



## **pharma& Receives MHRA Approval for Pegasys® Manufacturing Site Variation, Adding Loba biotech for API Production and Ensuring a Reliable, Long-term Supply in the UK**

- *Loba biotech, a manufacturing site in Austria, is a wholly owned subsidiary of pharma&*
- *This approval builds on the recent European Medicines Agency (EMA) approval, securing the beginning of Pegasys replenishment across the United Kingdom, restoring access for eligible patients who rely on this treatment*

*Intended for the Healthcare Media*

**Vienna, Austria, May 28, 2025** – pharmaand GmbH (pharma&) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted a variation to the Marketing Authorization for Pegasys® (peginterferon alfa-2a), enabling Loba biotech GmbH, a wholly owned manufacturing subsidiary of pharma&, to be a recognized facility for producing the active pharmaceutical ingredient (API), peginterferon alfa-2a. This allows pharma& to begin Pegasys product replenishment across the United Kingdom (UK) and further strengthens the long-term supply chain stability of the medicine. pharma& anticipates eligible patients in the UK should start to experience improved Pegasys availability in the coming weeks.

"We are delighted that the MHRA has granted approval for the production of Pegasys API at Loba biotech GmbH. This marks a critical step forward, building on the recent EMA approval, securing the path forward for Pegasys replenishment across the United Kingdom," said Elmar Zagler, Founder and Managing Director, pharma&. "Since acquiring Pegasys, pharma& has remained dedicated to maintaining continuous access to this medicine for eligible patients. The MHRA's approval, along with our investment in Loba biotech, represents pharma&'s ongoing commitment to preserving the availability of essential medicines and foster their development worldwide to leave no patient behind."

In 2019, F. Hoffmann La Roche AG (Roche) announced that it would cease commercializing Pegasys globally. pharma& acquired the global rights to Pegasys in 2021 from Roche, intending to ensure continuity of care for eligible patients. Following its acquisition of Pegasys, pharma& encountered a surge in product demand. As a result of the growing need among eligible patients, pharma& committed to investing in bio-manufacturing capabilities at pharma&'s wholly owned manufacturing plant subsidiary, Loba biotech GmbH. This significant investment was essential for the new plant to produce the API in Pegasys.

Replenishing Pegasys outside of the United Kingdom and Europe remains a top priority, and pharma&, alongside its partners, is actively collaborating with regulatory authorities to enhance availability for eligible patients in the U.S. and other regions as swiftly as possible.

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## About Pegasys® (alfa-2a)

Pegasys is a type I interferon. The type I interferons present in humans are IFN- $\alpha$ , IFN- $\beta$ , IFN- $\epsilon$ , IFN- $\kappa$  and IFN- $\omega$ .<sup>i</sup> Interferons (IFNs) and their receptors are a subset of class 2 alpha-helical cytokines that have existed in early chordates for about 500 million years and represent early elements in innate and adaptive immunity.<sup>ii</sup> IFNs are noted for their ability to "interfere" with viral replication within the host cells.<sup>iii</sup> All type I IFNs bind to a specific cell surface receptor complex, the IFN- $\alpha$  receptor (IFNAR), consisting of IFNAR1 and IFNAR2 chains.<sup>iv</sup>

Pegasys is made when interferon alfa-2a undergoes the process of pegylation in which one or more chains of polyethylene glycol (PEG) are attached to another molecule.<sup>v</sup> In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.<sup>v,vi</sup> To prolong the pharmacokinetic the high molecular weight (40 kilodaltons) branched PEG is covalently bound to IFN alfa 2a to exert in Pegasys.<sup>viii</sup>

## **Pegasys® (peginterferon alfa-2a) Medicines and Healthcare products Regulatory Agency (MHRA) authorized use and access to the full SmPC, including complete safety information.**

In the UK, Pegasys was previously approved for the treatment of chronic hepatitis B (CHB) in adults and children aged 3 years and older or chronic hepatitis C (CHC) in adults and children aged 5 years and older in combination with other medicinal products in adults or ribavirin in children.<sup>vi</sup>

For a full list of adverse events and information on dosage and administration and other precautions when using Pegasys, please refer to the current MHRA SmPC [here](#).

Healthcare professionals should report any suspected adverse reactions via their national reporting systems.

For medical information inquiries outside of the U.S., contact pharma& at [medinfo@pharmaand.com](mailto:medinfo@pharmaand.com).

For medical information inquiries within the U.S., contact pharma& at [medinfo.us@pharmaand.com](mailto:medinfo.us@pharmaand.com).

You may report adverse events to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Alternatively, to report an adverse event or reaction, contact pharma& at [pv@pharmaand.com](mailto:pv@pharmaand.com).

To report a product complaint, contact pharma& at [complaints@pharmaand.com](mailto:complaints@pharmaand.com).

## About pharma& ([pharmaand.com](https://pharmaand.com))

pharmaand GmbH (pharma&), a privately owned global company, aspires to breathe new life into proven medicines. The Company is dedicated to preserving the availability and fostering the further development of essential medicines worldwide to leave no patient behind. Over the past five years, pharma& has acquired and integrated 10+ medicines, expanding its portfolio across a wide range of therapy areas, with an increasing focus on hematology and oncology treatments. The Company's unique synthesis of subsidiaries, joint ventures, and partners enables pharma& to provide its portfolio of medicines to eligible patients worldwide by spanning the continuum of development, product and active pharmaceutical ingredients (API) manufacturing, partner distribution, healthcare provider engagement, distribution and services to patients.

*pharma& cautions that any forward-looking statements or projections made, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. pharma& does not undertake to update or revise any forward-looking statements.*

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### References

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