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 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) code in accordance with the requirements of the World Health Organisation (WHO), from the pharmacological groups as follows:

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;

- Humalog KwikPen, Solution for injection, 100 IU/ml - 3 ml, Pack: 10;

- Toujeo Solution for injection 300 IU/ml - 1.5 ml, Pack: 5;

- Humalog Solution for injection 100 IU/ml - 3 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” – medicinal product Ozempic solution for injection (INN Semaglutide).

4. J01 “Antibacterial medicinal products for systemic use” – medicinal products from the INN group: Azithromycin in pharmaceutical forms “powder for oral suspension” and “granules for oral suspension”.

5. A07EC “Aminosalicylic acid and similar agents” – only medicinal products with INN: Mesalazine;

II. Grounds:

Diabetes is a chronic disease with an extremely high prevalence in Bulgaria, leading to increased blood sugar levels, the main danger being late complications. According to data provided by the International Diabetes Federation, more than 520,000 persons in Bulgaria have diabetes. Over time, the disease causes serious damage to nerves, blood vessels, eyes, kidneys and the cardiovascular system, leading to heart attacks and strokes. In order to analyse the availability of medicinal products for the treatment of diabetes and anti-infectious medicinal products on the pharmaceutical market and patients’ access to such products, information was requested from the Bulgarian Drug Agency (BDA) on the 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 availability of medicinal products, as large and smaller settlements were covered. Information on the currently available quantities of medicinal products from group A10A “Insulins and analogues”, group A10BK “Sodium-glucose co-transporter 2 inhibitors” (SGLT-2), group A07EC “Aminosalicylic acid and similar agents” – only medicinal products with INN has been requested from the marketing authorisation holders: Mesalazine; and the medicinal product with INN Semaglutide, by batch number and expiry date, as well as information on quantities delivered since the beginning of the year for medicinal products from the same groups, and planned deliveries for the next 6 months. 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 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.

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 14 % of the districts in the country for the medicinal product Jardiance and 14 % for the medicinal product Forxiga, respectively. For the medicinal products Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of health insured persons) treated with the specified products has increased significantly. Between August 2024 and August 2025, the increase in patients undergoing therapy (reimbursed by the NHIF) with Jardiance 10 mg is almost 1.5 times. The increase in patients receiving therapy (reimbursed by the NHIF) with the medicinal product Forxiga 10 mg is also about 1.5 times. 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).

Regarding a medicinal product of the pharmacological group “A10B – Blood sugar lowering medicines, excluding insulins” – medicinal product with trade name 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 less quantities of the medicinal product with trade name Ozempic solution for

injection (INN Semaglutide). For this product, problems have been found in 5 districts in the country.

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

Regarding the analysis on the availability of the medicinal products from the J01 “Antibacterial 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 Name (INN): Azithromycin.

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

Over recent months, the Ministry of Health has received numerous reports from citizens regarding a shortage of medicinal products belonging to INN in pharmacies: Mesalazine. The therapeutic indications of medicinal products under this international non-proprietary name include ulcerative colitis (treatment of acute conditions and prevention of relapse) and Crohn’s disease (treatment of acute conditions). The highest number of shortage signals is observed for the medicinal product with INN: Mesalazine in tablet form – 79% of districts in the country, with shortages of this medicinal product has been reported in 201 pharmacies. The remaining pharmaceutical forms also show shortages, with shortages depending on the pharmaceutical form – between 39 % and 61 % of the districts. Due to these data, the need for an export ban shall be justified for all medicinal products corresponding to INN: Mesalazine.

Despite the presence of mechanisms to restrict the export of medicinal products in the legislation, i.e. 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 I, 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 24.11.2025 until 23.01.2026.

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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Prof. Dr. Silvi Kirilov, MD
Minister of Health