

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, subject to prior authorisation

The Minister for Public Health,

Having regard to the Act 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(2), of the Act of 25 March 1964 on medicinal products, Article 4(1), (2), first subparagraph, and (3), first subparagraph;

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, subject 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, subject to prior authorisation;

Having regard to the decision of 16 June 2025 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, subject to prior authorisation;

Having regard to the decision of 3 December 2025 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, subject 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 until 30 September 2026 inclusive has been notified to the FAMHP;

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 non-administration of the medicinal product would lead to destabilisation of schizophrenic patients who are unaware of their disease and compliance with the treatment;

Whereas no other authorised medicinal product is available for maintenance treatment of the above-mentioned conditions;

The conditions laid down in Article 4(1) of the Royal Decree of 19 January 2023 implementing Article 12f(2), of the Law of 25 March 1964 on medicinal products for human use have therefore been 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, subject to prior authorisation until 30 September 2026 inclusive.

This decision shall enter into force on the day of its notification to wholesale distributors.

Brussels, [date]

Frank VANDENBROUCKE