Message 001

Communication from the Commission - TRIS/(2025) 0045

Directive (EU) 2015/1535

Notification: 2025/0008/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: 20250045.EN

1. MSG 001 IND 2025 0008 BG EN 07-01-2025 BG NOTIF

2. Bulgaria

3A. Министерство на икономиката и индустрията,
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3B. Министерство на здравеопазването,
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4. 2025/0008/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 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 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 - x5
- Insulatard Penfill Suspension for injection 100 IU/ml - 3 ml - x5
- Levemir Penfill Solution for injection 100 U/ml - 3 ml - x10
- Fiasp Solution for injection 100 U/ml – 3 ml – 10 (2x5) pre-filled pens (multipack)
- Humalog Solution for injection 100 IU/ml - 3 ml (3.5 mg/ml) - x10
- NovoMix 30 Penfill Suspension for injection 100 U/ml - 3 ml - x10
- Toujeo Solution for injection 300 IU/ml - 1.5 ml - x5
- Lyumjev Solution for injection 200 U/ml – 3 ml – x10
- Tresiba, Solution for injection 100 IU/ml – 3 ml – 5 Pre-filled pen (FlexTouch).
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. J06BD "Antiviral monoclonal antibodies" - Synagis Solution for injection 100 mg/ml - 0.5 ml - x1.
4. J01 "Antibacterial medicinal products for systemic use" – medicinal products from the INN group: ‘Amoxicillin, clavulanic acid’ and INN: ‘Azithromycin’ in pharmaceutical forms “powder for oral suspension” and “granules for oral suspension”.
The ban will be in force from 21 January 2025 to 20 February 2025.

9. The reasons for the order issued shall be as follows:
Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. Increased blood sugar, hyperglycemia, is the result of uncontrolled diabetes and over time leads to serious damage to many of the body’s systems, especially nerves and blood vessels.
Type 1 diabetes (known as insulin dependent) is characterised by insufficient insulin production and requires daily parenteral insulin administration.
Type 2 diabetes affects the way glucose in the body is absorbed and transformed into energy. This is a pathological condition in which cells either fail to respond normally to the hormone insulin or reduce the number of insulin receptors in response to hyperinsulinaemia.
The main danger in diabetes is its chronic complications. Diabetes leads to the development of damage to the eyes, kidneys, nervous system, cardiovascular diseases, brain strokes, pain in the lower extremities, etc.
In order to analyse the situation regarding the availability of medicinal products for the treatment of diabetes, anti-infectious medicinal products and the medicinal product with INN Palivizumab on the pharmaceutical market and patients’ access to them, information from the Bulgarian Drug Agency (BDA) on the available

quantities of medicinal products from pharmacological groups subject to the export ban for the wholesalers and marketing authorisation holders, information from the Regional Health Inspectorates on checks carried out in community pharmacies on the availability of medicinal products, covering large and smaller settlements, was requested. 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 Palivizumab by batch number and expiry date, as well as information on delivered quantities since the beginning of the year of medicinal products and planned follow-up deliveries of the same group, was requested from the marketing authorisation holders. From the website of the National Health Insurance Fund (NHIF), an inquiry was made on the consumption of medicinal products and the number of health insured persons.

Following aggregation and review of the information received from the above-mentioned institutions and from the marketing authorisation holders, it could be distinctly noticed that the medicinal products with trade name: Actrapid Penfil (Insulin – human), Insulatard Penfil (Insulin – human) and Levemir Penfill (Insulin detemir) have irregular delivery, reduced delivery, or delayed delivery in 14 out of all districts in the country, or about 50%. For the medicinal products Fiasp Flex touch, Humalog 300 IU, NovoMix 30 Penfill and Toujeo, problems were observed in approximately and above 30 % of all districts, while for the medicinal products under the trade names Lyumjev and Tresiba, shortages were reported in approximately 25 % of all districts in the country. For the rest of the insulins that were reported to suffer delay/irregular supply or refusal by the wholesaler, problems were observed in single districts.

It is striking that of all insulins with reports of supply bottlenecks, insulin under the trade name Levemir penfil has the biggest number of reports from pharmacies of refusal from wholesalers' warehouses. The insulins with the biggest number of reports from pharmacies on irregular deliveries are those with the following trade names: Insulatard Penfil, Tresiba and Actrapid Penfil.

