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 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 following pharmacological groups:

1. A10A ‘Insulins and analogues’ – medicinal products from the group with the following trade names:

- Insulatard Penfill suspension for injection 100 IU/ml - 3 ml, Pack: 5;
- Mixtard 30 Penfill, Suspension for injection, 100 IU/ml-3 ml, Pack 5
- Actrapid Penfill solution for injection 100 IU/ml - 3 ml, Pack: 5;
- Humalog Solution for injection 100 IU/ml - 3 ml, Pack: 10;
- Tresiba solution for injection 100 IU/ml – 3 ml, Pack: 5; cartridges;
- Fiasp solution for injection 100 U/ml – 3 ml, Pack: 10, cartridges;
- Levemir Penfill solution for injection 100 U/ml - 3 ml, Pack: 10;

- NovoMix 30 Penfill, suspension for injection, 100 U/ml - 3 ml, Pack: 10

2. J01 ‘Anti-infectious medicinal products for systemic use’ – medicinal products from the group including INN: Cefuroxime in ‘powder for oral suspension’ and ‘granules for oral suspension’ pharmaceutical forms.

3. 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;

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

5. M05BX – ‘Other medicines affecting bone structure and mineralisation’ – only medicinal products with INN: ‘Denosumab’ and trade name ‘Prolia’;

6. B03XA ‘Other antianaemic preparations’ – medicinal products with 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 (13333 IU/ml - 0.3 ml) x 6 pre-filled syringes.

7. L01AA – ‘Nitrogen yperite analogues’ – medicinal products with INN Ifosfamide and INN Cyclophosphamide

8. L04AG – ‘Monoclonal antibodies’ – medicinal product with INN Vedolizumab.

II. Grounds:

The medicinal products subject to the export ban are intended for the treatment of diabetes, chronic inflammatory diseases of the intestinal tract, osteoporosis, renal failure and certain types of anaemia. The above chronic diseases have social significance and if their treatment is interrupted, this might lead to serious complications and damage to health. If these diseases are not treated, this would lead to a significant increase in hospitalisations of patients, which in turn would place an exceptional burden on hospital care as a health system sector.

In order to analyse the situation regarding the availability of medicinal products for the treatment of diabetes, 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, medicinal products for the treatment of renal failure 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 big and smaller towns and villages were covered by the checks. The marketing authorisation holders were asked to provide information on the currently available quantities of medicinal products from the A10A 'Insulins and analogues' group, the 'Anti-infectious medicinal products for systemic use' group, the A10BK 'Sodium-glucose co-transporter 2 (SGLT-2) inhibitors' group, the A07EC 'Aminosalicylic acid and similar agents' group (medicinal products with INN: 'Mesalazine'), M05BX group – 'Other medicines affecting bone structure and mineralisation' – (medicinal product with INN: 'Denosumab' and trade name: 'Prolia'), medicinal products with trade name: 'NeoRecormon' (INN: Erythropoietin (Epoetin beta), 'Nitrogen yperite analogues' – medicinal products with the INN Ifosfamide and INN Cyclophosphamide, and medicinal products from L04AG 'Monoclonal antibodies' group – medicinal product with INN Vedolizumab by batch number and expiry date, as well as information on the quantities supplied over the last 6 months in respect of the medicinal products from the same groups and on the planned future supplies over the next 6 months. Information on the medicinal products covered by NHIF and the number of persons with health coverage was obtained from the website of the National Health Insurance Fund (NHIF).

The information received was reviewed and analysed, and as a result it was found that a difficulty in supplying both pharmacies and patients with the medicinal products referred to in point I exists.

