REPUBLIC OF BULGARIA

Ministry of Health

Minister of Health

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 for use 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 which have received an authorisation for use pursuant to Article 26(1) of the Law on Medicinal Products for Human Use, classified according to an anatomical therapeutic chemicalal (ATC) code in accordance with the requirements of the World Health Organisation (WHO), from 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 inhibitors" (SGLT-2) – 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.

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 and anti-infective medicinal products on the pharmaceutical market and patients' access to such products, information was requested from the Bulgarian Drug Agency (BDA) on the stock quantities of medicinal products from the pharmacological groups subject to the export ban held by wholesalers and marketing authorisation holders, from the Regional Health Inspectorates on the checks carried out in community pharmacies regarding the stocks of medicinal products, as large and smaller settlements were covered. The marketing authorisation

holders were asked to provide information on the currently available quantities of medicinal products of group A10A "Insulins and analogues", group A10BK "Sodium-glucose co-transporter 2 (SGLT-2) inhibitors" and the medicinal product with INN Semaglutide and group J01 "Antibacterial medicinal products for systemic use" by batch number and expiry date, as well as information on the quantities of the medicinal products from the same groups supplied since the beginning of the year and on the planned supplies for the following 6 months. 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 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. It has been clearly established that the following insulins with 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 the districts.

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 about 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 have been reported in 4–5 districts of the country, representing 14% to 18% of all districts in Bulgaria. For the rest of the reported insulins, problems have been observed in individual pharmacies in some districts.

Following an analysis of the data, it is necessary to impose a ban on the export of the medicinal products referred to in point 1.

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 have been reported in about 21% 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 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. Due to the increased number of patients undergoing therapy with the aforementioned medicinal products, a noticeable increase in consumption has been observed.

For the medicinal product Invokana film-coated tablet 100 mg (INN Canagliflozin), there has been a minimal increase in consumption and there has been no difficulty for patients in accessing it.

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).

Regarding a medicinal product of the pharmacological group "A10B – Blood sugar lowering medicines, excluding insulins" – medicinal product Ozempic solution for injection (INN Semaglutide):

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 have reported problems related to its supply, of which 27 pharmacies reported irregular supplies.

In view of the above, an export ban is also imposed on the medicinal product Ozempic.

Regarding the analysis on the availability of medicinal products of the J01 "Anti-infective medicinal products for systemic use" pharmacological group – all medicinal products in the group in "powder for oral suspension" and "granules for oral suspension" pharmaceutical forms:

From the data provided by the Regional Health Inspectorates (RHIs), it may be noted that irregularities in supplies as well as refusal of wholesalers' warehouses have been established only for the medicinal products corresponding to the International Nonproprietary Names: Amoxicillin /clavulanic acid; Cefuroxime and Azithromycin. For the remaining medicinal products from the group "Antibacterial medicinal products for systemic use", alerts of shortage have been observed in single pharmacies in some districts.

It should be noted that for two of the medicinal products from the group in "powder for oral suspension" and "granules for oral suspension" pharmaceutical forms, a notification for permanent suspension of sales has been submitted, and the marketing authorisation of another product has been terminated.

Considering the above, there are grounds for imposing an export ban in respect of the antibacterial medicinal products referred to in point 4.

Despite the presence of legislation mechanisms 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, the analysis of the data received from the above-mentioned institutions points to a continuing shortage of the medicinal products that fall within the scope of the ban. 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 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 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 ban referred to in point I shall be in effect from 26 August 2025 until 24 September 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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