EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2025/0515/BG (Bulgaria)

# Draft Order prohibiting the export of certain medicinal products

Date received : 10/09/2025
End of Standstill : Not applicable

## Message

Message 001

Communication from the Commission - TRIS/(2025) 2502

Directive (EU) 2015/1535

Notification: 2025/0515/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: 20252502.EN

1. MSG 001 IND 2025 0515 BG EN 10-09-2025 BG NOTIF

2. Bulgaria

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4. 2025/0515/BG - C10P - Pharmaceuticals

5. Draft Order prohibiting the export of certain medicinal products

6. Medicinal products

7.

8. The export is prohibited 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 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) in accordance with the requirements of the World Health Organisation (WHO), into the pharmacological groups as follows
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;
– Mixtard 30 Penfill, Suspension for injection, 100 IU/ml – 3 ml;
– Lantus, Solution for injection, 100 IU/ml – 3 ml, Pack: 5;
– Humalog KwikPen, Solution for injection, 100 IU/ml – 3 ml, Pack: 10.
2. A10BK "Sodium-glucose co-transporter 2 (SGLT-2) inhibitors" – medicinal products with the following trade names:
– Forxiga Film-coated tablet 10 mg x30;
– Jardiance Film-coated tablet 10 mg x30.
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 with the INN: Amoxicillin/clavulanic acid and with the INN Cefuroxime in the pharmaceutical forms "powder for oral suspension" and “granules for oral suspension” pharmaceutical forms.
5. L04AD "Calcineurin inhibitors" – medicinal products with the following trade names:
– Sandimmun Neoral, Capsule, soft, 25, mg, Pack: 50;
– Sandimmun Neoral, Capsule, soft, 50, mg, Pack: 50;
– Sandimmun Neoral, Oral solution, 100 mg/ml – 50 ml, –, Pack: 1
6. J06BD "Antiviral monoclonal antibodies" – medicinal product with the trade name – Synagis Solution for injection 100 mg/ml – 0.5 ml – x1.
The prohibition shall apply as follows:
1. In the case of the medicinal products referred to in point I, subparagraphs (1) to (5), from 25 September 2025 to 23 November 2025;
2. For the medicinal product referred to in point I, subparagraph (6), it shall be from 25 September 2025 to 31 March 2026.

9. In order to analyse the situation on the availability of medicines for the treatment of diabetes and anti-infective medicines and patients’ access to them, information was requested from the Bulgarian Drug Agency (BDA) on the quantities available, the Regional Health Inspectorates (RHI) to carry out checks in "open type" pharmacies for their availability. From the marketing authorisation holders (MAH) was requested information on quantities currently available, as well as information on quantities delivered since the beginning of the year. A reference is made to the medicines paid by the National Health Insurance Fund (NHIF) and the number of health insured persons. The data were analyzed and it

was found that there was a difficulty in supplying both pharmacies and patients with the medicinal products of the pharmacological group A10A “Insulins and analogues” with the above-mentioned trade names. Alerts of shortage, difficulty, or refusal of delivery have been reported in about 14% of the districts in the country for Jardiance and 11% for Forxiga, respectively. For Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of persons insured with sickness insurance) treated with them has increased significantly. Between June 2024 and June 2025, the number of patients treated with Jardiance 10 mg (reimbursed by the NHIF) has almost doubled. The increase in patients receiving therapy (reimbursed by the NHIF) with the medicinal product Forxiga 10 mg was about 1.6-fold. As regards a medicine belonging to the pharmacological group "A10B – Blood sugar lowering medicines, excluding insulins": The checks carried out by the RHI established the following: irregular supplies, refusal from the warehouse of the wholesaler who supplies it, delay in supplies or supply of insufficient quantities of Ozempic solution for injection (INN Semaglutide). For this product, problems have been found in 6 districts in the country. Regarding the analysis on the availability of medicines of the J01 "Antibacterial medicinal products for systemic use" pharmacological group – all products in the group in "powder for oral suspension" and "granules for oral suspension” pharmaceutical forms: From the data provided by the Regional Health Inspectorates (RHIs), it may be noted that irregularities in supplies as well as refusal of wholesalers' warehouses have been established only for the products corresponding to the International Nonproprietary Names: Amoxicillin /clavulanic acid; Cefuroxime and Azithromycin. For products belonging to the pharmacological group "L04AD "Calcineurin inhibitors": The Ministry of Health received a letter from the MAH reporting a discontinuation of sales of Sandimmun Neoral, Capsule, soft, 25 mg, Pack: 50 due to unforeseen circumstances – delays in the production of the batch intended to Bulgaria. Sandimmun Neoral Capsule, soft 25 x 50 is most frequently affected by shortages. Signs of shortages are also observed in connection with the other medicines in the group. For the medicine Synagis Solution for injection 100 mg/ml – 0.5 ml: The Ministry of Health received a letter from the MAH that in connection with Synagis, solution for injection, 100 mg/mL – 0.5 mL – x1 (INN Palivizumab), production and delivery in the country of a quantity for the vaccination period (autumn and winter season) is envisaged, which corresponds to the expected number of patients. On the basis of the analysis, compared with the information available to the NHIF on the costs and number of patients using the product, as well as in view of the expected increasing consumption during the winter months, it is necessary to impose an export ban on the product. The aim of this step is to ensure that Bulgarian patients have access to them. The duration of the ban and the specific medicines 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 TFEU.

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

11. Yes

12. Following an analysis of the market situation for the stock of medicinal products referred to in point 8, it was found that certain medicinal products for the treatment of diabetes, certain anti-infective medicinal products and medicinal products in the field of transplantology and for the prevention of serious lower respiratory tract diseases requiring hospitalisation caused by Respiratory Syncytial Virus (RSV) in children at high risk of RSV disease were 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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