Message 001

Communication from the Commission - TRIS/(2025) 3765

Directive (EU) 2015/1535

Notification: 2025/0788/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: 20253765.EN

1. MSG 001 IND 2025 0788 BG EN 23-12-2025 BG NOTIF

2. Bulgaria

3A. Министерство на икономиката и индустрията,
дирекция "Европейски въпроси и законодателство на ЕС за стоки и услуги",
ул. "Славянска" № 8
1000 София
Tel.: +359 2 940 7336; +359 2 940 75 22
+359 2 940 7565
email: infopointBG@mi.government.bg

3B. Министерство на здравеопазването,
дирекция "Лекарствена политика"
пл. "Св. Неделя" № 5
1000 София
Тел.: +359 2 930 1298
email: vvasiyanova@mh.government.bg

4. 2025/0788/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, pre-filled pens;
– 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;
– Actrapid Penfill solution for injection 100 IU/ml – 3 ml, pack: 5;
– Humalog KwikPen, solution for injection, 100 IU/ml – 3 ml, pack: 10;
– Humalog, solution for injection 100 IU/ml – 3 ml, pack: 10;
– NovoRapid Penfil, solution for injection 100 U/ml – 3 ml; pack: 10
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. A10B – ‘Blood sugar lowering medicines, excluding insulins‘ – medicinal product Ozempic solution for injection (INN Semaglutide).
4. J01 "Antibacterial medicinal products for systemic use" – medicinal products from the INN group: ‘Azithromycin‘, INN: ‘Clarithromycin‘ and INN: ‘Amoxicillin/clavulanic acid’ in ‘powder for oral suspension’ and ‘granules for oral suspension’ pharmaceutical forms.
5. A07EC ‘Aminosalicylic acid and similar preparations‘ – only medicinal products with INN: Mesalazine;
6. M05BX – ‘Other medicines affecting bone structure and mineralisation‘ – medicinal product marketed as ‘Prolia, solution for injection 60 mg/1 ml‘ (INN: Denosumab);
7. B03XA ‘Other antianaemic preparations’ – medicinal products with the following 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 (10 000 IU/ml – 0.3 ml) x 6 pre-filled syringes,
– Neorecormon, solution for injection 4000 IU (13 333 IU/ml – 0.3 ml) x 6 pre-filled syringes,
The ban shall be in force from 24.01.2026 until 24.03.2026.

9. For the purposes of carrying out an analysis of the availability of medicines (medicinal products, MP) for diabetes, anti-infective MP, chronic inflammatory diseases of the intestinal tract, osteoporosis in postmenopausal women and in men at increased risk of fractures and certain types of anaemia, information

was requested from the Bulgarian Drug Agency (BDA) on the available quantities of MP from pharmacological groups subject to the export ban in wholesalers and marketing authorisation holders (MAHs), from the Regional Health Inspectorate (RHI) on checks carried out in community pharmacies aiming to establish the availability of MP, as both large and small towns and villages were covered. MAHs 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‘ (with INN: Mesalazine), group L04AD ‘Calcineurin inhibitors‘ (INN: Ciclosporin, oral formulation), group M05BX ‘Other medicines affecting bone structure and mineralisation‘ (INN: ‘Denosumab‘, and trade name: ‘Prolia‘), MP with trade name: ‘NeoRecormon‘ (INN: ‘Erythropoietin‘ (Epoetin beta), with trade name ‘Ozempic‘, by batch number and expiry date, as well as information on the quantities supplied since the beginning of 2025 for medicinal products from the same groups, and planned supplies for the next 6 months. Information about the MP covered by the National Health Insurance Fund and 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‘ 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 of shortages/difficulties in terms of supply or of refusals by warehouses have been reported in 29 % of provinces as regards the MP ‘Jardiance‘ and in 25 % of provinces as regards the MP ‘Forxiga‘. As regards ‘Jardiance‘, 10 mg and ‘Forxiga‘, 10 mg, the number of persons with health coverage treated with them has increased significantly. Between October 2024 and October 2025, the number of patients undergoing therapy (reimbursed by the National Health Insurance Fund) with ‘Jardiance‘, 10 mg increased almost 1.5 times. Therefore, consumption has increased and exports must be banned. As regards the medicinal products from the group A10B – Blood sugar lowering medicines, excluding insulins with trade name ‘Ozempic‘, solution for injection (INN Semaglutide): the inspections carried out by the Regional Health Inspectorate established irregular supplies, refusals to supply by the warehouse of the supplier, delays in supplies or delivery of smaller quantities. Regarding the availability of MP from the J01 ‘Antibacterial medicinal products for systemic use‘ group, all from the ‘powder for oral suspension’ and ‘granules for oral suspension’ pharmaceutical forms: according to data supplied by the RHI, supplies are irregular and wholesalers' warehouses refuse to supply INN: ‘Azithromycin‘, INN: ‘Clarithromycin‘ and INN: ‘Amoxicillin/clavulanic acid‘. In recent months, the Ministry of Health has received reports of a shortage in the pharmacy network of medicinal products with INN: ‘Mesalazine‘, marketed under the trade name ‘Salofalk‘. The majority of the reports are related to the trade name ‘Salofalk‘, gastro-resistant tablet 500 mg – in 79 % of the provinces, with shortages of this medicinal product reported in 211 pharmacies (over 60 % of all pharmacies inspected). Therefore, difficulties in supplying the trade name ‘Salofalk‘ are observed for all representatives. With regard to the medicinal product with the trade name ‘Prolia‘ (INN ‘Denosumab‘), the Ministry of Health has been receiving signals about difficulties in supplying the trade name ‘Prolia‘ (INN: ‘Denosumab‘). According to the information provided by RHI, the MP ‘Prolia‘ has a reported shortage in 89 % of all provinces, with a total of 227 pharmacies out of the 332 pharmacies inspected by the RHI experiencing difficulties with stocks of the product. Regarding the trade names ‘Neorecormon‘, solution for injection, 2000 IU, ‘Neorecormon‘, solution for injection, 3000 IU and ‘Neorecormon‘, solution for injection, 4000 IU, according to the BDA, the sale of these medicinal products has been temporarily suspended (Article 54 of the Law on Medicinal Products for Human Use) until June 2027 for production reasons. The aim is to ensure accessibility for patients, based on the principle of proportionality, protection of health and prohibition of

discrimination or disguised restrictions on trade between Member States, in accordance with 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 regarding the availability of the medicinal products referred to in point 8, a shortage was identified in the pharmacy network of certain medicinal products for the treatment of diabetes, certain 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, and medicinal products for the treatment of certain types of anaemia. 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

****
European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu