17 September 2020
EMA/CHMP/447855/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nyvepria

pegfilgrastim

On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nyvepria, intended to reduce the duration of neutropenia and to help prevent febrile neutropenia after cytotoxic chemotherapy.

The applicant for this medicinal product is Pfizer Europe MA EEIG.

Nyvepria will be available as a 6-mg solution for injection. The active substance of Nyvepria is pegfilgrastim, an immunostimulant and colony stimulating factor (ATC code: L03AA13), which stimulates the production and release of neutrophils from the bone marrow.

Nyvepria 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 Nyvepria 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).

Nyvepria therapy should be initiated 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

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