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European Medicines Agency

Recommendations of the Executive Steering Group on the Shortages and Safety of Medicinal Products on shortages of intravenous ifosfamide and cyclophosphamide

1. Introduction

Shortages of medicines containing ifosfamide (powder for concentrate for solution for infusion) and cyclophosphamide (powder for concentrate for solution for infusion) from a primary supplier have been affecting EU member states and EEA countries since late 2025 and are likely to continue throughout 2026. These medicines are included in the Union list of critical medicines[1] which identifies medicines for human use for which continuity of supply is a priority and shortages should be avoided. This is because as these medicines are considered critical for EU healthcare systems to function properly.

The severity of the shortages of ifosfamide and cyclophosphamide differs among EU/EEA Member States, particularly for cyclophosphamide. The shortages are due to manufacturing issues at the site that the primary European supplier uses. This has led to temporary reduced capacity and inadequate supply to the market (see EMA shortage catalogue entries for ifosfamide and cyclophosphamide).

EMA and the EU medicines regulatory network are closely monitoring these shortages through the Medicines Shortages Single Point of Contact working party (SPOC WP) and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). Regular meetings are being held with the affected marketing authorization holder and other alternative suppliers, and current and forecasted supply of both medicines is being carefully monitored. EMA is also exchanging information with its international counterparts.

On 5 March 2026 and 12 June 2026, the MSSG discussed potential recommendations for measures to be undertaken proactively by all stakeholders to mitigate the shortage of both products and ensure supply of these medicines to patients.

2. Recommendations

2.1. Recommendations to concerned marketing authorisation holders

- Marketing authorisation holders experiencing shortages should
  - Create a fair and equitable allocation plan to be implemented during the critical shortage

[1] Union list of critical medicines | European Medicines Agency (EMA)

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  - Regularly submit updated supply plans to EMA and the relevant national competent authorities
  - Monitor supply closely to prevent stock out situations from occurring
  - Review manufacturing operations to determine whether opportunities exist to optimise or prioritise production of certain strengths or pack sizes or to create a single shared English language pack to increase output, even temporarily
  - Ensure effective implementation of shortage mitigation measures
- Marketing authorisation holders should continue engaging with Regulatory Authorities with respect to supply of ifosfamide and cyclophosphamide
- Marketing authorisation holders should involve SPOC WP and MSSG proactively in all decisions impacting supply and availability of these products in EU/EEA
- Marketing authorisation holders should prepare Shortage Prevention Plans for these medicines, in anticipation of the upcoming pharmaceutical legislation
- Marketing authorisation holders should engage with EMA to identify opportunities for EU level coordinated regulatory support, in particular those flexibilities set out in the MSSG toolkit on recommendations on tackling shortages of medicinal products
- Marketing authorisation holders should make use of EMA's central coordination approach to the assessment and coordination of defective product reports when appropriate

2.2. Recommendations to manufacturers

- Manufacturers at all stages of the supply chain should implement appropriate measures to increase production capacity and ensure continued and sufficient supply
- Manufacturers at all stages of the supply chain should ensure sufficient safety/buffer stocks are in place to protect against planned or unplanned operations shutdowns which may otherwise impact supply

2.3. Recommendations to member states

- Member states should implement regulatory flexibilities as needed to mitigate the impact of these shortages[2]
- Member states should implement mitigation measures and monitor their effectiveness
- Member states should closely monitor supply and demand, and communicate any additional needs to EMA and the SPOC WP early
- Member states should ensure that the published information remains up to date

2.4. Recommendations to EMA

- EMA should facilitate the implementation of regulatory flexibilities including those categorised as exception in the MSSG toolkit on recommendations on tackling shortages of medicinal products.

[2] MSSG toolkit on recommendations on tackling shortages of medicinal products

2.5. Recommendations to healthcare professionals

- Healthcare professionals should practice rational prescribing to ensure existing patients are prioritised for treatment
- Before initiating new patients, ensure that sufficient quantities of the required medicine are available to complete the course of treatment, also taking into account the information provided in Medicine Shortage Communications for ifosfamide and cyclophosphamide.

2.6. Recommendations to patients and members of the public

No targeted recommendations to patients or members of the public have been identified at this time.

3. Adoption of recommendations by the MSSG

- The recommendations were adopted by the MSSG on 23 March 2026 and updated on 15 July 2026, with a possibility to be further updated whenever necessary.

[2]MSSG toolkit on recommendations on tackling shortages of medicinal products