



Republic of Serbia
MINISTRY OF HEALTH

No.: 515-04-07673/2020-11

Date: November 10th, 2020

Belgrade, Nemanjina 22-26

VV

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 – state law and 113/2017 – state law), Article 37 of the Law on Inspection Oversight ("Official Gazette of the Republic of Serbia", No. 36/2015, 44/2018 – state 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, 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 in the territory of the Republic of Serbia, from the office and storage space of a total area of 360.35 m² in Belgrade, Peke Dapčevića Boulevard No. 17, 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 515-04-05418/2019-11 of October 10th, 2019 **IS REVOKED**.



Grounds for the decision

The company "INO-PHARM" DOO Belgrade, was issued the Decision by the Ministry of Health, number 515-04-05418/2019-11 of October 10th, 2019 with the wholesale distribution authorisation for medicinal products from the office and storage space in Belgrade, at the address Milošev Kladenac 9v.

On October 22nd, 2020, the company "INO-PHARM" DOO Belgrade, due to the relocation of its storage facilities to the new address, submitted a request to the Ministry of Health for the issuance of a 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 360.35 m² in Belgrade, Peke Dapčevića Boulevard No. 17, 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, clinically tested medicines.

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. 30/10 and 107/12, the medicinal products and medical devices inspector performed an inspection of the space and equipment for storage of medicinal products, the inspection of vehicles, as well as verification of compliance with requirements regarding employee qualifications as set out in the protocol of the inspection number 515-04-07673/2020-11 dated November 5th and November 10th, 2020.

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. 30/10 and 107/12) 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. 10/12 and 17/17).

By passing this Decision, the Decision issued by the Ministry of Health, No. 515-0405418/2019-11 dated October 10th, 2019 is 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 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. 38/2019).

Served to:

1. "INO-PHARM" DOO, Belgrade,
Belgrade, Bore Stankovica No. 2
2. Archives Department

MINISTER

Zlatibor Lončar, M.D.
(signed and sealed)

Certified in full conformity with the original text in Serbian by Milan Vurdelja, Sworn Court Translator by appointment of the Ministry of Justice, Belgrade (#740-06-773/98-04).

Number: 072-2/20
Date: 02/12/2020



Milan Vurdelja