Message 001

Communication from the Commission - TRIS/(2025) 1485

Directive (EU) 2015/1535

Notification: 2025/0288/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: 20251485.EN

1. MSG 001 IND 2025 0288 BG EN 10-06-2025 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. 2025/0288/BG - C10P - Pharmaceuticals

5. Draft Order prohibiting the export of certain medicinal products

6. Medicinal products

7.

8. It shall be prohibited to export, within the meaning of Article 217a(3) of the Law on Medicinal Products for Human Use, the following medicinal products, which have received a marketing 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 with marketing authorisation issued under Article 26(1) of the Law on Medicinal Products for Human Use, classified according to an anatomical therapeutic chemical classification compliant with the requirements of the World Health Organisation (WHO) into the following pharmacological groups: 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 (FlexTouch); - Actrapid Penfill solution for injection 100 IU/ml - 3 ml, Pack: 5; - Mixtard 30 Penfill, Suspension for injection, 100 IU/ml-3 ml; - Humulin R, Solution for injection, 100 IU/ml - 3 ml.
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 x30. 3. A10B "Blood sugar lowering medicines excluding insulins" – a medicinal product with INN Semaglutide in injectable dosage form. 4. J01 "Antibacterial medicinal products for systemic use" – medicinal products from the INN group: Azithromycin in pharmaceutical forms "powder for oral suspension" and "granules for oral suspension".
Although the mechanisms laid down to restrict the export in Chapter Nine "b" "Export of Medicinal Products". Specialised electronic system for follow-up and analysis of medicinal products" in the Law on Medicinal Products for Human Use, the data analysis shows a shortage that continues to be observed. This is also evidenced by the lack of these medicinal products in pharmacies, found by the Regional Health Inspectorate. These products could be exported from Bulgaria to other countries in quantities that create conditions for potential shortages on the Bulgarian market. By setting a time limit on the export ban, a balance will be achieved between the objective of the measure – to ensure sufficient quantities of these medicines necessary for the treatment of Bulgarian patients, to protect their health and to guarantee the continuity of their drug therapy – on the one hand, and on the other hand, not to violate for a long period of time the right of economic operators to carry out the free movement of the goods they trade in – in that case - medicines. The objective sought – to ensure that medicines sufficient to meet the needs of the population are available on the Bulgarian pharmaceutical market, should be proportionate to the potential economic benefits that the marketing authorisation 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 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 MS referred to in Article 36 of the TFEU.
The ban shall be in force from 24 June 2025 to 24 July 2025.

9. In order to analyse the situation, information from the Bulgarian Drug Agency (BDA) regarding the availability of medicines from the groups, subject of the export ban in relation to wholesalers and marketing authorisation holders (MAHs) was requested, information from the Regional Health Inspectorate on checks carried out in community pharmacies, covering large and smaller settlements, was requested. Information on the currently available quantities of group A10A "Insulins and analogues", A10BK "Sodium-glucose co-transporter 2 (SGLT-2) inhibitors" and INN Semaglutide by batch number and expiry date, and data on the quantities of the medicines of the same group, delivered since the beginning of the year and on the planned deliveries for the following 6 months, was requested from the marketing authorisation holders. From the National Health Insurance Fund (NHIF), there is a reference on the medicines paid and the number of health insured persons. It was found that there was a difficulty in supplying both pharmacies and patients with medicines of group A10A “Insulins and analogues” with the above-mentioned trade names. Insulins with a commercial name: Fiasp 100 IU/ml – 3 ml. cartridges (INN: Insulin aspart), Actrapid Penfil (INN: Insulin human) and Insulatard Penfil (INN: Insulin human) – irregularly supplied, supplied in insufficient quantities or in 11 or 13 of all districts in the country, or about 40 %. For the medicines Levemir Penfill (INN: Insulin detemir), Mixtard 30 Penfill (INN: Insulin human), Humulin R (INN: Insulin human) and Tresiba penfil (INN: Insulin degludec), problems were established in about 30 % of all districts. For Fiasp Flex touch (INN: Insulin aspart) problems have been reported in 6 districts representing 21 % of all districts. For the rest, problems have been established in individual districts and pharmacies. For “Sodium-glucose co-transporter 2 (SGLT-2) inhibitors“: With a valid marketing authorisation and with an approved price are: Forxiga film-coated tablet 10 mg (INN Dapagliflozin), Jardiance film-coated tablet 10 mg (Empagliflozin) and Invokana film-coated tablet 100 mg (INN Canagliflozin). Medicines, according to the approved Summary of Product Characteristics, are indicated for the treatment of adults with inadequate control of type 2 diabetes mellitus: as monotherapy in cases where the use of metformin is inappropriate due to intolerability or in addition to other medicines for the treatment of diabetes. There have been shortage, difficulty or refusal of supply in around 29 % for Jardiance and 29 % for Forxiga, respectively. For Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of persons insured with sickness insurance) treated has increased significantly. Between April 2024 and April 2025, the number of patients treated with Jardiance 10 mg (reimbursed by the NHIF) almost doubled. The increase of therapy (reimbursed by the NHIF) with Forxiga 10 mg was about 1.6-fold. For Invokana film-coated tablet 100 mg (INN Canagliflozin) there is minimal increase and no difficulty. A ban only on Forxiga film-coated tablet 10 mg (INN Dapagliflozin) and Jardiance film-coated tablet 10 mg (Empagliflozin). For a product of A10B "Blood sugar lowering medicines excluding insulins" – a medicinal product with INN Semaglutide in injectable dosage form", there are irregularities, refusal from the wholesaler's warehouse to deliver it, delay in deliveries or the delivery of a smaller quantity for the medicinal product with INN Semaglutide in injectable dosage form. Problems have been identified for it in 11 districts. For the product, a total of 97 pharmacies reported problems related to its provision, of which 83 pharmacies reported irregularities in deliveries. Therefore, there is also an export ban for a product with INN Semaglutide. For medicines of J01 "Antibacterial medicinal products for systemic use" – all of "powder for oral suspension" и "granules for oral suspension": The Regional Health Inspectorate found that there were irregularities in deliveries, as well as a refusal from the wholesaler's warehouse only for a medicine corresponding to INN Azithromycin 100mg/5ml. According to the BDA, there are no quantities available for this medicine by the MAHs and wholesalers. For the remaining group "Antibacterial medicinal products for systemic use", alerts of shortage have been observed in single pharmacies in the country. A notification of

permanent suspension of sales has been submitted for two of the medicines of the "powder for oral suspension" и "granules for oral suspension" group.

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

11. Yes

12. Following an analysis of the market situation for the stocks of medicinal products referred to in point 8, certain medicinal products for the treatment of diabetes and certain anti-infectious medicinal products were found to be unavailable 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

****

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