FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending the requirement for prior authorisation for the export of the medicinal product Actosolv 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 6 December 2023 making the export of the medicinal product Actosolv intended for the Belgian market subject to prior authorisation;

Having regard to the decision of 31 August 2024 extending the requirement for prior authorisation for the export of the medicinal product Actosolv intended for the Belgian market;

Considering that the extension of 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 product Actosolv, has been communicated to the FAMHP;

Considering that the unavailability of the medicinal product Actosolv will continue until 31 August 2025;

Considering that the medicinal product Actosolv is used for the treatment of extensive and acute pulmonary embolism accompanied by an unstable cardiovascular state, the treatment of recent thrombosis of the popliteal vein or more proximal veins, the treatment of acute arterial embolism or

thrombosis of the abdominal arteries or limb arteries and for the treatment of thrombosed central venous catheters;
Whereas the administration of the medicinal product Actosolv should take place as soon as possible after the onset of symptoms, and the time interval during which the medicinal product is administered determines the outcome;
Considering that failure to administer the medicinal product can lead to death, serious and permanent disability or amputation;
Considering that 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 12f, subparagraph 2, of the Law of 25 March 1964 on medicinal products are therefore fulfilled;
DECIDES to extend the requirement for prior authorisation for the export of the medicinal product Actosolv 100000 IU sol. inj./perf. (pdr) i.v./i.arter. and Actosolv 600000 IU sol. inj./perf. (pdr) i.v./i.arter intended for the Belgian market until 31 August 2025 inclusive.
This decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE