FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending the submission for prior authorisation of the export of the medicinal products Fluorouracil Accord Healthcare 50 mg/ml inj./inf. sol. i.v./i.arter. vial 20 ml and 100 ml and Fluracedyl 50 mg/ml inj. sol. i.v./i.arter. vial 100 ml 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), (2), subparagraph 1, and (3), subparagraph 1;

Having regard to the decision of 8 July 2024 subjecting the export of the medicinal products Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. vial 20 ml and 100 ml and Fluracedyl 50 mg/ml i.v./i.arter. sol. for inj. 100 ml intended for the Belgian market to prior authorisation;

Considering that the unavailability, within the meaning of Article 2(29) of the Royal Decree of 14 December 2006 on medicinal products for human use, of Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. 20 ml vial until 28.02.2025, Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. 100 ml vial until 28 February 2025 and Fluracedyl 50 mg/ml i.v./i.arter. sol. for inj. 100 ml vial until 22 April 2025 has been notified to the FAMHP and that there is still uncertainty as to the

dates of the next deliveries;
Considering that these medicinal products are used for the treatment of metastatic colorectal cancer, adjuvant treatment of colorectal cancer, treatment of advanced gastric cancer, treatment of advanced pancreatic cancer, treatment of advanced oesophagal cancer, treatment of advanced or metastatic breast cancer, adjuvant treatment in patients with operable invasive primary breast cancer, treatment of inoperable locally advanced epidermoid cancer of the head and neck in patients who have not received previous treatment and treatment of locally recurrent or metastatic epidermoid cancer of the head and neck;
Considering that the necessary dose depends on the body surface area and mass, the indication and the treatment protocol used;
Considering that the delay or discontinuation of treatment may lead to relapse, worsening of the disease or death;
Considering that no other authorised medicinal product is sufficiently available for the treatment of each of the above-mentioned pathologies;
Whereas the conditions referred to in Article 4(1) of the Royal Decree of 19 January 2023 implementing Article 12f, subparagraph 2, of the Law of 25 March 1964 on medicinal products are therefore fulfilled;
HEREBY DECIDES to extend the submission for prior authorisation of the export of the medicinal products Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. 20 ml vial, Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. vial 100 ml vial and Fluracedyl 50 mg/ml i.v./i.arter. sol. for inj. 100 ml vial intended for the Belgian market until 23 June 2025 inclusive.
This decision shall enter into force on the

day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE