

Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-3537/2021-11
Date: 25 May 2021
Belgrade, Nemanjina 22-26
Tel.: 011 26-00-749
DBM

The Minister of Health of the Republic of Serbia, in consideration of the Application of Limited Liability Company PHOENIX PHARMA DOO, BEOGRAD, Belgrade-Čukarica, 2 Bore Stankovića Street, for the issuance of a Marketing Authorization for the wholesale of medicines, and pursuant to Article 212, Paragraph 6 of the Law on Medicines and Medical Devices ("Official Gazette of the RS", number 30/2010, 107/12), Article 37, Paragraph 1 of the Law on Inspection Control ("Official Gazette of the RS", number 36/2015), and Articles 136 and 184 of the Law on General Administrative Procedure ("Official Gazette of the Republic of Serbia", number 18/2016), renders the following

DECISION

I THE MARKETING AUTHORIZATION IS HEREBY ISSUED to Limited Liability Company **PHOENIX PHARMA DOO, BEOGRAD, Belgrade-Čukarica, 2 Bore Stankovića Street, for the wholesale of medicines** – import, export, procurement, storage and distribution, in the territory of the Republic of Serbia, from business and storage premises with total surface area of 5,248.20 m² whereof the surface area of 5,098.24 m² is intended for the trade in medicines, located in **Šimanovci, 33 Dositejeva Street**, in particular:

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

- A** – Alimentary tract and metabolism (medicines that act on diseases of the digestive system and metabolism),
- B** – Blood and blood forming organs (medicines intended for the treatment of diseases of blood and blood forming organs),
- C** – Cardiovascular system (medicines that act on the cardiovascular system),
- D** – Dermatologicals (medicines intended for the treatment of diseases of the skin and subcutaneous tissue),
- G** – Genitourinary system and sex hormones (medicines intended 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** – Musculo-skeletal system (medicines intended for the treatment of diseases of the musculo-skeletal system),
- N** – Nervous system (medicines that act on the nervous system),
- P** – Antiparasitic products, insecticides and repellents,



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- R** – Respiratory system (medicines intended for the treatment of diseases of the respiratory system),
- S** – Sensory organs (medicines that act on the eye and ear),
- V** – Various, excluding the medicines of the main therapy subgroups: V09 (radiopharmaceuticals) and V10 (therapeutic radiopharmaceuticals).

2. Medicines for human use that are tested in clinical trials in accordance with the Clinical Trial Authorization issued by the Medicines and Medical Devices Agency of Serbia, of all the anatomic groups according to the ATC (Anatomical Therapeutic Chemical) classification, stated in Item 1 of this Decision;

3. Herbal medicines

4. Traditional herbal medicines

5. Homeopathic medicines

6. Starting substances for the production and manufacture of galenic and magistral medicines in the original packaging of the manufacturer, except penicillin antibiotics, cytostatics, starting substances that belong to psychoactive controlled substances, i.e. precursors, belonging to the group of poisons.

II Decision number: 515-04-00474/2018-11 dated 26 February 2018, issued by the Ministry of Health, IS HEREBY CANCELLED.

Statement of Reasons

Limited Liability Company PHOENIX PHARMA DOO, BEOGRAD, Belgrade-Čukarica, 2 Bore Stankovića Street, holds Decision number: 515-04-00474/2018-11 dated 26 February 2018, issued by the Ministry of Health, for the wholesale of the medicines stated in the operative part of the Decision, from the business and storage premises with total surface area of 6,104.01 m² in Šimanovci, 33 Dositejeva Street.

On 19 April 2021, Limited Liability Company PHOENIX PHARMA DOO, BEOGRAD, Belgrade-Čukarica, 2 Bore Stankovića Street, submitted to the Ministry of Health the Application for the issuance of the Marketing Authorization for the wholesale of medicines, due to a decrease in the surface area of the business and storage space from 6,104.01 m² to 5,248.20 m² whereof the surface area of 5,098.24 m² is intended for the trade in medicines. Along with the Application, the client has submitted the required evidence.

In consideration of the submitted Application and pursuant to Article 208, Paragraph 3, Item 2 of the Law on Medicines and Medical Devices ("Official Gazette of the RS", No. 30/10 and 107/12), the Inspector for Medicines and Medical Devices has examined the space and equipment for keeping and storage of medicines in Šimanovci, at 33 Dositejeva Street, and he has also verified the fulfilment of the requirements regarding the education of employees, as stated in the Inspector's Records number 515-04-3537/2021-11 dated 24 May 2021.

Based on the Inspector's Records and submitted documentation, it has been established that the prescribed requirements are fulfilled for the performance of the activity of wholesale of medicines as referred to in Articles 120-123 of the Law on Medicines and Medical Devices ("Official Gazette of the RS", No. 30/10 and 107/12) and Articles 3, 4, 10, 11, 13, 15,



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30 of the Rulebook on the Requirements for Wholesale Trade of Medicines and Medical Devices, Data to Be Registered in the Register of Marketing Authorizations Issued for the Wholesale Trade of Medicines and Medical Devices, and on the Manner of Registration ("Official Gazette of the RS", number 10/12 and 17/17), and therefore it has been decided as stated in Item I of the operative part of this Decision.

By the issuance of this Decision, Decision number: 515-04-00474/2018-11 dated 26 February 2018, issued by the Ministry of Health, is cancelled.

This Decision is final in the administrative procedure.

Against this Decision, an administrative dispute may be instituted before the Administrative Court within 30 (thirty) days from this Decision receipt date.

The applicant has paid the republic administrative fee for this Decision pursuant to Tariff Number 182 of the Law on Republic Administrative Fees ("Official Gazette of the RS", No. 98/20).

MINISTER

(Signature)
Dr Zlatibor Lončar

Round seal: Republic of Serbia – Belgrade – Ministry of Health

Delivered to:

1. **PHOENIX PHARMA DOO**
Belgrade-Čukarica, 2 Bore Stankovića Street
2. Archive

I, Ljubica Brzjer, Official Court Interpreter for the English language, appointed by Decision No. 740-02-00106/92-03 dated 3 June 1993, issued by the Minister of Justice of the Republic of Serbia, hereby certify with my signature and seal that this is a true and accurate translation of the text originally composed in Serbian.

Ljubica Brzjer
Official Court Interpreter for the English Language



Ljubica Brzjer