

Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-11509/2021-11
Date: 4 August 2022
Belgrade, Nemanjina 22-26
Tel.: 011 311 49 49
SI

The Minister of Health of the Republic of Serbia, in consideration of the Application of Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", 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, 107/2012, 113/2017-other law and 105/2017-other law), Article 37, Paragraph 1 of the Law on Inspection Control ("Official Gazette of the RS", No. 36/2015, 44/2018-other law and 95/2018), and Articles 136 and 184 of the Law on General Administrative Procedure ("Official Gazette of the RS", number 18/2016 and 95/2018-authentic interpretation), renders the following

DECISION

I THE MARKETING AUTHORIZATION IS HEREBY ISSUED to Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", 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, in the common storage space for medicines and medical devices in Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš, with total surface area of 5,577.92 m² (whereof the surface area of 5,030.15 m² is intended for the storage of medicines), in particular:

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

- A** – Medicines that act on diseases of the digestive system and metabolism
- B** – Medicines intended for the treatment of diseases of blood and blood forming organs
- C** – Medicines that act on the cardiovascular system
- D** – Medicines intended for the treatment of diseases of the skin and subcutaneous tissue
- G** – 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** – Medicines intended for the treatment of diseases of the musculo-skeletal system
- N** – Medicines that act on the nervous system
- P** – Antiparasitic products, insecticides and repellents
- R** – Medicines intended for the treatment of diseases of the respiratory system



S – Medicines that act on the eye and ear

V – Other therapy products (excluding the medicines of therapy groups V09 and V10);

1.2. Herbal medicines

1.3. Traditional herbal medicines

1.4. Homeopathic medicines

2. Starting substances for the production and manufacture of galenic and magistral medicines, or raw material for pharmaceutical use, in the original packaging of the manufacturer (except starting substances: penicillin antibiotics, cytostatics, flammable and explosive materials, raw materials that belong to psychoactive controlled substances and precursors, and raw materials belonging to the group of poisons).

3. 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 classification, stated in Item 1 of this Decision.

II Decision number: 515-04-01023/2014-11 dated 26 May 2014, issued by the Ministry of Health of the Republic of Serbia, **IS HEREBY CANCELLED**.

Statement of Reasons

Limited Liability Company “PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)”, Belgrade-Čukarica, 2 Bore Stankovića Street, holds Decision number: 515-04-01023/2014-11 dated 26 May 2014, issued by the Ministry of Health of the Republic of Serbia, for the wholesale – import, export, procurement, storage and distribution of the medicines and medical devices stated in the operative part of the Decision, in the territory of the Republic of Serbia, in the business and storage premises in Belgrade, Čukarica, 2 Bore Stankovića Street, with total surface area of 4,231.47 m².

On 28 December 2021, Limited Liability Company “PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)”, Belgrade-Čukarica, 2 Bore Stankovića Street, submitted to the Ministry of Health the Application for amendments to the Marketing Authorization for the wholesale of medicines, of the following groups according to the ATC classification: A, B, C, D, G, H, J, L, M, N, P, R, S, V (except V09, V10); starting substances for the production and manufacture of galenic and magistral medicines, or raw material for pharmaceutical use, in the original packaging of the manufacturer (except starting substances: penicillin antibiotics, cytostatics, flammable and explosive materials, raw materials that belong to psychoactive controlled substances and precursors, and raw materials belonging to the group of poisons); and medicines that are tested in clinical trials, of all the anatomic groups according to the ATC classification, from the storage space in Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš, with total surface area of 5,577.92 m² (whereof the surface area of 5,030.15 m² is intended for the storage of medicines), due to an increase in the total surface area of the storage space for the performance of the activity.

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. 30/2010, 107/2012, 113/2017-other law and 105/2017-other law), the Inspector for Medicines and Medical Devices has examined the space and equipment for keeping and storage of medicines and starting substances in the original packaging of the manufacturer, and medicines that are tested in clinical trials, stated in the operative part of the Decision, and the Inspector has also examined the means of transport and verified the fulfilment of the requirements regarding the education of employees, as stated in the Inspector's Records number 515-04-11509/2021-11 dated 1 August 2022.

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. 30/2010, 107/2012, 113/2017-other law and 105/2017-other law) and Articles 3, 4, 10, 11, 13, 15, 21, 22, and 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", No. 10/2012, 17/2017 and 84/2018-other regulation).

By the issuance of this Decision, Decision number: 515-04-01023/2014-11 dated 26 May 2014, issued by the Ministry of Health, is cancelled.

Based on the foregoing, it has been decided as stated in the operative part of this Decision.

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. 62/2021).

MINISTER

(Signature)

Dr Zlatibor Lončar

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

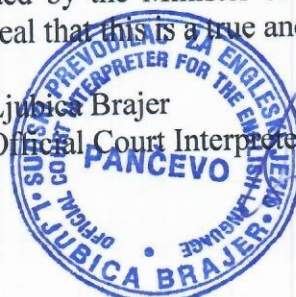
Delivered to:

1. "PHOENIX PHARMA" d.o.o.
Belgrade-Čukarica, 2 Bore Stankovića Street
2. Archive

I, Ljubica Brajer, 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 Brajer

Official Court Interpreter for the English Language



Ljubica Brajer