

Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-3619/2023-11
Date: 13/10/2023
Belgrade, Nemanjina 22-26
Phone: 011 26-00-749
VV

The Minister of Health of the Republic of Serbia, acting upon the application of The Limited Liability Company PHOENIX PHARMA DOO, BELGRADE (ČUKARICA), Belgrade-Čukarica, Bore Stankovića Street 2, for the issue of a license for the wholesale of medicines, and pursuant to article 212, paragraph 6 of the Law on medicines and medical devices ("Official Gazette of RS" number 30/2010, 107/12), article 37 paragraph 1 of the Law on inspection oversight ("Official Gazette of RS" number 36/2015), articles 136 and 184 of the Law on general administrative procedure ("Official Gazette of Republic of Serbia" number 18/2016) brings forward a

DECISION

I The Limited Liability Company **PHOENIX PHARMA DOO, BELGRADE (ČUKARICA)**, Belgrade-Čukarica, Bore Stankovića Street 2, **IS ISSUED A LICENSE** for the wholesale of medicines – importing, exporting, procuring, storage and distribution, at the territory of Republic of Serbia, on the commercial-warehouse premises encompassing a total area of 2136.79m², situated at Šimanovci, Dositejeva street 33, including:

1. Medicines for human use belonging to the following groups according to ATC (Anatomical Therapeutic Chemical) classification:

- A – Alimentary tract and metabolism (medicines for the treatment of the diseases of the digestive system and metabolism),
- B – Blood and blood-forming organs (medicines that treat disorders of blood and blood-forming organs),
- C – Cardiovascular system (medicines that act on the cardiovascular system),
- D – Skin and subcutaneous tissue (medicines for the treatment of skin and subcutaneous tissue diseases),
- G – Genitourinary system and sex hormones (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 – Musculoskeletal system (medicines for the diseases of the musculoskeletal system),
- N – Nervous system (medicines that act on the nervous system),
- P – Antiparasitic products, insecticides and repellents,
- R – Respiratory system (medicines for the treatment of the respiratory diseases),
- S – Sensory organs (medicines that act on the eye and ear),
- V – Various, except for the medicines in the main therapeutic subgroups: V09 (radiopharmaceuticals) and V10 (therapeutic radiopharmaceuticals)



2. Medicines for human use which are tested through clinical trials in accordance with the Clinical trial license of the Serbian Agency for medicines and medical devices, including all anatomical groups according to ATC (Anatomical Therapeutic Chemical) classification listed in item 1 of this Decision;

3. Herbal medicines

4. Traditional herbal medicines

5. Homeopathic medicines

6. Starting materials for production, i.e. manufacturing of galenic or magistral medicines in the original manufacturer's packaging, except for penicillin antibiotics, cytostatics, starting materials which belong to the psychoactive controlled substances, or precursors, that belong to the group of poisons.

II The decision of the Ministry of Health number: 515-04-03537/2021-11 dated 25/05/2021 is declared NULL AND VOID.

Reasoning

The Limited Liability Company PHOENIX PHARMA DOO, BELGRADE (ČUKARICA), Belgrade-Čukarica, Bore Stankovića Street 2, holds the decision of the Ministry of Health number: 515-04-03537/2021-11 dated 25/05/2021 for the wholesale of medicines, listed in the enacting terms of the decision, on the commercial-warehouse premises encompassing a total area of 5248.24m², situated at Simanovci, Dositejeva Street 33.

The Limited Liability Company PHOENIX PHARMA DOO, BELGRADE (ČUKARICA), Belgrade-Čukarica, Bore Stankovića Street 2, filed an application on 11/04/2023 to the Ministry of Health for the issue of a license for the wholesale of medicines because of the decrease in surface area of the commercial-warehouse space from 5098.20m² to 2136.79m². The wholesale of medical devices is also performed on the same premises, in the space functionally separated from the medicines. The party provided the necessary proofs to complete the application.

Acting upon the submitted application, and pursuant to article 208 paragraph 3 item 2 of the Law on medicines and medical devices ("Official Gazette of RS" number 30/10 and 107/12), the inspector for medicines and medical devices carried out an inspection of the space and equipment for storage and preservation of medicines situated at Simanovci, Dositejeva Street 33, as well as an evaluation of fulfillment of criteria regarding the education level of employees, as determined by the inspector's minutes number: 515-04-03619/2023-11 dated 21/09/2023.

On the basis of the inspector's records and the submitted documentation, it was determined that the prescribed criteria for performing an activity of the wholesale of medicines were fulfilled in accordance with articles 120-123, of the Law on medicines and medical devices ("Official Gazette of RS" number 30/10 and 107/12) and articles 3, 4, 10, 11, 13, 15, 21, 22 and 30 of the Rulebook on conditions for performing wholesale of medicines and medical devices, the data which are subject to registration in the Register of the issued licenses for the wholesale of medicines and medical devices, as well as the way of recording ("Official Gazette of RS" number 10/12 and 17/17) as decided in Item 1 of the wording of this decision.

The issue of this decision invalidates the decision of the Ministry of Health number: 515-04-03537/2021-11 dated 25/05/2021.

This decision is final in an administrative proceeding.

It is possible to initiate an administrative dispute against it before the competent court within 30 (thirty) days of the date it was served.

The applicant was charged a republic administrative fee for this decision on the basis of the tariff number 182 of the Law on republic administrative taxes ("Official Gazette of RS" number 98/20).

Delivered to:

1. **PHOENIX PHARMA DOO**

Belgrade-Čukarica, Bore Stankovića Street 2

2. Archives

MINISTER

Prof. Danica Grujičić, PhD

(Handwritten signature)

Round seal

-The end of translation-

I, the undersigned court authorised translator, appointed by the decision of the Ministry of Justice of the Republic of Serbia no. 740-06-747/2006-03, hereby certify that this translation fully corresponds to the Serbian original.

Belgrade, 17/01/2024

No. 176/2024

Court Authorised English Translator/Interpreter,
Ivana Ikodinović

