

<Date>

Pegasys® (peginterferon alfa-2a): supply shortage of 90/135/180 micrograms solution for injection in pre-filled syringes

Dear Healthcare Professional,

pharmaand GmbH and its affiliates (pharma&) in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary:

- **Increased overall demand for Pegasys (peginterferon alfa-2a) has led to an intermittent shortage of all approved strengths (90/135/180 micrograms) of Pegasys. The supply shortage is not related to a quality defect of the product or a safety issue.**
- **pharma& anticipates the shortage to last until the second half of 2025; additional product is currently estimated to be supplied before June 30, 2025.**
- **During the supply shortage prescribers are advised to follow the below recommendations:**
 - **No new patients should be started on Pegasys until supply has normalised. Available product should only be used to continue treatment of patients currently treated.**
 - **In case Pegasys is not available for patients currently under treatment, alternative treatment options should be considered based on your clinical judgement.**
 - **Always store supplies in the fridge and use the most appropriate strength to avoid wastage.**

Background

Pegasys is approved for the following indications:

Pegasys is approved for chronic hepatitis B and C in adults and children, Polycythaemia Vera and Essential Thrombocythemia in adults. Please refer to the product information 4.1 for the full indications.

Call for reporting

Adverse events including medication errors relating to Pegasys should be reported to pharma& [contact details to be provided according to country] or to local authorities [to be modified according to national requirements].

Company contact point

Further information can be obtained by contacting < pharma& [country contact details to be added] >.

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Pegasys (peginterferon alfa-2a)
Marketing authorisation holder(s)	pharma&
Safety concern and purpose of the communication	Increased overall demand for Pegasys (peginterferon alfa-2a) coupled with a manufacturing transfer of the Active Pharmaceutical Ingredient have led to an intermittent shortage. The supply shortage is not related to a quality defect of the products or a safety issue. pharma& anticipates limited availability of Pegasys® in all approved strengths starting in 2024; additional product supply is expected by June 30, 2025.
DHPC recipients	Hematologists, hepatologists and infectiologists. Pharmacists or other health care providers can be included in conjunction with each national competent authority, as needed.
Member States where the DHPC will be distributed	EU Member States where the product is marketed
Timetable	
DHPC and communication plan (in English) agreed by CHMP/CMDh	14 October 2024
Submission of translated DHPCs to the national competent authorities for review	28 October 2024
Agreement of translations by national competent authorities	~1-3 working days dependent upon respective NCA
Dissemination of DHPC	1-3 working days after final agreement with NCA