For the medicinal product Tresiba Solution for injection 100 IU/ml – 3 ml x 5 Pre-filled pen (FlexTouch) (INN: Insulin degludec) it should be specified that the Ministry of Health has received a letter from the marketing authorisation holder concerning the imminent permanent cessation of sales of the medicinal product.

Following an analysis on the information received, 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. In view of the above, it is necessary to prohibit the export of the medicinal products in question.

With regard to medicinal products belonging to the pharmacological group "Sodium-glucose co-transporter 2 (SGLT-2) inhibitors":

On the territory of our country, the following medicinal products have a valid marketing authorisation and an established 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, are indicated for the treatment of adults with inadequate control of type 2 diabetes mellitus as an adjunct to diet and exercise: as monotherapy in cases where the use of metformin is inappropriate due to intolerability or in addition to other medicinal products for the treatment of diabetes. The medicinal products Jardiance and Forxiga have been reported to have shortages/difficulties or refusal in warehouses in approximately 36 % of the districts in the country. For the medicinal products Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of persons insured with sickness insurance) treated with these products has increased significantly. Between January and October 2024, the increase in patients treated (reimbursed by the NHIF) with Jardiance 10 mg was approximately 1.8 times. The increase in patients receiving therapy (reimbursed by the NHIF) with the medicinal product Forxiga 10 mg is about 1.5 times.

Due to these data, the need for an export ban is justified only for the medicinal products Forxiga film-coated tablet 10 mg (INN Dapagliflozin) and Jardiance film-coated tablet 10 mg (Empagliflozin).
With regard to medicinal products of the following pharmacological group – J01 “Anti-infectious medicinal products for systemic use”:
From the data provided by the Regional Health Inspectorates (RHIs), it could be noted that delays and irregularities in deliveries, including refusal of wholesalers' warehouses, are observed mainly for medicinal products belonging to INN Azithromycin and INN: Amoxicilline, clavulanic acid.
Currently, there is an increase in respiratory diseases in the country; consequently, the use of the above-mentioned medicinal products has increased. That entails the imposition of an export ban on those medicinal products.
For the medicinal product with the trade name Synagis Solution for injection 100 mg/ml - 0.5 ml - x1:
Synagis, solution for injection, 100 mg/ml - 0.5 ml - x1 (INN Palivizumab) is authorised in the country under the EU centralised procedure. The product is indicated 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.
The medicinal product is included in Annexes 1 and 4 of the Positive Drug List and is the only medicinal product in the PDL corresponding to INN Palivizumab.
During the current winter period, there has been an increase in demand for Palivizumab due to the increased risk of respiratory syncytial virus (RSV) disease among newborns and young children, which warrants a ban on its export.
Although the mechanisms laid down in the legislation to restrict the export of medicinal products laid down 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 lack of these medicinal products in pharmacies, found by the RHI, while one of the possible reasons for this shortage is that these products may be exported from the territory of the Republic of Bulgaria to other countries in quantities, creating prerequisites for a potential shortage of these medicinal products on the Bulgarian market.
Regardless of the legal nature of the activity carried out, the export of medicinal products referred to in point 8, as well as the observed delays in the deliveries, disrupts the balance between the medicinal products supplied on the territory of the country and the increased demand for them to meet the health needs of the population.
Following an in-depth analysis of the current situation with regard to the availability of the above-mentioned groups of medicinal products and the information provided above, it was found necessary to introduce an export prohibition on the groups of medicinal products identified in point 8.
In addition, by setting the time limit for the ban on the export of the medicinal products referred to in point 8, a balance will be achieved between the objective of the measure - to ensure a sufficient quantity of these medicinal products 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 this case, medicinal products.
The objective sought – to provide the Bulgarian pharmaceutical market with sufficient medicinal products to meet the needs of the population – should be proportionate to the potential economic benefits that would accrue to the holders of marketing authorisations for medicinal products if they were able to export the described products during the period in question. 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.

10. References to 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, some types of medicinal products for the treatment of diabetes, anti-infectious medicinal products and antiviral monoclonal antibodies were found to be unavailable in the pharmacy network. The medicinal products under paragraph 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 paragraph 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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