Message 001

Communication from the Commission - TRIS/(2025) 2174

Directive (EU) 2015/1535

Notification: 2025/0444/BG

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20252174.EN

1. MSG 001 IND 2025 0444 BG EN 13-08-2025 BG NOTIF

2. Bulgaria

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4. 2025/0444/BG - C10P - Pharmaceuticals

5. Draft Order prohibiting the export of certain medicinal products

6. Medicinal products

7.

8. Export within the meaning of Article 217a(3) of the Medicinal Products in Human Medicine Act of the medicinal products Neorecormon, solution for injection, 2000 iu (6667 iu/mL - 0.3 mL) x 6 pre-filled syringes and Neorecormon, solution for injection, 3000 iu (10000 iu/mL– 0.3 mL) x 6 pre-filled syringes belonging to the International Non-Proprietary Name (INN) Erythropoietin (Epoetin beta), (recombinant human erythropoietin), authorised for use pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, shall be prohibited.
The prohibition shall be in force until 15 February 2026.

9. The medicinal products Neorecormon, solution for injection, 2000 iu (6667 iu/ml–0.3 ml) x 6 pre-filled syringes and Neorecormon, solution for injection, 3000 iu (10000 iu/ml–0.3 ml) x 6 pre-filled syringes have been authorised for use in the country following a centralised EU procedure. The treatment of Bulgarian citizens with these two medicines is reimbursed by the National Health Insurance Fund (NHIF) for the following diseases: N18.8 ‘Other chronic kidney disease’ and N18.0 ‘End-stage renal disease’. The frequency of administration of the products in the therapeutic diagnostic algorithm set out in the ‘NHIF requirements for the predialytic treatment of chronic renal failure in outpatient care’ may vary between 3 times a week (for corrective treatment) and 1 to 3 times a week (in the case of supportive treatment), as the level of haemoglobin is taken into account in determining the dosage, which in turn implies continuity in the supply chain. Letters from the authorised representative of the marketing authorisation holder (MAH) for the medicines referred to in point 8 were received at the Ministry of Health (MoH)), announcing an expected suspension of sales in Bulgaria of the medicines NeoRecormon solution for injection in a pre-filled syringe, INN Erythropoietin (Epoetin beta), as a result of unforeseen circumstances affecting the production of the product. The MoH has requested that the Bulgarian Drug Agency (BDA) carry out a check in a timely manner on wholesalers and MAH to check the available quantities of medicines, supplies carried out since the beginning of the year, and planned supplies in the country in respect of medicines belonging to INN: Erythropoietin (Epoetin beta). Information has also been requested regarding the interval at which MAH supply to wholesalers in the country, as well as plans for future supplies. It has been established that the planned supplies for August have not been carried out. Based on the data provided by the BDA, an analysis regarding the consumption and availability of the indicated products on the pharmaceutical market has been carried out. According to that analysis, the overall availability of the medicine Neorecormon, Solution for injection, 2 000 IU has decreased by 355 packages for a period of about 2 months, which significantly exceeds–by more than 3.4 times–the average monthly sales reimbursed by the NHIF. Regarding the medicine Neorecormon, Solution for injection, 3000 IU, a downward trend in the number of patients and, respectively, reimbursed packages is observed, which could also be due to the fact that patients’ access to this product has been hindered and the demand for a therapeutic alternative has increased. The total availability for a period of about 2 months has decreased by 500 packages, which exceeds the average monthly sales reimbursed by the NHIF for the period since the beginning of the year by more than 1.8 times.

If the medicine is not exported from the country and provided that the current rate of consumption is maintained, the available quantities of this product would be sufficient to cover the needs of patients by mid-September this year (for about a month and a half months). In view of this analysis, and taking into account the fact that sales of these medicines will be suspended until January and February 2026, it is necessary to prohibit their export. According to the analysis of the data, there is a high risk of shortage of the medicines referred to in point 8. Any export of the medicines would upset the balance between the quantities supplied throughout the country and the increased need to satisfy demand. The indicated export ban will result in a balance among ensuring sufficient quantity for the treatment of patients with chronic renal failure, safeguarding their health, and non-infringement of the right of economic operators to carry out free movement of goods for a long period of time. The duration of the ban has been determined in strict compliance with the principle of proportionality in order to protect the general health and in compliance with the prohibition of arbitrary discrimination or disguised restriction on trade between MS referred to in Article 36 of the TFEU.

10. References of the Basic Texts: There is no main text

11. Yes

12. Following an analysis of the market situation as regards the availability of the medicinal products referred to in point 8, it was established that the quantities available on the Bulgarian market, combined with the suspension of their sales, would not cover the treatment needs of patients with end-stage renal disease and other kidney disease. The medicinal products referred to in point 8 are vital for the patients – irregular deliveries/delays or refusal from wholesalers' warehouses for these medicines would compromise the treatment and endanger their health and life. On the basis of an analysis of the data, including those provided by the BDA, compared to the data on the average monthly consumption of medicinal products by the insured persons, published by the NHIF, it was established that patients face a supply shortage risk for the medicinal products referred to in point 8. The need for the immediate measure was established after a thorough analysis of the current situation with the availability of medicines. The measure will achieve timely and adequate provision of sufficient quantities of these medicines for the treatment of Bulgarian patients, which will ensure the protection of their health and will guarantee the continuity of their drug therapy.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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