FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending the requirement for prior authorisation for the export of the medicinal product Bleomycine Sanofi 15000 IU intended for the Belgian market

The Minister for Public Health,

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

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

Having regard to the Decision of 16 February 2023 making the export of the medicinal product Bleomycine Sanofi 15000 IU intended for the Belgian market subject to prior authorisation;

Having regard to the decisions of 20 April 2023 and 27 March 2024 extending the requirement for prior authorisation for the export of the medicinal product Bleomycine Sanofi 15000 IU intended for the Belgian market

Considering that the interruption of the placing on the market, within the meaning of Article 2(30) of the Royal Decree of 14 December 2006 on medicinal products for human use, of the medicinal product Bleomycine Sanofi 15000 IU was communicated to the FAMHP;

Considering that the unavailability of Bleomycine Sanofi 15000 IU shall continue until 2 March 2026;

Considering that the medicinal product Bleomycine Sanofi 15000 IU is used for the treatment of squamous cell carcinomas of the mouth, nasopharynx and paranasal sinuses, larynx, oesophagus, external

genitalia, cervix and skin, Hodgkin’s disease and non-Hodgkin lymphomas and testicular carcinomas;
Whereas the administration of the medicinal product should be done once or twice a week as indicated;
Whereas failure to administer the medicinal product may lead to disease progression, hospitalisation and death;
Whereas no other authorised medicinal products are available for the treatment of the above-mentioned conditions;
Whereas the conditions laid down in Article 4(1) of the Royal Order of 19 January 2023 implementing Article 12f, subparagraph 2, of the Law of 25 March 1964 on medicinal products for human use are therefore met;
DECIDES to extend the requirement for prior authorisation for the export of the medicinal product Bleomycine Sanofi 15000 IU solution for injection (pdr) i.m./i.perit./i.tumour./i.v./i.pleur./i.arter./s. c. vial 15000 UI intended for the Belgian market until 2 March 2026 inclusive.
This decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE