Message 001

Communication from the Commission - TRIS/(2026) 0754

Directive (EU) 2015/1535

Notification: 2026/0122/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: 20260754.EN

1. MSG 001 IND 2026 0122 BG EN 10-03-2026 BG NOTIF

2. Bulgaria

3A. (МИИ)(Министерство на икономиката и индустрията,
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3B. Министерство на здравеопазването,
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4. 2026/0122/BG - C10P - Pharmaceuticals

5. Draft Order prohibiting the export of certain medicinal products

6. Medicinal products

7.

8. The export within the meaning of Article 217a(3) of the Law on Medicinal Products for Human Use of the following medicinal products which have received an authorisation 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, and of medicinal products which have received an authorisation pursuant to Article 26(1) of the Law on Medicinal Products for Human Use, classified according to an Anatomical Therapeutic Chemical (ATC) classification in accordance with the requirements of the World Health Organisation (WHO) into the following pharmacological groups, shall be banned:
1. A10A 'Insulins and analogues' – medicinal products from the group with the following trade names:
• 'Levemir Penfill', solution for injection 100 U/ml – 3 ml, pack: 10;
• 'Fiasp', solution for injection 100 U/ml – 3 ml, pack: 10, cartridges;
• 'Insulatard Penfill', suspension for injection 100 IU/ml – 3 ml, pack: 5;
• 'Tresiba', solution for injection 100 IU/ml – 3 ml, pack: 5; cartridges;
• 'Actrapid Penfill', solution for injection 100 IU/ml – 3 ml, pack: 5;
• 'Humalog', solution for injection 100 IU/ml – 3 ml, pack: 10;
• 'Mixtard 30 Penfill', suspension for injection, 100 IU/ml – 3 ml; pack 5
2. A10BK 'Sodium-glucose co-transporter 2 (SGLT-2) inhibitors' – medicinal products with trade names:
- 'Forxiga' film-coated tablet 10 mg x30;
- 'Jardiance' film-coated tablet 10 mg x 30.
3. A07EC 'Aminosalicylic acid and similar agents' – medicinal products with INN: Mesalazine.
4. M05BX – 'Other medicines affecting bone structure and mineralisation' – medicinal product 'Prolia', solution for injection 60 mg/ml with INN: Denosumab.
5. B03XA 'Other antianemic preparations' – medicinal products with INN Erythropoietin (Epoetin beta) and trade names:
• 'Neorecormon', solution for injection 2000 IU (6667 IU/ml – 0.3 ml) x 6 pre-filled syringes,
• 'Neorecormon', solution for injection 3000 IU (10000 IU/ml – 0.3 ml) x 6 pre-filled syringes,
• 'Neorecormon', solution for injection 4000 IU (13333 IU/ml – 0.3 ml) x 6 pre-filled syringes.
The ban referred to in point I shall apply from 25.3.2026 to 26.5.2026.

9. In order to analyse the situation regarding the availability of medicinal products for the treatment of diabetes, anti-infective medicinal products, medicinal products for the treatment of chronic inflammatory diseases of the intestinal tract, medicinal products for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, medicinal products for the treatment of renal failure and medicinal products for the treatment of certain types of anaemia on the pharmaceutical market and patients' access to them, the Bulgarian Drug Agency (BDA) was asked to provide information on the available quantities of medicinal products from the pharmacological groups subject to the export ban in wholesalers and marketing authorisation holders, the Regional Health Inspectorates were asked to provide information on the checks carried out in community pharmacies on the availability of medicinal products, as big and small towns and villages were covered by the checks. Marketing authorisation holders were asked to provide information on the available quantities of medicinal products from group A10A 'Insulins and analogues',

group A10BK ‘Sodium-glucose cotransporter 2 inhibitors' (SGLT-2), group A07EC ‘Aminosalicylic acid and similar preparations‘ (medicinal products with INN: Mesalazine), M05BX group – ‘Other medicines affecting bone structure and mineralisation’ (medicine with INN: Denosumab, and trade name: ‘Prolia‘), and medicinal product with trade name: NeoRecormon (INN: Erythropoietin (Epoetin beta)), by batch number and expiry date, as well as information on quantities supplied for the last six months in respect of medicinal products from the same groups, and planned supplies in the upcoming 6 months. The website of the National Health Insurance Fund (NHIF) provided information on the medicinal products covered by NHIF and on the number of persons with health coverage. The analysis of this information has revealed that there is a difficulty in the supply of medicinal products from the A10A ‘Insulins and analogues‘ pharmacological group with the specified trade names. For medicinal products from the ‘Sodium-glucose co-transporter 2 inhibitors‘ (SGLT-2) group, the following medicinal products have an approved price and have been granted a marketing authorisation in Bulgaria: ‘Forxiga’ film-coated tablet 10 mg (INN Dapagliflozin), ‘Jardiance’ film-coated tablet 10 mg (Empagliflozin) and ‘Invokana’ film-coated tablet 100 mg (INN Canagliflozin). Signals for shortages/difficulty to supply or refusal by warehouses have been registered in 21% of the regions in the country for the medicinal product ‘Jardiance’, and in 29% of the regions for the medicinal product ‘Forxiga’. As regards the medicinal products ‘Jardiance’ 10 mg and ‘Forxiga’ 10 mg, the number of patients (the number of persons with health coverage) undergoing therapy with these products has significantly increased. Due to the increased number of patients undergoing therapy with the aforementioned medicinal products there has been an increase in consumption, and therefore exports must be banned. In recent months, the Ministry of Health has received signals that the medicinal products with INN: Mesalazine, marketed under the trade name Salofalk, has not been available in the pharmacy network. The highest number of shortage signals were given for the medicine marketed under the trade name ‘Salofalk’, gastro-resistant tablet 500 mg – in 79% of the regions, with shortages of this medicine reported in 165 pharmacies. Based on the analysed data, we can conclude that the difficulty to supply the medicinal products with the trade name ‘Salofalk’ is observed for all representatives. For medicinal products with the trade name ‘Prolia’ (INN Denosumab): the Ministry of Health has received reports of supply difficulties regarding medicinal products with the trade name ‘Prolia’ (INN: Denosumab). According to the information provided by RHI, the medicinal product ‘Prolia‘ has a reported shortage in 71% of all regions in the country, with a total of 111 pharmacies out of the 323 pharmacies inspected by the RHI experiencing difficulties supplying the medicinal product. As regards medicinal products with trade names: ‘Neorecormon‘, solution for injection 2000 IU, ‘Neorecormon‘, solution for injection 3000 IU, and ‘Neorecormon‘, solution for injection 4000 IU, the Bulgarian Drug Agency has informed that the medicinal products listed above have been temporarily suspended from sales (Article 54 of the Law on Medicinal Products for Human Use) until the end of June 2027 for production reasons, which makes access to therapy more difficult. The aim is to ensure that Bulgarian patients have access to them. The duration of the ban and the specific medicinal products have been determined in accordance with the principle of proportionality, in order to protect the health of the population, and in compliance with the prohibition of arbitrary discrimination or disguised restriction of trade between Member States under Article 36 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 stocks of medicinal products referred to in point 8, it was established that certain medicinal products for the treatment of diabetes, chronic inflammatory

diseases of the intestinal tract, osteoporosis, renal failure and certain types of anaemia, are not available in the pharmacy network. 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 from the BDA, comparable to the data on the average monthly consumption of medicinal products by the insured persons, published by the NHIF, it was found that there is a difficulty in supplying both pharmacies and patients with 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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