



REPUBLIC OF BULGARIA

Ministry of Health

Minister of Health

DRAFT!

O R D E R

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Pursuant to Article 36 of the Treaty on the Functioning of the European Union, Article 10 of Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports, Article 73 of the Code of Administrative Procedure and in relation to the shortage of medicinal products for certain life-threatening diseases,

I H E R E B Y O R D E R:

I. I prohibit the export within the meaning of Article 217a(3) of the Law on Medicinal Products for Human Use of 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 and 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 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;
- NovoMix 30 Penfill, Suspension for injection, 100 U/ml - 3 ml, Pack: 10;
- Humalog, Solution for injection, 100 IU/ml - 3 ml (3.5 mg/ml), Pack: 10;
- Lyumjev, Solution for injection, 200 U/ml – 3 ml, Pack: 10;
- Xultophy, Solution for injection in pre-filled pen, 100 U/ml/3.6 mg/ml - 3 ml, Pack: 3.

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. J01 "Antibacterial medicinal products for systemic use" – medicinal products from the INN group: Amoxicillin, clavulanic acid и INN: Azithromycin in pharmaceutical forms "powder for oral suspension" and "granules for oral suspension".

4. A10B "Blood sugar lowering medicines excluding insulins" – a medicinal product with INN Semaglutide in injectable dosage form.

II. Grounds:

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 Semaglutide 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 Semaglutide by batch number and expiry date, as well as information on delivered quantities since the beginning of the year of medicinal products and planned deliveries of the same group for the following 6 months, was requested from the marketing authorisation holders. From the website of the National Health Insurance Fund (NHIF), an inquiry was made on the medicinal products paid by NHIF and the number of health insured persons.

The information received was considered and analysed, and as a general conclusion 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 specified medicinal products.

With regard to the 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. Alerts of shortage, difficulty, or refusal of delivery are observed in about 25 % of the districts in the country for the medicinal product Jardiance and 32 % for the medicinal product Forxiga, respectively. 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 the specified products has increased significantly. Between January and December 2024, the increase of the patients' number treated (reimbursed by the NHIF) with Jardiance 10 mg was approximately twice. The increase in patients receiving therapy (reimbursed by the NHIF) with the medicinal product Forxiga 10 mg was about 1.7-fold. Due to the increased number of patients undergoing therapy with the aforementioned medicinal products, a noticeable increase in consumption has been observed.

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).

As regards the medicinal products of the following pharmacological group: J01 "Anti-infectious medicinal products for systemic use" – all medicinal products in the group in pharmaceutical forms "powder for oral suspension" and "granules for oral suspension":

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, have been observed mainly for the medicinal products belonging to INN: Amoxicilline, clavulanic acid; and INN: Azithromycin in pharmaceutical forms "powder for oral suspension" and "granules for oral suspension".

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.

As regards a medicinal product of the pharmacological group "A10B – Blood sugar lowering medicines excluding insulins" – a medicinal product with INN Semaglutide in injectable dosage form. The checks carried out by the Regional Health Inspectorates found that there were irregularities, refusal from the wholesaler's warehouse who delivered 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 this product in 10 districts, accounting for 36 % of all districts in the country. For the product, a total of 81 pharmacies reported problems related to its provision, of which 67 pharmacies reported irregularities in deliveries.

The marketing authorisation holder of the medicinal product has informed the Ministry of Health about a notification submitted to the BDA under Article 54(4) of the Law on Medicinal Products for Human Use for temporary suspension of sales due to unforeseeable circumstances. The Ministry of Health has been also notified of an expected temporary shortage of the medicinal product and, according to the information received, the expected shortage of the product will cover the period 28 March 2025 to 11 April 2025. The expected shortage has been also notified to the European Medicines Agency. The company has provided information that it experiences global production problems that lead to a temporary suspension of deliveries of the above-mentioned product to certain regions and pharmaceutical markets.

Due to the above-mentioned information, an export ban is also imposed on the medicinal product with INN Semaglutide.

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 I.

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 struck between, on the one hand, the objective of the measure applied – i.e. 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 – and, on the other hand, to not infringe for a long period of time the right of economic operators to carry out the free movement of the goods in which they trade, in the case at hand: 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.

III. The prohibition under point I shall apply from 25.3.2025 to 24.4.2025.

IV. The order shall be published on the website of the Ministry of Health and shall be sent to the Customs Agency for information and implementation.

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