

/coat of arms/

Republic of Serbia

MINISTRY OF HEALTH

No.: 515-04-11536/2021-11

Date: 04/02/2022

Belgrade, Nemanjina 22-26

SI

The Minister of Health of the Republic of Serbia, deciding upon the application of the company "INO-PHARM" d.o.o., Belgrade, Bore Stankovića Str. No. 2, for the issuance of a wholesale distribution authorisation for medicinal products, pursuant to Article 212, Paragraph 6 of the Medicines and Medical Devices Act ("Official Gazette of the Republic of Serbia", No. 30/2010, 107/2012, 105/2017 – other law and 113/2017 – other law), Article 37 of the Law on Inspection Oversight ("Official Gazette of the Republic of Serbia", No. 36/2015, 44/2018 – other law and 95/2018), and Articles 136 and 184 Paragraphs 1 and 2 of the General Administrative Procedure Act (Official Gazette of the Republic of Serbia No. 18/2016 and 95/2018-authentic interpretation), passes the following

DECISION

I The trade and services company "INO-PHARM" d.o.o., Belgrade (Čukarica), Bore Stankovića Str. No. 2, IS GRANTED AN AUTHORISATION for the wholesale distribution – import, export, supply, storage and distribution of medicinal products on the territory of the Republic of Serbia, from the office and storage premises with a total area of 250.50 m² in **Belgrade (Čukarica), Bore Stankovića Str. No. 2, of the following:**

1. Medicines for human use in accordance with the ATC (Anatomical Therapeutic Chemical) classification of the following main anatomical groups:

Group A – Medicines affecting digestive and metabolic diseases

Group B – Medicines for the treatment of diseases of blood and blood-forming organs

Group C – Medicines affecting the cardiovascular system

Group D – Medicines for the treatment of diseases of skin and subcutaneous tissue

Group G – Medicines for the treatment of the genitourinary system and sex hormones

Group H – Systemic hormonal preparations

Group J – Anti-infectives for systemic use

Group L – Antineoplastic and immunomodulating agents

Group M – Medicines for the diseases of the musculoskeletal system

Group N – Medicines affecting the nervous system

Group P – Antiparasitic products, insecticides and repellents

Group R – Medicines for the treatment of respiratory tract diseases

Group S – Medicines affecting the eye and the ear

Group V – Other therapeutic products (excluding medicines in the main therapeutic groups V09 and V10).

2. Herbal medicines

3. Traditional medicines



4. Homoeopathic medicines

5. Clinically tested medicines

II The AUTHORISATION issued by the Ministry of Health, number 515-04-06623/2021-11 of July 30th, 2021 IS REVOKED.

Grounds for the decision

The company "INO-PHARM" DOO Belgrade, was issued the Decision by the Ministry of Health, number 515-04-06623/2021-11 of July 30th, 2021, with the wholesale distribution authorisation for medicinal products from the office and storage space in Belgrade, at the address Bore Stankovića Str. No. 2.

On December 29th, 2021, the company "INO-PHARM" DOO Belgrade, due to the extension of its storage facilities, submitted a request to the Ministry of Health for the issuance of a new wholesale distribution authorisation – import, export, supply, storage and distribution of medicinal products on the territory of the Republic of Serbia, from the office and storage premises with a total area of 250.50 m² in Belgrade (Čukarica), Bore Stankovića Str. No. 2, for medicinal products for human use in accordance with the ATC (Anatomical Therapeutic Chemical) classification for all the main anatomical groups, herbal medicines, traditional medicines, homoeopathic medicines and clinically tested medicines. The application was accompanied by the necessary supporting evidence.

Acting upon the submitted request, pursuant to Article 208, Paragraph 3, Item 2) of The Medicines and Medical Devices Act (Official Gazette of the Republic of Serbia, No. 30/2010, 107/2012, 105/2017 – other law and 113/2017 – other law), the medicinal products and medical devices inspector performed an inspection of the space and equipment for storage of medicinal products, the inspection of the vehicles, as well as verification of compliance with requirements regarding the employees qualifications as set out in the protocol of the inspection number 515-04-11536/2021-11 dated February 3rd 2022.

Based on the inspector's protocol and the submitted documentation, it has been determined that the requirements for the performance of wholesale distribution of medicinal products stipulated by the Medicines and Medical Devices Act (Official Gazette of the Republic of Serbia, No. 30/2010, 107/2012, 105/2017 – other law and 113/2017 – other law), and Article 3, Article 8 Paragraph 1, Item 1), Articles 9, 10, 11, 15. Paragraph 1, Items 1), 2) and 3), Article 19, Article 24, Paragraph 5 and Article 30 of the Regulations on Requirements for Wholesale Distribution of Medical Devices, the data entered into the Register of issued authorisations for wholesale distribution of medicinal products and medical devices, as well as the method of entry (Official Gazette of the Republic of Serbia No. 10/2012, 17/2017 and 84/2018 – other law). Medical devices will also be stored in the same space, but they will be organizationally separated.

By passing this Decision, the Decision issued by the Ministry of Health, No. 515-04-06623/2021-11 dated July 30th, 2021 is revoked.



Certified Translation from Serbian into English Language

On the basis of the foregoing, it was decided as in the wording of the document. This Decision shall be final in the administrative procedure.

The Decision may be disputed in the administrative proceedings initiated before the competent court within 30 days as of the receipt hereof.

The applicant paid the administrative fee for this application according to tariff No. 182 of the Administrative Fees Act (Official Gazette of the Republic of Serbia No. 98/2020, 144/20, 62/21).

MINISTER

Zlatibor Lončar, M.D.

(signed and sealed)

Served to:

1. "INO-PHARM" DOO Belgrade,
Belgrade, Čukarica, Bore Stankovića Str. No. 2
2. Archives Department

- End of translation -

I, the undersigned court authorised translator, appointed by the Decision of the Ministry of Justice of the Republic of Serbia no. 128-4-2016-1, hereby certify that this translation fully corresponds to the Serbian original.

*In Pancevo, February 22, 2022
No.91 /2022*

*Court Authorised
Translator/Interpreter,
Ana Lješević*

