FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision to extend the requirement for pre-clearance for the export of injectable medicinal products whose principle active pharmaceutical ingredient is etoposide intended for the Belgian market

The Minister for Public Health,

Having regard to the Act of 25 March 1964 on medicinal products for human use, Article 12*f*, subparagraph 2;

Having regard to the Royal Decree of 19 January 2023 implementing Article 12*f*, subparagraph 2, of the Act of 25 March 1964 on medicinal products, Article 4(1), (2), subparagraph 1, and (3), subparagraph 1;

Having regard to the decision of 2 October 2024 requiring pre-clearance for the export of injectable medicinal products containing the active substance etoposide intended for the Belgian market;

Considering that the unavailability, within the meaning of Article 2(29) of the Royal Decree of 14 December 2006 on medicinal products for human use, of the following medicinal products has been notified to the FAMHP: Etoposide Sandoz 20 mg/ml ground perf. (to be diluted) i.v. vial 5 x 5 ml until 29 April 2025, Etoposide Accord Healthcare 20 mg/ml ground perf. (to be diluted) i.v. vial 25 ml until 30 April 2025, Etoposide Accord Healthcare 20 mg/ml ground perf. (to be diluted) i.v. vial 5 ml and Etoposide Accord Healthcare 20 mg/ml ground perf. (to be diluted) i.v. vial 12.5 ml until 31 July 2025, Eposin 20 mg/ml ground perf. (to be diluted) i.v. vial 25 ml until 8 September 2025 and Eposin 20 mg/ml ground perf. (to be diluted) i.v. vial 5 ml until 19 January 2026;

Considering that the active substance etoposide is indicated in testicular cancer, small cell lung cancer, Hodgkin's lymphoma, non-Hodgkin's lymphoma, acute myelocytic leukemia, gestational trophoblastic tumour and ovarian cancer;
Considering that no other authorised medicinal products are available for the treatment of the above-mentioned conditions;
Whereas the lack of administration of the medicinal product may lead to hospitalisation and death;
Whereas the conditions referred to in Article 4(1) of the Royal Decree of 19 January 2023 implementing Article 12*f*, subparagraph 2, of the Act of 25 March 1964 on medicinal products are therefore fulfilled;
HAS DECIDED to extend the requirement for pre-clearance for the export of injectable medicinal products whose principle active pharmaceutical ingredient is etoposide intended for the Belgian market up to and including 19 January 2026.
This decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE