FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending submission of the export of the medicinal product Visudyne 15 mg powder for solution for IV infusion 15 mg vial 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), first subparagraph, and (3), first subparagraph;

Having regard to the Decision of 1 July 2025 submitting export of the medicinal product Visudyne 15 mg powder for solution for IV infusion 15 mg vial 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 product Visudyne 15 mg powder for solution for IV infusion 15 mg vial until 31 December 2026 has been notified to the FAMHP;

Whereas administration of the medicine Visudyne 15 mg powder for solution for IV infusion 15 mg vial is urgent and necessary for patients suffering from the following pathologies, as photodynamic therapy with Visudyne 15 mg is the only therapeutic option requiring rapid intervention:
Absolute priority for:

- monocular vision, or visual acuity of the other eye not exceeding 0.5, with:
  - choroidal haemangioma with submacular fluid;
  - central serous chorioretinopathy with persistent subfoveal fluid (no improvement after three months) documented by OCT with a leak source inaccessible to the focal laser;
  - polypoidal choroidal vasculopathy with foveal intra- or subretinal fluid or hard (para)foveal exudates that are inaccessible to the focal laser and worsen when treated with anti-VEGF injections every four weeks, even when the anti-VEGF agent is changed;
  - non-inflammatory choroidal neovascularisation with foveal intraretinal fluid or subfoveal fluid containing > 200 µm hard (para)foveal exudates that worsen when treated with anti-VEGF injections every four weeks, even when the anti-VEGF agent is changed.
- children under 18 years of age with submacular fluid in a choroidal haemangioma;
- subretinal neovascularisation with contraindication to anti-VEGF medicine (e.g. recent < 3 m acute myocardial infarction or stroke).

High priority for: - choroidal haemangioma with extensive extramacular fluid where the patient has monocular vision or where the visual acuity of the other eye does not exceed 0.5; - choroidal haemangioma with submacular fluid and visual acuity of the other eye ≥ 0.5; - central serous chorioretinopathy with persistent subfoveal fluid documented by OCT (no improvement after three months or gradual but steady improvement after six months) with a leak source inaccessible to the focal laser and where visual acuity of the other eye is ≥ 0.5; - polypoidal choroidal vasculopathy with foveal intra- or subretinal fluid or hard (para)foveal exudates that are inaccessible to the focal laser and worsen when treated with anti-VEGF injections every four weeks, even when the anti-VEGF agent is changed, and where visual acuity of the other eye is ≥ 0.5.
Whereas non-administration of Visudyne 15 mg powder for solution for IV infusion 15 mg vial may result in permanent loss of vision;
Whereas the unavailability cannot be sufficiently compensated by other authorised medicinal products that have the same therapeutic effect, irrespective of the active substance;
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 have therefore been met;
HEREBY DECIDES to extend submission of the export of the medicinal product Visudyne 15 mg powder for solution for IV infusion 15 mg vial intended for the Belgian market to prior authorisation until 31 December 2026.
This Decision shall enter into force on the day of its notification to wholesale distributors.
Brussels, [date]
Frank VANDENBROUCKE