



# Ongoing critical shortages and activities

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# Ongoing critical shortages (1/2)

	<b>Beriglobin NAP</b> MAH: CSL Behring 	<b>Risperidone NAP (prolonged -release suspension for injection)</b> MAH: TEVA, Accord, Janssen Cilag 
Timeline	<ul style="list-style-type: none"> <li>Manufacturing stopped in August 2024.</li> <li>Marketing in EU/EEA markets will cease.</li> <li>This discontinuation will lead to shortages and non-availability.</li> </ul>	<ul style="list-style-type: none"> <li>Shortage started in 2024, but supply situation deteriorated in 2025.</li> <li>Supply constraints will continue for some of the formulations.</li> </ul>
Cause(s)	<ul style="list-style-type: none"> <li>Marketing cessation was due to commercial reasons and not due to any safety, efficacy or quality concerns with the medicine.</li> </ul>	<ul style="list-style-type: none"> <li>Manufacturing issues and increase in demand.</li> </ul>
Ongoing actions and next steps	<ul style="list-style-type: none"> <li>MSC and shortage catalogue entry published.</li> <li>Existing stocks of Beriglobin should be reserved for patients for whom there is no alternative treatment.</li> <li>No new patients should be prescribed Beriglobin for indications for which there is an alternative treatment.</li> </ul>	<ul style="list-style-type: none"> <li>Contact alternative MAHs to find support for countries in critical need and identify potential for increase of manufacturing.</li> <li>Regular meetings with impacted MAHs to monitor closely the situation and ensure fair distribution of stock among all MSs.</li> <li>EMA shortage catalogue entry drafted (to be published shortly).</li> </ul>

# Ongoing critical shortages (2/2)

	<b>Zypadhera CAP</b>  MAH: Cheplapharm (olanzapine, for injection)	<b>Visudyne CAP</b>  MAH: Cheplapharm (verteporfin, for injection)
Timeline	<ul style="list-style-type: none"> <li>Shortage since 2024; expected to continue until Q2 2026.</li> </ul>	<ul style="list-style-type: none"> <li>Ongoing since May 2020</li> <li>Partially resolved in Q1 2022, but controlled distribution expected to continue until end Q2 2026.</li> </ul>
Cause(s)	<ul style="list-style-type: none"> <li>Manufacturing issues with the needle used for administration.</li> <li>Delays with supplies and supplier issues.</li> <li>Equipment issues and quality defects.</li> </ul>	<ul style="list-style-type: none"> <li>Reduced manufacturing capacity (partially restored in 2022).</li> <li>Manufacturing issues related to establishment of new supply chain.</li> </ul>
Ongoing actions and next steps	<ul style="list-style-type: none"> <li>Close engagement with the MAH, with weekly updates to EU/EEA countries and involvement of SPOC WP and MSSG.</li> <li>Shortage catalogue entry and MSC published in August 2025: no new patients should be initiated.</li> <li>Support provided via VSM procedure in August 2025.</li> <li>SPP has been requested to the MAH.</li> </ul>	<ul style="list-style-type: none"> <li>Close engagement with MAH, with involvement of SPOC WP and MSSG.</li> <li>Continued oversight of controlled distribution up to full supply restoration.</li> <li>Regulatory support to establish new supply chain.</li> <li>Shortage catalogue entry updated and MSC published in September 2025, following previous DHPCs published in 2021, 2022: no new patients should be initiated.</li> </ul>



# Preparedness: availability of antibiotics for the winter season (1/2)

## Discussion at the level of the SPOC Working Party

This month, during the SPOC WP meeting, the members reported no signs of pressure on supply or increased demand for antibiotics.

Some national-level shortages noted, but overall magnitude remains low.

## Engagement with industry

On 10 September, EMA reached out to 16 key MAHs of antibiotics\* for respiratory infections to get an overview on:

- supply gaps expected for autumn/winter 2025–2026;
- if MAHs expect to reach the desired safety stocks;
- if any additional stock will be available for importation by MSs, if needed.

Based on information self-reported by the key MAHs, the overall picture appears reassuring:

- Very small number of expected supply gaps reported.
- MAHs are expecting to meet their target safety stock levels.
- Additional stock of most of the key antibiotics will be available.

\*amoxicillin, amoxicillin/clavulanic acid, penicillin V, azithromycin, clarithromycin, piperacillin/tazobactam.

# Preparedness: availability of antibiotics for the winter season (2/2)

## Public communication

In October, EMA launched again a social media campaign promoting the prudent use of antibiotics.



## Cooperation with global partners

EMA reached out to Australia to get information on antibiotic supply situation during their winter season (June–August).

- No significant changes in usage between the 2024 and 2025 winter seasons.
- 2 critical shortages identified:
  - Rifampicin capsules (300mg), due to API manufacturing issues.
  - Benzathine benzylpenicillin pre-filled syringes for injection, due to global supply issues and manufacturing issues.

## Outcome:

- Overall, current situation is stable.
- Individual potential shortages have been foreseen based on engagement with industry and are being closely monitored.
- Member states are aware of alternative sources in case of shortage.



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