution issues - Export restrictions/bans

Description: Shortage caused by export restrictions or bans imposed

by the country of origin, preventing the medicine from reaching a specific Member State.

b) Distribution issues - Import/export delays

Description: Shortage caused by import/export delays of medicinal products between countries.

Examples: Prolonged customs clearance for imported finished products, delays in obtaining import/export licenses or documentation.

c) Distribution issues - Transport issues

Description: Disruptions during transportation of the finished product affecting timely delivery.

Please specify the level of the transport line the issue occurs (e.g. sea, land, air).

Examples: Carrier strike, vehicle breakdown, route disruptions, geopolitical situations.

d) Distribution issues - GDP non-compliance

Description: These refer to non-compliance with regulatory standards for the transport and distribution of medicines, which may compromise product quality.

Examples: Temperature excursions during transport of cold-chain medicines, exposure to humidity due to damaged packaging, or improper handling during distribution.

e) Distribution issues - Other distribution issues

Description: Any other distribution-related problems not covered above. Please specify.

Examples: Distribution issues caused by unpredicted major events and natural disasters, logistic issues in the documentation of orders, storage issues at the warehouse, IT/cyber threats/hacking related action affecting distribution operations and order management.

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6. Commercial reasons

Description: Company driven decisions linked to business aspects and strategical aspects

a) Commercial reasons - Change of the MAH
Description: Temporary supply disruption due to the delay in transferring the marketing authorisation. Change of the national representative/distributor

b) Commercial reasons - Business strategy
Description: Temporary withdrawal of the medicinal product due to commercial reasons.
Examples: Product not/no longer listed on reimbursement scheme, low economic viability, tender issues.

c) Commercial reasons - Insolvency proceedings of the manufacturer or MAH
Description: Disruption due to bankruptcy or financial instability of the MAH or manufacturer.
Example: Manufacturer enters liquidation; MAH enters insolvency and cannot finance manufacturing or distribution activities, manufacturer files for bankruptcy and production site shuts down.

d) Commercial reasons - Other commercial reasons
Description: Any other commercial-related issues not covered above. Please specify.
Examples: Disruption due to bankruptcy or financial instability of the MAH or manufacturer.

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