REPUBLIC OF BULGARIA

Ministry of Health

Minister for 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 of 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 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;
- Lantus, Solution for injection, 100 IU/ml – 3 ml, Pack: 5;
- Humalog KwikPen, 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, INN: Amoxicillin/clavulanic acid and INN Cefuroxime in 'powder for oral suspension' and 'granules for oral suspension' pharmaceutical forms.

5. L04AD 'Calcineurin inhibitors' – medicinal products with trade names:

- Sandimmun Neoral, Capsule, soft, 25, mg, Pack: 50;
- Sandimmun Neoral, Capsule, soft, 50, mg, Pack: 50;
- Sandimmun Neoral, Oral solution, 100 mg/ml - 50 ml, -, Pack: 1.

6. J06BD 'Antiviral monoclonal antibodies' – medicinal product with trade name 'Synagis Solution for injection' 100 mg/ml – 0.5 ml.

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 the nerves, blood vessels, eyes, kidneys, and 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 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 the 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. Marketing authorisation holders were asked to provide information on the currently available quantities of the medicinal products from the A10A 'Insulins and analogues' group, the A10BK 'Sodium-glucose co-transporter 2 (SGLT-2) inhibitors' group and the medicinal product with INN Semaglutide, by batch number and expiry

date, as well as information on the quantities of the medicinal products delivered since the beginning of the year and on the quantities of the same group planned for delivery in the next 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 a general conclusion was reached that a difficulty exists regarding the supply of the medicinal products from the A10A 'Insulins and analogues' pharmacological group with the above-mentioned trade names to both pharmacies and patients.

According to the 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 'Sodium-glucose co-transporter 2 (SGLT-2) inhibitors' pharmacological group:

On the territory of our country, a valid marketing authorisation and an established price exist in respect of the following medicinal products: Forxiga film-coated tablet 10 mg (INN Dapagliflozin), Jardiance film-coated tablet 10 mg (Empagliflozin) and Invokana film-coated tablet 100 mg (INN Canagliflozin). These medicinal products, according to the approved Summary of Product Characteristics, have been indicated for the treatment of adults with inadequate control of type 2 diabetes as an addition to their diet and exercise: as monotherapy in cases where the use of metformin is inappropriate due to intolerance 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 11% for the medicinal product Forxiga, respectively. For the medicinal products Jardiance 10 mg and Forxiga 10 mg, the number of patients (the number of insured persons) treated with the specified products has increased significantly. Between June 2024 and June 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 is 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.

In consideration of this data, only the export ban for the medicinal products Forxiga film-coated tablet 10 mg (INN Dapagliflozin) and Jardiance film-coated tablet 10 mg (Empagliflozin) can be justified.

Regarding the medicinal product from the ‘A10B – Blood sugar lowering medicines, excluding insulins’ pharmacological group – the 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). In respect of this product, problems have been found in 6 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:

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: Amoxicillin /clavulanic acid; Cefuroxime and Azithromycin.

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

With regard to the medicinal products from the L04AD ‘Calcineurin inhibitors’ pharmacological group – medicinal products with trade names:_Sandimmun Neoral, Capsule, soft, 25, mg, Pack: 50, Sandimmun Neoral, Capsule, soft, 50, mg, Pack: 50, and Sandimmun Neoral, Oral solution, 100 mg/ml – 50 ml, Pack: 1.

The Ministry of Health (MH) received a letter from the marketing authorisation holder, announcing the discontinuation of sales of the medicinal product Sandimmun Neoral, Capsule, soft, 25 mg, Pack: 50 due to unforeseen circumstances – a delay in the production of the medicinal product batch intended for Bulgaria. A check in the Bulgarian Drug Agency (BDA) register of notifications submitted under Article 54 of the Law on Medicinal Products in Human Medicine showed that a notice of discontinuation of sales was received by the BDA in respect of the above number on 8 August 2025.

Sandimmun Neoral is an immunosuppressive agent that extends the life of allogeneic skin, heart, kidney, pancreas, bone marrow, small intestine and lung transplants. As such, it has indications both inside and outside the field of transplantology, such as nephrotic syndrome, rheumatoid arthritis, psoriasis, atopic dermatitis, etc.

It should be noted that the highest incidence of shortages has been onserved in respect of Sandimmun Neoral Capsule, soft 25 x 50. At the same time, signals regarding shortages have also been reported in respect of the medicinal product Sandimmun Neoral Capsule, soft 50 x 50.

Based on the above, it is necessary to impose a ban on the export of the medicinal products referred to in point 5.

In respect of the medicinal product with the trade name Synagis Solution for injection 100 mg/ml – 0.5 ml:

The Ministry of Health has received a letter from the Marketing Authorisation Holder informing that for the medicinal product Synagis, solution for injection, 100 mg/ml – 0.5 ml – x1 (INN Palivizumab), a quantity sufficient for the vaccination period (autumn/winter season), corresponding to the expected number of patients, has been planned for production and supply in the country.

The medicinal product Synagis, solution for injection, 100 mg/ml – 0.5 ml – x1 (INN Palivizumab) has received a marketing authorisation for the country under a centralised EU procedure. The product is indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease.

Following an analysis of the information received by the Ministry of Health, in conjunction with the information available on the NHIF's website on the costs and number of patients using the medicinal product, and in view of the expected increase in the use of the medicinal product Synagis during the winter months, it is necessary to impose an export ban on the medicinal product referred to in point 6.

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 fact (established by the RHIs) that these medicinal products are not available in pharmacies. One of the possible reasons for this shortage is that these medicinal products may be exported from the Republic of Bulgaria to other countries in such quantities that a shortage may occur 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 in 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 is necessary to impose an export ban on the medicinal products identified in point I.

In addition, by setting the time limit referred to in point III for the export ban on the medicinal products referred to in point I, 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, the non-infringement of the economic operators' right (for an extended period of time) to carry out the free movement of the goods in which they trade (in this case, medicinal products).

The objective sought – to secure the availability on the Bulgarian pharmaceutical market of sufficient quantities of the medicinal products necessary to meet the needs of the population – should be proportionate to the potential economic benefits the marketing authorisations holders would have had, had they been able to export the described products during the period in question. The ban period 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 any rights and legitimate interests to a greater extent than necessary for the purpose for which the act has been 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 prohibition referred to in point I shall be in effect, as follows:

1. In respect of the medicinal products referred to in point I(1) to (5) – from 25 September 2025 to 23 November 2025;

2. In respect of the medicinal product referred to in point I(6) – from 25 September 2025 to 31 March 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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Minister of Health