pharma& Receives Health Canada Approval for Pegasys® Manufacturing Site Variation, Adding Loba biotech for API Production

- *Loba biotech, a manufacturing site in Austria, is a wholly owned subsidiary of pharma&*
- *This approval supports long-term access to Pegasys for eligible patients who depend on this critical therapy*

Intended for the Healthcare Media

Vienna, Austria, April 23, 2026 – pharmaand GmbH (pharma&) today announced that Health Canada has approved a variation to the Marketing Authorization for Pegasys® (peginterferon alfa-2a), allowing Loba biotech GmbH, a wholly owned manufacturing subsidiary of pharma&, to be included as an approved site for the production of the active pharmaceutical ingredient (API), peginterferon alfa-2a.

"We are thrilled to announce Health Canada's approval for peginterferon alfa-2a API production at Loba biotech GmbH. This is another key milestone on the path to Pegasys replenishment worldwide," said Elmar Zagler, Founder and Managing Director, pharma&. "Since acquiring peginterferon alfa-2a, pharma& has been committed to ensuring this important medicine's continuous availability to eligible patients. Our investment in Loba biotech and Health Canada's approval is another step in delivering on pharma&'s mission to preserve the availability and foster the further development of essential medicines 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 peginterferon alfa-2a in 2021 from Roche to ensure continued access to this treatment and continuity of care for eligible patients. Following the acquisition, 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 active pharmaceutical ingredient (API) in Pegasys.

Replenishing peginterferon alfa-2a worldwide remains a top priority, and pharma&, alongside its partners, is actively collaborating with regulatory authorities to enhance availability for eligible patients globally. To date, pharma& has obtained a drug substance manufacturing site change to Loba biotech for peginterferon alfa-2a API production across the European Union, United Kingdom, Switzerland, Kosovo, Singapore, United Arab Emirates, Hong Kong, Albania and Australia. Further approvals are under review in numerous countries and are pending.

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About Pegasys® (peginterferon alfa-2a)

Pegasys is a type I interferon. The type I interferons present in humans are IFN-α, IFN-β, IFN-ε, IFN-κ, and IFN-ω.[i] [i]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.[ii] IFNs are noted for their ability to "interfere" with viral replication within the host cells.[iii] All type I IFNs bind to a specific cell surface receptor complex, the IFN-α receptor (IFNAR), consisting of IFNAR1 and IFNAR2 chains.[iv]

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.[v, vi] In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.[v, vi] To prolong the pharmacokinetic, the high molecular weight (40 kilodaltons) branched PEG is covalently bound to IFN alfa 2a to exert in Pegasys.[vii]

Peginterferon alfa-2a Canadian authorized use and Important Safety Information

Healthcare Professionals should refer to the Canadian Product Monograph for peginterferon alfa-2a available in English and French via these links:

English - https://pdf.hres.ca/dpd_pm/00074540.PDF
French - https://pdf.hres.ca/dpd_pm/00082528.PDF

In Canada, peginterferon alfa-2a is indicated for:

Chronic Hepatitis C (CHC)
Peginterferon alfa-2a is indicated for the treatment of Chronic Hepatitis C in:

- Adult patients without cirrhosis
- Adult patients with compensated cirrhosis

including HCV/HIV co-infection patients with stable HIV disease with or without antiretroviral therapy.

Chronic Hepatitis B (CHB)
Peginterferon alfa-2a is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in:

- Patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease).

Geriatrics (> 65 years of age): Clinical studies of peginterferon alfa-2a alone or in combination with COPEGUS did not include sufficient numbers of subjects aged 65 or over to determine whether they respond differently from younger subjects.

Pediatrics (< 18 years of age): Peginterferon alfa-2a is not authorized for use in children and adolescents under the age of 18 years.

Patients and healthcare professionals should be aware that peginterferon alfa-2a is not appropriate for all individuals. Use of this medication is associated with important risks that must be considered alongside its potential benefits.

Contraindications: Peginterferon alfa-2a should not be used in patients with known hypersensitivity to peginterferon alfa-2a, to alpha interferons, to E. coli-derived products, to polyethyleneglycol, or to any component of the formulation. It is also contraindicated in individuals with autoimmune hepatitis, decompensated cirrhosis, HIV-HCV patients with cirrhosis and a base-line Child-Pugh score ≥ 6, with a history of autoimmune disease, neonates and infants, who have a pre-existing severe psychiatric condition or a history of a severe psychiatric disorder, who have pre-existing thyroid abnormalities for which thyroid function cannot be maintained in the normal range by medication, and in women who are breast feeding.

Serious Warnings and Precautions: Alpha interferons, including peginterferon alfa-2, cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening signs or symptoms of these conditions should be withdrawn from therapy. In many cases, but not all cases, these disorders resolve after stopping interferon therapy. Use with caution in individuals with relevant comorbidities, as outlined in the Product Monograph.

Common Adverse Reactions: The most frequently reported adverse reactions include flu-like symptoms such as unusual tiredness, fever, chills, muscle aches, joint pain, and headaches, which were generally mild to moderate in severity. Additional adverse reactions are described in the Adverse Reactions section of the Product Monograph.

Drug Interactions: Caution is advised when peginterferon alfa-2a is used with Methadone, Theophylline, Telbivudine, and sho-saiko-to, a Chinese herbal medicine, also known as Xiao-Chai-Hu, as interactions may increase the risk of adverse effects or reduce therapeutic efficacy.

Use in Specific Populations: Safety and effectiveness have not been established in pediatric, pregnant, breastfeeding or geriatric populations unless otherwise specified in the Product Monograph.

For **complete risk information**, including detailed contraindications, warnings, precautions, and adverse reactions, please consult the **Product Monograph.**

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

For medical information inquiries outside of the U.S., contact pharma& at medinfo@pharmaand.com.

Alternatively, to report an adverse event or reaction, contact pharma& at pv@pharmaand.com.

To report a product complaint, contact pharma& at complaints@pharmaand.com.

About pharma& (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. Since its inception, 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 research and development, in-house product and active pharmaceutical ingredients (API) manufacturing, distribution via its global partner network, healthcare provider engagement, patient safety services, and patient access services through U.S. Market Access.

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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