30 January 2025
EMA/24523/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dyrupeg

pegfilgrastim

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dyrupeg, intended to shorten the duration of neutropenia and help prevent febrile neutropenia after cytotoxic chemotherapy.

The applicant for this medicinal product is CuraTeQ Biologics s.r.o.

Dyrupeg will be available as a 6 mg solution for injection in pre-filled syringe. The active substance of Dyrupeg is pegfilgrastim, an immunostimulant, colony-stimulating factor (ATC code: L03AA13), which stimulates the development and differentiation of mature and functionally active neutrophils from precursor cells in the bone marrow.

Dyrupeg is a biosimilar medicinal product. It is highly similar to the reference product Neulasta (pegfilgrastim), which was authorised in the EU on 22 August 2002. Data show that Dyrupeg has comparable quality, safety and efficacy to Neulasta (pegfilgrastim). More information on biosimilar medicines can be found here.

The full indication is:

> Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Treatment with Dyrupeg should be prescribed and supervised by physicians experienced in oncology and/or haematology.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union