As regards medicinal products from the pharmacological group A10A – 'Insulins and analogues' bearing the abovementioned trade names:

It has been clearly established that the following insulins with trade names: 'Fiasp cartridges' (Insulin aspart), 'Insulatard Penfil' (INN: Insulin human), 'Tresiba penfil' (INN: Insulin degludec), 'Mixtard 30 Penfill' (INN: Insulin human), 'Levemir Penfill' (INN: Insulin detemir), 'Actrapid Penfil' (INN: Insulin human), 'Humalog 300 IU (INN: Insulin Lispro) and NovoMix 30 Penfill (INN: Insulin aspart) are not regularly supplied/are supplied in insufficient quantities or their supply is delayed in 6 to 13 of all the regions in the country, or in about 18% to 50% of the regions.

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.

As regards the medicinal products from the 'Anti-infectious medicinal products for systemic use' pharmacological group – medicinal products from the group including INN: Cefuroxime in 'powder for oral suspension' and 'granules for oral suspension' pharmaceutical forms.

The data provided by the Regional Health Inspectorates (RHIs) indicate that delayed and irregular supplies, including refusal by the wholesalers' warehouses, have been observed in 21% of the regions as regards the medicinal products belonging to INN Cefuroxime.

Following an analysis of the data, it is necessary that an export ban be imposed as regards the medicinal products referred to in point 2.

As regards 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 not appropriate due to intolerability or in addition to other medicinal products for the treatment of diabetes.

Reports of shortages, supply difficulties or refusals by warehouses have been observed in about 21% of the regions as regards the medicinal product 'Jardiance' and 18% of the regions as regards the medicinal product 'Forxiga'.

In consideration of 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 with INN Mesalazine:

The therapeutic indications of the medicinal products with the trade name 'Salofalk' include ulcerative colitis (treatment of acute conditions and prevention of relapse) and Crohn's disease (treatment of acute conditions).

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 50% of the regions, as shortages of this medicinal product have been reported in 90 pharmacies. Based on the analysed data, we can conclude that the difficulty to supply the medicinal products with the trade 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.

Given these circumstances, it is necessary to impose a ban on the export of medicinal products containing INN 'Mesalazine'.

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

In recent months, citizens have alerted the Ministry of Health to difficulties in obtaining the medicinal product with the trade name ‘Prolia’ (INN Denosumab). According to the approved summary of product characteristics, ‘Prolia’ is intended for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures.

The medicinal product ‘Prolia’ has been reported as being in short supply in 57% of all regions in the country. Out of the total number of 327 pharmacies inspected by the RHI, 133 (i.e. more than 40%) signalled for difficulties in obtaining the medicinal product. An in-depth review of the information shows that 80 pharmacies reported irregular supply, 16 pharmacies reported being supplied smaller quantities than the quantities ordered, and 58 pharmacies reported refusals by the wholesaler’s warehouse.

Data on the number of persons with health coverage and the number of packs of the ‘Prolia’ medicinal product covered by the NHIF for the period from March 2025 to March 2026 demonstrate a relatively stable 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.

For medicinal products with INN ‘Erythropoietin’ (Epoetin beta) and 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:

The above-mentioned medicinal products belonging to INN ‘Erythropoietin’ (Epoetin beta) are authorised for use in the country under a centralised EU procedure. Treatment of Bulgarian citizens with these two medicinal products is reimbursed by the National Health Insurance Fund (NHIF) for the following diseases: N18.8 ‘Other manifestations of chronic renal failure’ and N18.0 ‘Terminal stage of renal disease’. The frequency of administration of the products in the therapeutic diagnostic algorithm set out in the ‘Requirements of the NHIF for the treatment of chronic renal failure in predialysis in outpatient care’ may vary between 3 times a week (for corrective treatment) and from 1 to 3 times a week (in the case of supportive treatment), with the dosage taking into account the haemoglobin level, which in turn implies continuity in the supply chain.

For the above-mentioned medicinal products, a check in the publicly accessible database of the Bulgarian Drug Agency (BDA) showed that on 19 November 2025, the BDA received a notification of discontinuation of sales until the end of June 2027.

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 insulin consumption, given that these types of products are usually supplied to the patient after a prior request at a pharmacy.

Analysis of information on the consumption of the medicinal products in the period October 2024–December 2025 has revealed that at the end of 2024, consumption of the medicinal product ‘Neorecormon’ 3000 IU has sharply declined, and a downward trend was observed in the months that followed. Similar dynamics is 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 the obstructed patient access to this medicinal product.

With respect to medicinal products with INN Ifosfamide and INN Cyclophosphamide.

According to the Summary of Product Characteristics for medicinal products with the INN Ifosfamide, these are indicated for:

- testicular tumours,
- combination therapy in patients with advanced tumours at stages II to IV, according to the TNM classification, who have shown an inadequate response or no response to initial chemotherapy;
- Ovarian carcinoma;
- Cervical cancer;
- As monotherapy of patients with advanced tumours and in cases of recurrence;
- Breast carcinoma.
- For palliative treatment of advanced refractory or recurrent breast carcinoma;
- For use as monotherapy or in combination chemotherapy of patients with inoperable or metastatic tumours;
- Small cell bronchial carcinoma;
- Soft tissue sarcomas;
- Ewing sarcoma;
- Pancreatic carcinoma;
- Non-Hodgkin's lymphomas;
- Hodgkin's disease;

A search of the Bulgarian Drug Agency’s (BDA) publicly accessible register of notifications submitted by marketing authorisation holders regarding the temporary or permanent suspension of sales (pursuant to Article 54 of the Law on Medicinal Products for Human Use)

revealed that, as regards the medicinal product ‘Holoxan’ powder for solution for infusion, 2 g, pack: 1, on 4 March 2026, the BDA received a notification from the marketing authorisation holder regarding a temporary suspension for operational reasons. The period of suspension of sales is from 7 May 2026 to 31 March 2027. The information gathered shows that in the month in which the BDA received the notification of the temporary suspension of sales of the medicinal product, the number of packs delivered to hospital pharmacies during that month increased significantly.

In view of the importance of the medicinal product and its role in treatment regimens for patients with malignant diseases, as well as the information received from the BDA regarding a potential shortage of the medicinal product at European level, combined with the notification received from the marketing authorisation holder regarding the temporary suspension of sales of ‘Holoxan’ powder for solution for infusion, 2 g for the period from 7 May 2026 to 31 March 2027, we can conclude that if the product’ export is not banned, in the upcoming months patients will face difficulties in accessing the medicinal product.

Regarding the medicinal products with INN Cyclophosphamide. A search of the BDA’s publicly accessible register of notifications submitted by marketing authorisation holders regarding the temporary or permanent suspension of sales (pursuant to Article 54 of the Law on Medicinal Products for Human Use) revealed that, regarding the medicinal product ‘Endoxan’ powder for solution for injection, 500 mg, pack: 1, a notification has been submitted to the IAL by the marketing authorisation holder regarding a temporary suspension for operational reasons. The period of suspension of sales is from 7 May 2026 to 31 March 2027.

According to the Summary of Product Characteristics for the medicinal product with trade name ‘Endoxan’ powder for solution for injection, 500 mg, it is used as part of a combination chemotherapy regimen or as monotherapy for leukaemia, malignant lymphomas, or metastatic and non-metastatic malignant solid tumours. It is also used in cases of progressive autoimmune diseases, during immunosuppressive therapy following organ transplantation, and in the period leading up to allogeneic bone marrow transplantation.

In view of the extended period of suspension of sales until 31 March 2027, we propose that the possibility for exporting the product be restricted.

As regards the medicinal products with the trade name ‘Entyvio’ (INN Vedolizumab).

Over the last months, the Ministry of Health has received numerous reports from patients regarding a shortage in pharmacies of medicinal products with the trade name ‘Entyvio’. According to the Summary of Product Characteristics, these products are indicated for the treatment of ulcerative colitis and Crohn’s disease. Based on the available information regarding stock levels at wholesalers and patient numbers, as well as on signals received by the Ministry of Health, we can conclude that the medicinal products with the trade name ‘Entyvio’ are not regularly supplied; therefore, its export must be restricted.

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 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, 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 apply from 27 May 2026 to 26 July 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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