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) 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 having 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;

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

– ‘NovoRapid Penfil’, solution for injection 100 U/ml – 3 ml, pack: 10

2. A10BK ‘Sodium-glucose co-transporter 2 (SGLT-2) inhibitors’ – medicinal products having the trade names:

– ‘Forxiga’, film-coated tablet 10 mg x 30;

– ‘Jardiance’, film-coated tablet 10 mg x 30.

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 of the group with INN: Azithromycin, INN: Clarithromycin and INN: Amoxicillin/clavulanic acid in ‘powder for oral suspension’ and ‘granules for oral suspension’ pharmaceutical forms.

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

6. M05BX – ‘Other medicines affecting bone structure and mineralisation’ – medicinal product marketed as ‘Prolia’, solution for injection 60 mg/1 ml (INN: Denosumab);

7. B03XA ‘Other antianaemic preparations’ – medicinal products with the following trade names:

– ‘Neorecormon’, solution for injection 2000 IU (6667 IU/ml - 0.3 ml) x 6 pre-filled syringes,

– ‘Neorecormon’, solution for injection 3000 IU (10000 IU/ml - 0.3 ml) x 6 pre-filled syringes,

– ‘Neorecormon’, solution for injection 4000 IU (13 333 IU/ml - 0.3 ml) x 6 pre-filled syringes,

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 situation regarding the availability of medicinal products for the treatment of diabetes, anti-infective

medicinal products, medicinal products for the treatment of chronic inflammatory diseases of the intestinal tract, medicinal products for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures and medicinal products for the treatment of certain types of anaemia on the pharmaceutical market and patients' access to them, the Bulgarian Drug Agency (BDA) was asked to provide information on the available quantities of medicinal products from the pharmacological groups subject to the export ban in wholesalers and marketing authorisation holders, the Regional Health Inspectorates were asked to provide information on the checks carried out in community pharmacies on the availability of medicinal products, as large and smaller towns and villages were covered by the checks. The marketing authorisation holders were asked to provide iInformation 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' (medicinal products with INN: Mesalazine), group L04AD 'Calcineurine inhibitors' (medicinal products with INN: Ciclosporin, in oral form), group M05BX 'Other medicines affecting bone structure and mineralisation' (medicinal product with INN: Denosumab, and trade name: Prolia), medicinal products with the trade name: NeoRecormon (INN: Erythropoietin (Epoetin beta); and the medicinal product with trade name Ozempic, by batch number and expiry date, as well as information on the quantities supplied since the beginning of the year as regards the medicinal products from the same groups, and on the planned supplies for the next 6 months. The website of the National Health Insurance Fund (NHIF) provided information on the medicinal products covered by NHIF and the number of persons with health coverage.

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: *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; Humalog Solution for injection 100 IU/ml – 3 ml, pack: 10; NovoRapid Penfil solution for injection 100 U/ml – 3 ml, pack: 10,* are not regularly supplied/are supplied in insufficient quantities or their supply is delayed in 4 to 9 of all provinces in the country, or in 14 % to 32 % of the provinces. For the rest of the medicinal products in the group, problems are observed in some of the provinces.

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 not appropriate due to intolerability or in addition to other medicinal products for the treatment of diabetes. Signals of shortage, difficulty, or refusal of supply have been reported in about 29 % of the provinces in the country for the medicinal product Jardiance and, respectively, 25 % for the medicinal product Forxiga. For the medicinal products Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of persons with health coverage) treated with the specified products has increased significantly. Between October 2024 and October 2025, the number of patients undergoing therapy (reimbursed by the NHIF) with Jardiance 10 mg has increased 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).

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

Regarding the analysis of 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:

The data provided by the Regional Health Inspectorates (RHIs) shows that irregular supplies and refusal by the warehouses of the wholesalers have been established in respect of the

medicinal products corresponding to the following International Nonproprietary Names (INN): Azithromycin, INN: Clarithromycin and INN: Amoxicillin/clavulanic acid.

It is apparent from the foregoing that, in view of the beginning of the winter period, which is characterised by a high frequency of acute respiratory diseases, including influenza, which leads to traditionally higher consumption of antibiotic medicinal products, there are grounds for imposing an export ban also with regard to the antibacterial medicinal products referred to in point 4.

As regards the medicinal products with INN Mesalazine:

Over recent months, the Ministry of Health has received numerous reports from citizens regarding a shortage in pharmacies of medicinal products belonging to INN: Mesalazine, with trade name Salofalk.

The highest number of shortage signals has been given for the medicinal product with trade name: Salofalk, gastro-resistant tablet 500 mg – in 79% of provinces, as shortages of this medicinal product have been reported in 211 pharmacies (over 60% of all pharmacies inspected). Based on the analysis we can conclude that the difficulty to supply the medicinal products with the brand name Salofalk is observed for all representatives. It is evident that a large part of the signals concerning medicinal products shortages are related to wholesaler refusal to supply to the pharmacy. In consideration of the above, it follows that the export of the medicinal product with INN Mesalazine referred to in point 5 shall be prohibited.

With regard to the medicinal product with the trade name Prolia (INN Denosumab):

In recent months, citizens and non-governmental organisations have alerted the Ministry of Health to difficulties in obtaining the medicinal product with the trade name Prolia (INN: Denosumab).

According to data presented by the Regional Health Inspectorates (RHI), the medicinal product Prolia has been reported to be in short supply in 89% of all provinces in the country, with a total of 227 pharmacies out of the 332 pharmacies inspected by the RHI experiencing difficulties in obtaining the medicinal product.

Data on the number of persons with health coverage and the number of packs of the medicinal product Prolia covered by the National Health Insurance Fund (NHIF) for the January–October 2025 period demonstrate a relatively stable upward trend for both indicators. The increase in the number of patients undergoing therapy has been gradual and consistent, and the dynamics of covered packs has been following the same trend. In consideration of this information, the export of the medicinal product with the trade name Prolia, corresponding to INN Denosumab, must be prohibited.

With regard to medicinal products bearing the following trade names: Neorecormon solution for injection 2000 IU (6667 IU/ml – 0.3 ml) x 6 pre-filled syringes, Neorecormon

solution for injection 3000 IU (10000 IU/ml – 0.3 ml) x 6 pre-filled syringes, and Neorecormon solution for injection 4000 IU (13333 IU/ml – 0.3 ml) x 6 pre-filled syringes:

Given the specific nature of the product and its relatively limited consumption in the country, it would not be appropriate to require information from the Regional Health Inspectorates collected on the basis of the sample checks they have carried out, which is the practice used to prepare analyses of the consumption of insulin and other medicinal products, given that these types of products are usually supplied to the patient after a prior request at a pharmacy. According to information provided by the BDA, sales of the above-mentioned medicinal products have been temporarily suspended (Article 54 of the Law on Medicinal Products for Human Use) until June 2027 for manufacturing reasons, which in turn hinders patients' access to treatment.

An analysis of the information on the consumption of medicinal products in the period October 2024–October 2025 reveals that consumption of the medicinal product Neorecormon 3000 IU sharply decreased at the end of 2024, with similar dynamics observed for the other two products – Neorecormon 2000 IU and Neorecormon 4000 IU, but to a lesser extent. Similarly, a comparison can be made with the data on the number of persons with health coverage undergoing therapy with the aforementioned medicinal products. The observed downward trend in the number of patients and, accordingly, reimbursed packs could also be due to difficulties in patient access to this medicinal product.

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 export 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, as 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 24.01.2026 to 24.03.2026.

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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