Message 001

Communication from the Commission - TRIS/(2025) 1252

Directive (EU) 2015/1535

Notification: 2025/0237/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: 20251252.EN

1. MSG 001 IND 2025 0237 BG EN 13-05-2025 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. 2025/0237/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 of the group with the following trade names:
- Actrapid Penfill, Solution for injection, 100 IU/ml - 3 ml, Pack: 5;
- Levemir Penfill, Solution for injection, 100 U/ml - 3 ml, Pack: 10;
- Insulatard Penfill, Suspension for injection, 100 IU/ml - 3 ml, Pack: 5;
- Tresiba Solution for injection 100 IU/ml –3 ml -5 Pre-filled pen (FlexTouch);
- Fiasp, Solution for injection, 100 U/ml – 3 ml, Pack: 10 (2x5) pre-filled pens (multipack);
- Fiasp, Solution for injection, 100 U/ml-3 ml, Pack: 10 Cartridges;
- Humalog solution for injection 100 IU/ml - 3 ml (3.5 mg/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 x30.
3. A10B "Blood sugar lowering medicines excluding insulins" – a medicinal product with INN Semaglutide in injectable dosage form.
The ban shall be in force from 25 May 2025 to 23 June 2025.
The prohibition 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.

9. In order to analyse the situation regarding the availability of medicinal products for the treatment of diabetes and anti-infectious medicinal products on the pharmaceutical market and patients’ access to them, information was requested from the Bulgarian Drug Agency (BDA) on the quantities of medicinal products from the pharmacological groups, subject to the export ban, available in wholesalers and marketing authorisation holders, and from the Regional Health Inspectorates on "open type" checks carried out in pharmacies on the availability of medicinal products, as both large and smaller settlements were covered. Information on the currently available quantities of medicinal products of group A10A "Insulins and

analogues", A10BK "Sodium-glucose co-transporter 2 (SGLT-2) inhibitors" and the medicinal product with INN Semaglutide by batch number and expiry date, as well as information on the quantities of the medicinal products 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 website of the National Health Insurance Fund (NHIF), a reference was made on the medicinal products paid by NHIF and the number of health insured persons. The information received was examined and analysed, and, in summary, it was established that a difficulty exists in the supply of the medicines of the pharmacological group A10A “Insulins and analogues” with the above trade names to both pharmacies and patients. The checks carried out by the Regional Health Inspectorates established irregularities, refusal by the warehouse belonging to the wholesaler supplying it, delay in deliveries or delivery of a smaller quantity of the medicinal product with INN Semaglutide in solution for injection form. Problems have been identified for this product in 15 districts, accounting for 54 % of all districts in the country. For the product, a total of 116 pharmacies reported problems related to its provision, of which 99 pharmacies reported irregularities in deliveries. Due to the above-mentioned information, an export ban is also imposed on the medicinal product with INN Semaglutide. As regards the analysis on the availability of anti-infectious medicinal products, it should be noted that, to date, there are currently no prerequisites for an export ban on those medicinal products. Therefore, they have remained outside the scope of this Order. Notwithstanding the export restriction mechanisms set out in legislation 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, as it could be noted from the analysis of the data received from the above-mentioned institutions, a shortage of medicinal products continues to be observed. This is also evidenced by the fact that these medicinal products are not available in pharmacies, as established by the RHI. One of the possible reasons for this shortage is that these products may be exported from the Republic of Bulgaria to other countries in quantities that may lead to a potential shortage of these medicines on the Bulgarian market. By setting a time limit on the export ban for medicines referred to in point 8, 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. 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 during the period in question.

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

11. Yes

12. Following an analysis on the availability on the market of stocks of the medicinal products referred to in point 8, it was found that some types of medicinal products for the treatment of diabetes 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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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu