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 Medicinal Products in Human Medicine Act of the medicinal products Neorecormon, solution for injection, 2000 iu (6667 iu/ml — 0.3 ml) x 6 pre-filled syringes and Neorecormon, solution for injection, 3000 iu (10000 iu/ml - 0.3 ml) x 6 pre-filled syringes, belonging to the international non-proprietary name (INN) Erythropoietin (Epoetin beta) (recombinant human erythropoietin), which have been granted a marketing authorisation under 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.

II. Grounds:

The medicinal products Neorecormon, solution for injection, 2000 iu (6667 iu/ml — 0.3 ml) x 6 pre-filled syringes and Neorecormon, solution for injection, 3000 iu (10000 iu/ml — 0.3 ml) x 6 pre-filled syringes 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 a need for administration 3 times a week (for corrective treatment) and 1 to 3 times a week (in the case of supportive treatment), with the dosage taking into account the level of haemoglobin, which in turn implies continuity in the supply chain.

The Ministry of Health has received a letter from the authorised representative of the Marketing Authorisation Holder (MAH) of the medicinal products under item I, informing of the expected (from June) temporary suspension of sales in the Republic of Bulgaria of the medicinal product NeoRecormon injectable solution in pre-filled syringe, INN Erythropoietin (Epoetin beta) as a result of unforeseen circumstances in the manufacture of the product.

In this regard, the Ministry of Health has requested the Bulgarian Drug Agency (BDA) to carry out a timely inspection of wholesale distributors (WD) and MAHs regarding the available quantities of medicinal products, deliveries made since the beginning of the year, as well as planned deliveries in the country for medicinal products belonging to INN: Erythropoietin (Epoetin beta). Information is also required on the regularity of deliveries from the MAH to the WDs in the country, as well as on intentions for future supplies.

The expert councils of the medical specialties "Paediatric Nephrology and Haemodialysis" and "Nephrology" were also informed.

Subsequently, a second letter was received from the representative of the MAH in Bulgaria, informing the Ministry of Health of the extension until the next year of the temporary suspension of sales for the medicinal products referred to in item I (until January and February 2026).

In due time, the BDA was requested to re-examine the quantities available in the warehouses of MAHs and WDs, deliveries made since the beginning of the year, as well as planned deliveries in the country for medicinal products belonging to INNs: Erythropoietin (Epoetin beta). It has been established that the planned deliveries for the month of August have not taken place.

On the basis of the data provided by the BDA, an analysis has been conducted on the consumption and supply of the pharmaceutical market with the specified products, according to which it was established that for the medicinal product Neorecormon, Solution for injection, 2000 IU, the total stock for a period of about 2 months has decreased by 355 packages, which significantly exceeds the average monthly sales reimbursed by the NHIF by more than 3.4 times.

For the medicinal product Neorecormon, Solution for injection, 3000 IU, there is a downward trend in the number of patients and, consequently, reimbursed packages, which could also be due to the difficulty of patients' access to this medicinal product and the demand for a therapeutic alternative. The total availability for a period of about 2 months has decreased by 500 packages, which exceeds the average monthly sales reimbursed by the NHIF for the period since the beginning of the year by more than 1.8 times.

If it is not exported from the country and the current rate of consumption is maintained, the available quantities of this medicinal product would meet the needs of patients until mid-September this year (approximately one and a half months).

In view of the analysis carried out and the fact that sales of the medicinal products will be suspended until January and February 2026, it is necessary to impose a ban on their export.

Despite the presence of legislation mechanisms to restrict the export of medicinal products, laid down in Chapter Nine "b" "Export of Medicinal Products. A specialised electronic system for the traceability and analysis of medicinal products" in the Law on medicinal products in human medicine, as is apparent from the analysis of the data referred to above, that there is a high risk of shortages of the medicinal products referred to in item I. The export of medicinal products without restrictions creates a prerequisite for shortages on the internal market, especially in the light of limited availability.

Irrespective of the legal nature of the activity carried out, the export of the medicinal products referred to in item I would disturb the balance between the quantities supplied to the national territory and the increased needs to meet the requirements.

Furthermore, by setting the deadline specified in item III of the order for the prohibition of exports of the medicinal products Neorecormon, Solution for injection, 2000 IU, and Neorecormon, Solution for injection, 3000 IU, a balance will be achieved between the objective of the measure applied — ensuring sufficient quantities of the medicinal product necessary for the treatment of patients with chronic renal failure protecting their health and ensuring their well-being, on the one hand, 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 of ensuring that the Bulgarian medicinal market is supplied with sufficient quantities of the medicinal products to meet the needs of the population should be proportionate to the possible economic benefits that the marketing authorisation holders for medicinal products would have if they had been able to export the medicinal products during that period. The prohibition 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 prohibition has 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 under item I shall be in force from the issuance of this Order until 15 February 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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