

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH BEGINS

/coat of arms of the Republic of Serbia/

Republic of Serbia

MINISTRY OF HEALTH

Number: 004902233 2025 11900 008 004

530 128

Date: December 30th, 2025

Belgrade, Nemanjina 22-26

JPM

The Minister of Health of the Republic of Serbia, deciding upon the application of the Trade and Services Company “INO-PHARM” d.o.o. (Ltd.) Belgrade, Bore Stankovica Str. No. 2 for issuing a wholesale distribution authorisation for medicines, pursuant to Article 212, Paragraph 6 of the Medicines and Medical Devices Act (RS Official Gazette No. 30/2010, 107/12, 105/2017 – other law and 113/2017 – other law), and pursuant to Article 37 of the Law on Inspection Supervision (“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 Law on General Administrative Procedure (“Official Gazette of the Republic of Serbia”, No. 18/2016, and 95/2018 – authentic interpretation), hereby passes the following

DECISION

I The trade and services company “INO-PHARM” d.o.o., Belgrade (Cukarica), Bore Stankovica Str. 2, **IS GRANTED AN AUTHORISATION** for the wholesale distribution – import, export, supply, storage and distribution in the territory of the Republic of Serbia, from the office and storage space of a total area of 250.50 m² in Belgrade, (Cukarica), Bore Stankovica 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:

- A** – Medicines affecting digestive and metabolic diseases;
- B** – Medicines for the treatment of diseases of blood and blood-forming organs;
- C** – Medicines affecting the cardiovascular system;
- D** – Medicines for the treatment of diseases of skin and subcutaneous tissue;
- G** – Medicines for the treatment of the genitourinary system and sex hormones;
- H** – Systemic hormonal preparations;
- J** – Anti-infectives for systemic use;
- L** – Antineoplastic and immunomodulating agents;
- M** – Medicines for the diseases of the musculoskeletal system;
- N** – Medicines affecting the nervous system;
- P** – Antiparasitic products, insecticides and repellents;
- R** – Medicines for the treatment of respiratory tract diseases;
- S** – Medicines affecting the eye and the ear;
- V** – Other therapeutic products (including medicines in the groups V09 and V10).

2. Herbal medicines;
3. Traditional medicines;
4. Homeopathic medicines;
5. Clinically tested medicines.
6. Medicinal products for human use being clinically tested in accordance with the ALIMS (The Agency for Medicines and Medical Devices) license for conducting clinical trials of all anatomical groups according to the ATC (Analytical Medicines and Therapeutics) classification specified in Point 1.

II THE DECISION of the Ministry of Health number 515-04-11536/2021-11 of February 4th, 2022 **IS REVOKED**.

Grounds for the decision

The trade and services company “INO-PHARM” DOO Belgrade was issued the Decision of the Ministry of Health No. 515-04-11536/2021-11 of February 4th, 2022, with a the wholesale distribution authorisation for medicines, from the office and storage space in Belgrade-Cukarica, Bore Stankovica Str. no. 2, namely medicines for human use according to ATC (Anatomical Therapeutic Chemical) classification for all the main anatomical groups, except for V09 and V10 (within group V – other therapeutic products), herbal medicines, traditional medicines, homeopathic medicines and medicines being clinically tested.

On December 5th, 2025, the Trade and Services Company “INO-PHARM” DOO (Ltd.) Belgrade, due to the expansion of the range of the medicinal products being traded, submitted an application to the Ministry of Health for the issuance of an amendment to the wholesale distribution authorisation – import, export, supply, storage and distribution of medicines on the territory of the Republic of Serbia, from office and storage premises, with a total area of 250.50 m² in Belgrade (Cukarica), Bore Stankovica Str. no. 2. The amendment to the authorisation refers to the addition of medicines for human use according to the ATC (Anatomical Therapeutic Chemical) classification, namely: the therapeutic groups V09–diagnostic radiopharmaceuticals and V10–therapeutic radiopharmaceuticals are also included within the anatomical group of medicines V – other therapeutic products. Together with the application, the applicant submitted the necessary evidence regarding the premises, equipment and personnel for the trade in radiopharmaceuticals.

Acting upon the submitted application, and based on 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 Inspector for Medicines and Medical Devices inspected the premises and equipment for the housing and storage of medicines, inspected the means of transport, and checked whether the requirements regarding the professional qualifications of the employees had been met, as determined by the inspector's report No. 004902233 2025 11900 008 004 530 128 of December 29th, 2025.

Based on the inspector's report and the submitted documentation, it was established that the conditions for performing the activity of wholesale trade in medicines, prescribed 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, Item 1), 2) and 3), Article 19, Article 24, Paragraph 5 and Article 30 of the Regulations on Requirements for the Wholesale Distribution of Medicines and Medical Devices, the data entered in the Register of issued authorisations for the wholesale trade of medicines and medical devices, as well as the mode of entering (“Official Gazette of the Republic of Serbia”, No. 10/2012, 17/2017 and 84/2018 – other regulations). The medical devices, which are functionally separated from the medicines, will also be stored in the same area.

By adopting this Decision, the Decision of the Ministry of Health No. 515-04-11536/2021-11 of February 4th, 2022 is hereby revoked.

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 (thirty) days as of the receipt hereof.

The applicant has paid the republic administrative fee for this Decision according to tariff number 182 of the Republic Administrative Fees Act (“Official Gazette of the Republic of Serbia”, No. 98/20, 144/20, 62/21; 54/23; 59/24; 94/24; 55/25).

Served to:

1. “INO-PHARM” DOO, Belgrade (Cukarica),
Bore Stankovica Str. no. 2
2. Archives Department

MINISTER:

Zlatibor Lončar, M.D.
/signed: Zlatibor Lončar/

/Round seal: REPUBLIC OF SERBIA, MINISTRY OF HEALTH, BELGRADE/

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH ENDS

On this day, February 12, 2026, I, REBEKA BOŽOVIĆ, a permanent sworn-in court translator for English and Japanese, appointed on December 26, 2005 by the Decision of the Minister of Justice of the Republic of Serbia, with the registration number 740-06-638/2005-03, declare:

“I hereby confirm that this translation fully corresponds to the original text which is written in the Serbian language.”

