FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending submission of the export of the medicinal products Mimpara 30 mg film-coated tablets 28 and Mimpara 60 mg film-coated tablets 28 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 12*f*, subparagraph 2;

Having regard to the Royal Decree of 19 January 2023 implementing Article 12*f*, 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 3 September 2024 submitting the export of the medicinal products Mimpara 30 mg film-coated tablets 28, Mimpara 60 mg film-coated tablets 28 and Mimpara 90 mg film-coated tablets 28 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 Mimpara 30 mg film-coated tablets 28 and Mimpara 60 mg film-coated tablets 28 until 29 September 2025 has been notified to the FAMHP and a marketing stop has been notified for the medicinal product Mimpara 90 mg filmomhulde tablet 28 from 31 March 2025;

Whereas the medicinal product Mimpara is indicated for the treatment of secondary hyperparathyroidism (HPT): in adult dialysed patients with end-stage renal

disease (ESRD) as well as in children aged 3 years and over, dialysed, with end-stage renal disease (ESRD), in whom secondary HPT is not adequately controlled by the reference treatments. Mimpara is also indicated for the reduction of hypercalcaemia in adult patients with primary parathyroid cancer or hyperparathyroidism, where parathyroidectomy would be indicated on the basis of serum calcium levels (defined by current therapeutic recommendations) but where parathyroidectomy is contraindicated or not clinically appropriate;
Whereas the recommended starting dose of Mimpara for secondary hyperparathyroidism is 30 mg once a day in adults and the dose should not exceed 0.20 mg/kg of body weight per day in children aged 3 to less than 18 years. In the case of cancer of the parathyroid or primary hyperparathyroidism, the usual starting dose of Mimpara in adults is 30 mg twice a day;
Whereas Mimpara is essential for: adult patients already treated with Mimpara and with secondary hyperparathyroidism (because achieving optimal levels of PTH is a rather complicated process and destabilisation by a new medicine may lead to severe side effects), for paediatric patients with secondary hyperparathyroidism and for adult patients with primary hyperparathyroidism or parathyroid carcinoma, for whom parathyroidectomy is contraindicated or clinically impossible;
Whereas the lack of administration of the medicinal product may lead to hospitalisation and death;
Whereas no other authorised medicinal products are available for the treatment of the above-mentioned conditions;
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 Law of 25 March 1964 on medicinal products are therefore fulfilled;
HEREBY DECIDES to extend submission of the export of the medicinal products Mimpara 30 mg film-coated tablets 28 and Mimpara 60 mg film-coated tablets 28 intended for the Belgian market to prior authorisation up to and including 29 September 2025.
This decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE