Message 001

Communication from the Commission - TRIS/(2025) 3203

Directive (EU) 2015/1535

Notification: 2025/0678/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: 20253203.EN

1. MSG 001 IND 2025 0678 BG EN 11-11-2025 BG NOTIF

2. Bulgaria

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4. 2025/0678/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 shall be banned for 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 for 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 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;
– Humalog KwikPen, Solution for injection, 100 IU/ml – 3 ml, Pack: 10;
– Toujeo Solution for injection 300 IU/ml – 1.5 ml; Pack: 5;
– Humalog Solution for injection 100 IU/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 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;
The ban shall be in force from 24.11.2025 until 23.01.2026.

9. For the purposes of carrying out an analysis of the situation regarding the availability of medicinal products for the treatment of diabetes and anti-infective medicinal products on the pharmaceutical market and patients’ access to such products, information was requested from the Bulgarian Drug Agency (BDA) on the stock quantities of medicinal products from the pharmacological groups subject to the export ban held by wholesalers and marketing authorisation holders, from the Regional Health Inspectorates on the checks carried out in community pharmacies (in both big and small towns/villages) aiming to establish medicinal products stocks. Marketing authorisation holders were asked to provide information on the currently 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‘ – only medicinal products with INN: Mesalazine; and medicinal products with INN Semaglutide, by batch number

and expiry date, as well as information on quantities supplied since the beginning of the year in respect of medicinal products from the same groups, and planned supplies in the upcoming 6 months. Information was retrieved from the website of the National Health Insurance Fund (NHIF) regarding the medicinal products paid by the NHIF and the number of health insured persons. For medicinal products from the 'Sodium-glucose cotransporter 2 inhibitors' (SGLT-2) pharmacological group: in Bulgaria, the following medicinal products have a valid marketing authorisation and an approved price: Forxiga film-coated tablet 10 mg (INN Dapagliflozin), Jardiance film-coated tablet 10 mg (Empagliflozin) and Invokana film-coated tablet 100 mg (INN Canagliflozin). Medicinal products, according to the approved Summary of Product Characteristics, have been indicated for the treatment of adults whose type 2 diabetes control is inadequate, as an addition to their diet and exercise: as monotherapy in cases where the use of metformin is inappropriate due to intolerance, or in addition to other medicinal products for the treatment of diabetes. Alerts of shortage, difficulty or refusal to supply have been reported in 14% of the districts in the country in respect of Jardiance and 14% in respect of Forxiga. The number of insured persons has increased in respect of Jardiance 10 mg and Forxiga 10 mg. Between August 2024 and August 2025, the number of patients treated with Jardiance 10 mg and Forxiga 10 mg (reimbursed by the NHIF) has increased by around 1.5 times. The increase in the number of patients undergoing therapy with these medicinal products has led to an increase in consumption, and therefore exports must be banned. Regarding medicinal products from the A10B 'Blood sugar lowering medicines, excluding insulins' – medicinal product Ozempic solution for injection (INN Semaglutide): 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). Problems have been reported in five districts, therefore an export ban has been imposed on the medicinal product Ozempic. Regarding the analysis of medicinal products from the J01 'Antibacterial medicinal products for systemic use' pharmacological group – all medicinal products from the 'powder for oral suspension' and 'granules for oral suspension' pharmaceutical forms: The data provided by the Regional Health Inspectorate point to irregular supplies, as well as refusals from the warehouses of wholesalers in respect of medicinal products corresponding to the international non-proprietary name (INN): Azithromycin. The Ministry of Health has received numerous reports from citizens that medicinal products with INN: Mesalazine, are not available in the pharmacy network. The therapeutic indications for the medicinal product with this international non-proprietary name include ulcerative colitis (treatment of acute conditions and prevention of recurrence) and Crohn's disease (treatment of acute conditions). The highest number of reports of shortages have been observed in respect of medicinal products with INN: Mesalazine in tablet form – 79% of the districts, with 201 pharmacies reporting shortages for this medicinal product. Shortages have been observed in respect of other pharmaceutical forms as well, and depending on the pharmaceutical form, there is a shortage in between 39 % and 61 % of the districts. Therefore, exports of all medicinal products corresponding to the INN must be prohibited: Mesalazine, are not available in the pharmacy network. The aim of this step is to ensure that Bulgarian patients have access to them. The duration of the ban and 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 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 stocks of the medicinal products referred to in

point 8, it was established that certain medicinal products for the treatment of diabetes, certain anti-infectious medicinal products and a medicinal product for the treatment of ulcerative colitis (treatment of acute conditions and prevention of recurrence) and Crohn’s disease (treatment of acute conditions) 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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