Message 001

Communication from the Commission - TRIS/(2026) 1305

Directive (EU) 2015/1535

Notification: 2026/0237/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: 20261305.EN

1. MSG 001 IND 2026 0237 BG EN 11-05-2026 BG NOTIF

2. Bulgaria

3A. Министерство на икономиката и индустрията,
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3B. Министерство на здравеопазването,
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4. 2026/0237/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:
• ‘Insulatard Penfill’, suspension for injection 100 IU/ml – 3 ml, pack: 5;
• ‘Mixtard 30 Penfill’, suspension for injection, 100 IU/ml – 3 ml; pack 5
• ‘Actrapid Penfill’, solution for injection 100 IU/ml – 3 ml, pack: 5;
• ‘Humalog’, solution for injection 100 IU/ml – 3 ml, pack: 10;
• ‘Tresiba’, solution for injection 100 IU/ml – 3 ml, pack: 5; cartridges;
• ‘Fiasp’, solution for injection 100 U/ml – 3 ml, pack: 10, cartridges;
• ‘Levemir Penfill’, solution for injection 100 U/ml – 3 ml, pack: 10;
• NovoMix 30 Penfill, suspension for injection, 100 U/ml – 3 ml, pack: 10
2. J01 ‘Anti-infectious medicinal products for systemic use’ – medicinal products from the group with INN: Cefuroxime in ‘powder for oral suspension’ and ‘granules for oral suspension’ pharmaceutical forms.
3. 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.
4. A07EC ‘Aminosalicylic acid and similar agents’ – only medicinal products with INN: Mesalazine;
5. M05BX – ‘Other medicines affecting bone structure and mineralisation’ – only medicinal product with INN: ‘Denosumab’, and trade name ‘Prolia’:
6. B03XA ‘Other antianaemic preparations’ – medicinal products with 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.
7. L01AA – ‘Nitrogen mustard analogues’ – medicinal products with INN Ifosfamide and INN Cyclophosphamide
8. L04AG – ‘Monoclonal antibodies’ – medicinal product with INN Vedolizumab.
The ban referred to in point I shall be in force from 27.5.2026 to 26.7.2026.

9. Information was requested from the Bulgarian Drug Agency (BDA) on the available quantities of the medicinal products from the pharmacological groups subject of the export ban, kept by wholesalers and pharmacies, as well as from the Regional Health Inspectorates on checks carried out in community pharmacies regarding the availability of medicinal products, covering large and smaller towns and villages. The marketing authorisation holders were asked to provide information on the currently available quantities of medicinal products from group A10A ‘Insulins and analogues’, ‘Anti-infectious medicinal products for

systemic use' – group A10BK 'Sodium-glucose co-transporter 2 inhibitors' (SGLT-2), group A07EC 'Aminosalicylic acid and similar agents' (medicinal products with INN: 'Mesalazine'), M05BX group – 'Other medicines affecting bone structure and mineralisation' – (medicinal product with INN: 'Denosumab', and trade name: 'Prolia'), medicinal products with the trade name: 'NeoRecormon' (INN: Erythropoietin (Epoetin beta), 'Nitrogen mustard analogues' – medicinal products with the INN Ifosfamide and INN Cyclophosphamide, and medicinal products from L04AG group – 'Monoclonal antibodies' – medicinal product with INN Vedolizumab by batch number and expiry date, as well as information on quantities supplied over the last 6 months for the medicinal products from the same groups and planned future supplies over the next 6 months. Information on the medicinal products reimbursed by the National Health Insurance Fund (NHIF) and the number of persons covered by health insurance was retrieved from the website of the NHIF.

9a. By setting the time limit, referred to in point III, for the export ban for the medicinal products referred to in point I, a balance will be struck between, on the one hand, the objective of the measure applied, i.e. to guarantee sufficient quantities of these medicinal products necessary for the treatment of Bulgarian patients, to protect their health and to guarantee the continuity of their treatment, and, on the other hand, the non-violation for a long period of time of the right of economic operators to carry out free movement of the goods with which they trade, in this case – medicinal products.

9b. Following an analysis of the current situation with regard to the availability of the above-mentioned groups of medicinal products and the information provided, it is necessary to impose an export ban on the medicinal products identified in point I. This way there will be sufficient quantities of medicinal products on the Bulgarian medicinal market to meet the needs of the population.

9c. The objective sought – to secure the availability on the Bulgarian pharmaceutical market of sufficient quantities of the medicinal products necessary to meet the needs of the population – should be proportionate to the potential economic benefits the marketing authorisations holders would have had, had they been able to export the described products during the period in question. The ban period introduced does not violate the principle of proportionality laid down in the Administrative Procedure Code (APC), the main purpose of which is that the administrative act and its implementation may not affect rights and legitimate interests to a greater extent than necessary for the purpose for which the act is issued (Article 6(2) of the APC).
The duration of the prohibition, as well as the specific medicinal products, have been determined in strict compliance 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 on trade between Member States referred to in Article 36 of the Treaty on the Functioning of the European Union.

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 the 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, certain types of anaemia, and medicinal products for the treatment of patients with malignant diseases, 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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