FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending submission of the export of the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml intended for the Belgian market to prior authorisation

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), (2), subparagraph 1, and (3), subparagraph 1;

Having regard to the decision of 2 February 2024 submitting the export of the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml intended for the Belgian market to prior authorisation;

Having regard to the decision of 24 November 2024 extending submission of

the export of the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml intended for the Belgian market to prior authorisation;
Whereas 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 medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml was established by the FAMHP until 31 December 2025;
Whereas the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml are used for maintenance treatment in adult schizophrenic patients sufficiently stabilised with oral olanzapine during the initial treatment period;
Whereas the medicinal product Zypadhera should be administered once every two or four weeks;
Whereas the non-administration of the medicinal product would lead to destabilisation of schizophrenic patients who are unaware of their disease and/or of their compliance with treatment;

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 Decree of 19 January 2023 implementing Article 12f, subparagraph 2, of the Act of 25 March 1964 on medicinal products for human use are therefore met;
HEREBY DECIDES to extend submission of the export of the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml intended for the Belgian market to prior authorisation until 31 December 2025 inclusive.
This decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE