

# Ongoing critical shortages

PCWP/HCPWP

Point 7.3

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





# Availability of Perfusion Solutions following Hurricane Helene

# Shortages of IV solutions

Several key suppliers, **Baxter**, **Fresenius Kabi** (FK) and **B. Braun** foresee shortages of intravenous (**IV**) and **irrigation solutions** across EU/EEA **throughout 2025**

## Root causes:

- Demand continues to increase
- IV solutions used for irrigation purposes
- Internal safety stock levels compromised to maintain market supply.

## Mitigating measures:

- Maximising production capacity
- Allocating available stock to MSs based on existing contracts and historical demand
- Regulatory flexibilities: agreement of an **English EU label** to facilitate distribution of **sodium chloride IV solutions** – agreed by the MSSG on 26 February 2025 as a preventing/mitigating measure.





# Critical shortage of oncology products marketed by TEVA and Accord

# Information on ongoing shortages of oncology products

**Intermittent shortages of several oncology products marketed by Accord and Teva are ongoing in EU/EEA countries.**

## **Root causes:**

- Manufacturing issues at one of the manufacturing sites/ increase demand of alternative products marketed by other Marketing Authorisation Holders
- Decrease in manufacturing capacity

## **Shortage mitigation measure:**

- Increasing of manufacturing capacity
- Fair distribution, i.e. allocation of stocks according to historic demand to avoid stockpiling
- Providing regulatory support and regulatory flexibilities





# Supply and availability of insulin products

# Insulin products: update on the impact of discontinuation

**A subset of insulins products from the MAH Novo Nordisk will be discontinued until the end of 2026 in all EU/EEA countries**

- EMA and the SPOC WP currently assess the supply situation for all insulin products
- Interactions with MAHs are ongoing to get a comprehensive understanding of marketing plans, production capacity and short- to mid-term supply plans
- EMA undertakes a comprehensive analysis of shortages of insulins products in EU/EEA countries and globally via the Drug Shortages Global Regulatory Working Group
- The next meeting of the clinical expert group on insulin products and GLP-1 RA takes place on 2 April 2025 with a focus on the evaluation of alternative products substituting the discontinued medicines
- A detailed risk assessment is currently ongoing.





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