Message 001

Communication from the Commission - TRIS/(2025) 2092

Directive (EU) 2015/1535

Notification: 2025/0424/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: 20252092.EN

1. MSG 001 IND 2025 0424 BG EN 06-08-2025 BG NOTIF

2. Bulgaria

3A. Министерство на икономиката и индустрията
дирекция "Европейски въпроси и законодателство на ЕС за стоки и услуги"
ул. "Славянска" № 8, 1052 София
Tel.: +359 2 940 7336; +359 2 940 7522
E-mail: 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. 2025/0424/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;
– 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;
– Humalog 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" – medicinal product Ozempic solution for injection (INN Semaglutide).
4. J01 "Antibacterial medicinal products for systemic use" – medicinal products from the INN group: Azithromycin, INN: Amoxicillin/clavulanic acid and INN Cefuroxime in "powder for oral suspension” and “granules for oral suspension” pharmaceutical forms.
The prohibition will be in force from 26 August 2025 to 24 September 2025.
The duration of the prohibition 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 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.

9. In order to analyse the situation concerning the availability on the pharmaceutical market of medicinal products for the treatment of diabetes and of anti-infective medicinal products and the patients’ access to them, the Bulgarian Drug Agency (BDA) was asked to provide information on the quantities in stock, and the Regional Health Inspectorates were asked to provide information on the checks carried out in community pharmacies concerning medicinal products in stock. The marketing authorisation holders were asked to provide information on the quantities currently in stock, as well as information on the quantities of medicinal products delivered since the beginning of the year. Information on the medicinal products paid by the

National Health Insurance Fund (NHIF) and on the number of insured persons was retrieved from the website of the NHIF.
The information was analysed and it was established that the insulins with the following trade names: Fiasp 100 IU/ml – 3 ml. cartridges (INN: Insulin aspart), Levemir Penfill (INN: Insulin detemir), Insulatard Penfil (INN: Insulin human), Tresiba penfil (INN: insulin degludec) and Actrapid Penfil (INN: Insulin human) are not regularly supplied/are supplied in insufficient quantities or their supply is delayed in 9 to 19 of the districts in the country, or in about 32 % to 68 % of them.
As regards the medicinal products with trade names Fiasp Flex touch (INN: Insulin aspart), Humulin R (INN: Insulin human) and Mixtard 30 Penfill (INN: Insulin human), problems were established in 21 % of all districts. As regards the medicinal products with trade names Humalog 300 IU (INN: Insulin Lispro), Lyumjev (INN Insulin Lispro), NovoRapid (INN: Insulin aspart), Toujeo (INN: Insulin glargine), Humalog KwikPen 300 IU (INN: Insulin Lispro) Abasaglar (INN Insulin glargine), Lantus (INN Insulin glargine), Xultophy (INN insulin degludec/liraglutide), problems were established in 4–5 districts in the country, representing 14% to 18% of all districts in Bulgaria.
Next, alerts of shortage, difficulty, or refusal to deliver have been reported in about 21% of the districts in the country for the Jardiance medicinal product and in about 32% of the districts for the Forxiga medicinal product. The number of patients who have been prescribed treatment with the products mentioned has increased significantly. Between May 2024 and May 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.
The checks carried out by the Regional Health Inspectorates established the following: irregular supplies, refusal from the warehouse of the wholesaler who supplies it, delay in supplies or supply of insufficient quantities of the medicinal product Ozempic solution for injection (INN Semaglutide). For this product, problems have been found in 9 districts in the country. For the product, a total of 48 pharmacies reported problems related to its supply, of which 27 pharmacies reported that supplies are not regular.
With regard to the anti-infective medicinal products, the data provided by the RHI point to irregular supplies and refusal by the warehouses of wholesalers to supply the medicinal products corresponding to the international non-proprietary names (INN): Amoxicillin /clavulanic acid; Cefuroxime and Azithromycin. It should be noted that for two of the medicinal products from the group in "powder for oral suspension" and "granules for oral suspension" dosage forms, a notification for permanent suspension of sales has been submitted. The marketing authorisation of another medicinal product has been terminated.
On the basis of those data, it is necessary to impose an export ban on the medicinal products referred to in point 8.
The aim of this step is to ensure that Bulgarian patients have access to them.

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