FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending the submission of exports of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, 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*(2);

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

Having regard to the decision of 16 February 2023 subjecting the export of the medicinal product Ozempic, intended for the Belgian market, to prior authorisation;

Having regard to the decisions of 15 March 2023 and 15 December 2023 extending the submission of export of the medicinal product Ozempic, intended for the Belgian market, to prior authorisation;

Having regard to the decision of 15 December 2023 subjecting the export of the medicinal product Trulicity 0.75 mg solution for injection (s.c.) pre-filled pen 4 x 0.5 ml and Trulicity 1.5 mg solution for injection (s.c.) pre-filled pen 4 x 0.5 ml, intended for the Belgian market, to prior authorisation;

Having regard to the decision of 15 December 2023 subjecting the export of the medicinal product Rybelsus, intended for the Belgian market, to prior authorisation;

Having regard to the decision of 15 December 2023 subjecting the export of the medicinal product Victoza, intended for the Belgian market, to prior authorisation;

Having regard to the decision of 15 December 2023 subjecting the export of the medicinal product Bydureon 2 mg prolonged-release suspension for injection

(s.c.) pre-filled pen (box) 4 x 0.85 ml, intended for the Belgian market, to prior authorisation;
Having regard to the decision of 7 August 2024 extending the submission of exports of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, intended for the Belgian market, to prior authorisation;
Having regard to the decision of 18 February 2025 extending the submission of exports of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, intended for the Belgian market, to prior authorisation;
Having regard to the decision of 18 February 2025 subjecting the export of the medicinal product Mounjaro, 2.5 mg/dose KwikPen and the medicinal product Mounjaro 5 mg/dose KwikPen, intended for the Belgian market, to prior authorisation;
Whereas the serious risks of unavailability of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus will continue at least until 31 December 2025, given that availability problems will continue in 2025;
Whereas for certain packages of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, the unavailability will continue until 2025, there is also a high degree of uncertainty regarding timely and adequate supply of the Belgian market and, consequently, the unavailability of these medicines for patients in Belgium, and that it is therefore appropriate to set 31 December 2025 as the end date of this decision;
Whereas Mounjaro, as a new product, has been authorised in six different dosages, two of which have already been on the market since 15 November 2024 and two were placed on the market on 1 March 2025, while in light of the shortages of the other GLP-1 analogues, it will have to be fully deployed to respond to these shortages;

Whereas the medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, are used for the treatment of adults with inadequately regulated type 2 diabetes mellitus, either as a supplement to diet and exercise, or in monotherapy when metformin is deemed inappropriate due to intolerance or contraindications, or as a supplement to other medicines for the treatment of diabetes and the medicine must be administered regularly (either a daily or weekly subcutaneous injection, or a daily oral dose);

Whereas failure to administer the medicinal product can lead to inadequately regulated type 2 diabetes mellitus, increased glycaemia, hospitalisation and death;

Whereas the availability of other GLP-1 analogues authorised for the treatment of type 2 diabetes is not sufficiently guaranteed

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,

DECIDES to extend the submission of exports of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, intended for the Belgian market, to prior authorisation until 31 December 2025, namely the following medicinal products:

- **Mounjaro 2.5 mg/dose solution for injection (s.c.) pre-filled 2.4 ml KwikPen**
- **Mounjaro 5 mg/dose solution for injection (s.c.) pre-filled 2.4 ml KwikPen**
- **Ozempic 0.25 mg solution for injection (s.c.) pre-filled pen 1.5 ml**
- **Ozempic 0.5 mg solution for injection (s.c.) pre-filled pen 1.5 ml**
- **Ozempic 1 mg solution for injection (s.c.) pre-filled pen 3 ml**
- **Rybelsus 3 mg 30 tablets**
- **Rybelsus 7 mg 30 tablets**
- **Rybelsus 14 mg 30 tablets**

- **Trulicity 0.75 mg solution for injection (s.c.) pre-filled pen 4 x 0.5 ml** - **Trulicity 1.5 mg solution for injection (s.c.) pre-filled pen 4 x 0.5 ml** - **Victoza 6 mg/ml solution for injection (s.c.) pre-filled pen 2 x 3 ml;**
and decides to subject the export of the medicinal product Mounjaro 7.5 mg/dose solution for injection (s.c.) pre-filled 2.4 ml KwikPen and of the medicinal product Mounjaro 10 mg/dose solution for injection (s.c.) pre-filled 2.4 ml KwikPen, intended for the Belgian market, to prior authorisation until 31 December 2025.
This Decree shall enter into force on the day following its publication in the Belgian Official Gazette (Moniteur belge).
Brussels, [date]
Frank VANDENBROUCKE