



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Farydak panobinostat

On 25 June 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Farydak, intended for the treatment of relapsed and/or refractory multiple myeloma. Farydak was designated as an orphan medicinal product on 8 November 2012. The applicant for this medicinal product is Novartis Europharm Ltd.

Farydak will be available as capsules of 10, 15 and 20 mg. The active substance of Farydak is panobinostat, a histone deacetylase (HDAC) inhibitor (ATC code: L01XX42) that inhibits the enzymatic activity of HDACs resulting in increased acetylation of histone proteins, leading to transcriptional activation.

The benefits with Farydak, in combination with bortezomib and dexamethasone, are its ability to delay the progression of disease. The most common side effects are diarrhoea, fatigue, nausea, vomiting, thrombocytopenia, anaemia, neutropenia and lymphopenia.

The full indication is: "Farydak, in combination with bortezomib and dexamethasone, is indicated for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent". It is proposed that treatment with Farydak should be initiated by a physician experienced in the use of anti-cancer therapies.

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

