ORDER No RD-01-332 OF 15 MAY 2024 BANNING THE EXPORT OF MEDICINAL PRODUCTS WITHIN THE MEANING OF ARTICLE 217A, PARAGRAPH 3 OF THE LAW ON MEDICINAL PRODUCTS FOR HUMAN USE

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 for use 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 for use 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’ – all medicinal products in the group;

2. A10B ‘Blood sugar lowering medicines excluding insulins’ – a medicinal product with ATC code A10BJ06 in injection dosage form;

3. J01 ‘Anti-infectious medicinal products for systemic use’ – all medicinal products in the group in ‘powder for oral suspension’ and ‘granules for oral suspension’ dosage forms.

II. Grounds:

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. Increased blood sugar, hyperglycemia, is the result of uncontrolled diabetes and over time leads to serious damage to many of the body’s systems, especially nerves and blood vessels.

Type 1 diabetes (known as insulin dependent) is characterised by insufficient insulin production and requires daily parenteral insulin administration.

Type 2 diabetes affects the way glucose in the body is absorbed and transformed into energy. This is a pathological condition in which cells either fail to respond normally to the hormone insulin or reduce the number of insulin receptors in response to hyperinsulinaemia.

The main danger in diabetes is its chronic complications. Diabetes leads to the development of damage to the eyes, kidneys, nervous system, cardiovascular diseases, brain strokes, pain in the lower extremities, etc.

In mid-April, in accordance with Order No RD-01-277/15.04.2024 of the Minister for Health, the export of the medicinal products referred to in point I was banned. In order to analyse the situation regarding their availability on the market and patients' access to them, information was requested from the Bulgarian Drug Agency (BDA) on the availability of medicinal products from the pharmacological groups subject to the export ban in the warehouses of wholesalers and pharmacies, from the Regional Health Inspectorates on the checks carried out in open-type pharmacies on the availability of medicinal products, covering large and smaller towns and villages, as well as from Information Services AD on the prescribed and dispensed quantities of the medicinal products that fall within the scope of the ban.

Following an analysis of the data received from the above-mentioned institutions, there are indications of irregular deliveries/delays or refusals from wholesalers' warehouses to supply the medicinal products from the following pharmacological groups: A10A 'Insulins and analogues', J01 'Anti-infectious medicinal products for systemic use' (in 'powder for oral suspension' and 'granules for oral suspension' dosage forms) and A10B 'Blood sugar lowering medicines excluding insulins' – a medicinal product with ATC code A10BJ06 in injection dosage form.

Irregular supply, delays or refusals from the warehouses have been reported in respect of one of the insulins from the A10A 'Insulins and analogues' pharmacological group in more than 2/3 of all provinces in the country. Irregular supply, delays or refusals from the warehouses have been reported in respect of seven types of insulins from this pharmacological group in almost all provinces in the country.

Following an analysis of the information received from the BDA, compared to the information on the average monthly consumption of medicinal products by insured individuals published on the website of the National Health Insurance Fund (NHIF), a difficulty in the supply to both pharmacies and patients with the medicinal products of the A10A 'Insulins and analogues' pharmacological group was established.

As regards the medicinal product with INN Semaglutide:

The checks carried out by the Regional Health Inspectorates and the analysis of the information received from the BDA and of the average monthly consumption of the medicinal product established difficulties in the supply of the medicinal product in pharmacies in the following provinces: Blagoevgrad, Burgas, Varna, Lovech, Razgrad, Haskovo.

As regards the medicinal products from the J01 'Anti-infectious medicinal products for systemic use' pharmacological group – all medicinal products from the 'powder for oral suspension' and 'granules for oral suspension' drug forms:

Following a review and analysis of the information received, it was established that the greatest delays, irregular supplies and refusals from the warehouses of wholesalers have taken place in respect of medicinal products belonging to INN: Amoxicilline, clavulanic acid – seven

medicinal products out of 29 with reports of bottlenecks in supply. 86 % of the provinces in the country reported refusals and/or irregular supplies for one of these seven medicinal products. As regards the remaining six medicinal products, delays or refusals to supply have been reported in between 54 % and 32 % of the provinces in the country.

Notwithstanding the export restriction mechanisms set out in Chapter Nine ‘b’ ‘Export of Medicinal Products. Specialised electronic system for follow-up and analysis of medicinal products’ of the Law on Medicinal Products for Human Use, there is a continuous shortage of medicinal products, as evidenced by the analysis of the data received from the above-mentioned institutions. Proof of this are the continuous signals of missing medicines in the pharmacy network received at the Ministry of Health. One of the possible reasons for this shortage is the fact that these products are being exported from the Republic of Bulgaria to other countries in quantities that create conditions 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 used for the treatment of diabetes and of antibacterial medicinal products for systemic use, as well as the observed delays in the supply disturb the balance between the medicinal products supplied in the country and the increased needs for these medicinal products 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, a need has been identified to impose an export ban on the groups of medicinal products referred to in point I.

Next, setting the time limit in point III for the export ban on the medicinal products referred to in point I will lead to a balance 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 treatment, 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, i.e. 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 for the administrative act and its implementation to 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 prohibition, as well as 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 17.05.2024 until 16.06.2024.

IV. The order shall be published on the website of the Ministry of Health and sent to the Customs Agency for information and implementation.

DR. GALYA KONDEVA
MINISTER FOR HEALTH