

CERTIFIED TRANSLATION INTO ENGLISH



Republic of Serbia
MINISTRY OF HEALTH
No. 515-04-07513/2017-11
Date: October 20, 2017
Belgrade, Nemanjina 22-26
Phone: 011 311 4949
SJ

Pursuant to Article 212, paragraph 6 of the Medicines and Medical Devices Act ("Serbian Official Gazette" nos. 30/2010 and 107/2012), Article 37 of the Inspection Supervision Act ("Serbian Official Gazette" no. 36/15) and Article 192, paragraph 1 of the General Administrative Procedure Act ("The Official Gazette of the Federal Republic of Yugoslavia" nos. 33/97 and 31/01, "Serbian Official Gazette" no. 30/10), deciding in relation to the request for the issuance of a license for wholesale trade of medicines and medical devices submitted by the Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, the Serbian Minister of Health hereby renders the following

DECISION

I The Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, **IS HEREBY GRANTED THE LICENSE** for the **wholesale trade – import, export, supply, storage and distribution** of the below medicines and medical devices in the territory of the Republic of Serbia, at the business and storage facilities in Leskovac at the address: Moravska 73, with a total surface area of 4,262.15 m²:

1. Medicines for human use in accordance with the ATC (Anatomic Therapeutic Chemical) classification:

- A** Alimentary tract and metabolism
- B** Blood and blood forming organs
- C** Cardiovascular system
- D** Dermatologicals
- H** Systemic hormonal preparations
- G** Genito-urinary system and sex hormones
- J** Antiinfectives for systemic use
- L** Antineoplastic and immunomodulating agents
- M** Musculo-skeletal system
- N** Nervous system
- P** Antiparasitic products, insecticides and repellents
- R** Respiratory system
- S** Sensory organs
- V** Various (except for group V09-diagnostic radiopharmaceuticals and group V10-therapeutic radiopharmaceuticals)



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2. Herbal medicines;
3. Traditional medicines;
4. Homeopathic medicines;
5. Medical devices of the following classes and categories:

Class I

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 08 - ophthalmological and optical medical devices
- Category 09 - reusable instruments
- Category 10 - disposable medical devices
- Category 11 - technical aids for disabled persons

Class Im

- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 09 - reusable instruments

Class Is

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 05 - hospital equipment - apparatus
- Category 08 - ophthalmological and optical medical devices
- Category 09 - reusable instruments
- Category 10 - disposable medical devices
- Category 11 - technical aids for disabled persons

Class IIa

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 07 - inactive implantable medical devices
- Category 08 - ophthalmological and optical medical devices
- Category 09 - reusable instruments
- Category 10 - disposable medical devices
- Category 11 - technical aids for disabled persons
- Category 12 - diagnostic and therapeutic medical devices

Class IIb

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 07 - inactive implantable medical devices
- Category 08 - ophthalmological and optical medical devices
- Category 09 - reusable instruments
- Category 10 - disposable medical devices
- Category 12 - diagnostic and therapeutic medical devices

Class III

- Category 02 - anesthesia and respiratory medical devices



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Category 03 - dental medical devices
Category 04 - electromechanical medical devices
Category 07 - inactive implantable medical devices
Category 08 - ophthalmological and optical medical devices
Category 09 - reusable instruments
Category 10 - disposable medical devices
Category 12 - diagnostic and therapeutic medical devices

Class LIST A

Category 06 "in vitro" diagnostic medical devices

Class LIST B

Category 06 "in vitro" diagnostic medical devices

Class PRODUCTS FOR SELF-TESTING

Category 06 "in vitro" diagnostic medical devices

Class OTHER

Category 06 "in vitro" diagnostic medical devices

Class AIMD

Category 01 - active implantable medical devices

6. Starting substances for the production of medicines and preparation of galenic and magistral medicines in the original packaging;

II The Decision no. 515-04-03135/2009-05 rendered by the Ministry of Health on October 23, 2009 is hereby revoked.

E x p l a n a t i o n

The Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, is the holder of the decision no. 515-04-03135/2009-05 rendered by the Ministry of Health on October 23, 2009, which stipulates that it meets the requirements for the wholesale trade – import, export, supply, storage and distribution in the territory of Serbia, of medicines for human use from all groups of the ATC classification (except for groups V09 and V10), herbal medicines, traditional medicines, homeopathic medicines and medical devices of all classes and categories, from its business facilities in Leskovac, address: Moravska 73 (3rd floor), with a total surface area of 1,111.35 m².

Due to the expansion of the storage facility in Leskovac, address: Moravska 73 (3rd floor), from the total surface area of 1,111.35 m² to the total surface area of 4,262.15 m², on October 3, 2017 the above-mentioned company submitted a request for the issuance of a license for the wholesale trade – import, export, supply, storage and distribution in the territory of Serbia of the following: 1. medicines for human use from the groups A, B, C, D, G, H, J, L, M, N, P, R, S and V (except for groups V09 and V10), according to the ATC (Anatomic Therapeutic Chemical) classification, 2. herbal medicines, 3. traditional medicines, 4. homeopathic medicines, 5. medical devices of classes: I, Im, Is, IIa, IIb, III, List A, List B, Products for Self-Testing, Other, AIMD, categories 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12 and 6. starting substances for the production of medicines and preparation of galenic and magistral medicines in the original packaging.



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Acting upon the submitted request, the inspector for medicines and medical devices inspected the attached documents and performed the inspection of facilities and equipment for storage and keeping medicines and medical devices, inspected the means of transportation and verified the fulfillment of conditions regarding the professional qualifications of persons employed, as determined in the inspector's record no. 515-04-07513/2017-11 of October 17, 2017.

Based on the inspector's record and the submitted documents, it was established that the requirements had been met with regard to the wholesale trade of medicines, medical devices and starting substances for the production of galenic and magistral medicinal products in the original packaging from Articles 193, 194 and 198 of the Medicines and Medical Devices Act ("Serbian Official Gazette" no. 30/10) and Article 3, Article 8, paragraph 1, item 1, Article 9, Article 12, Article 15, paragraph 1, items 1, 2 and 3, Article 19, Article 24, paragraph 5 and Article 30 of the Rulebook on the Conditions for the Wholesale Trade of Medicines and Medical Devices, Data to be Entered in the Register of Issued Licenses for the Wholesale Trade of Medicines and Medical Devices and the Method of Entry Thereof ("Serbian Official Gazette" no. 10/12), as it is decided in item I hereof.

As this Decision refers to the medicines and medical devices described in the Decision no. 515-04-03135/2009-05 rendered by the Ministry of Health on October 23, 2009, the aforesaid decision shall be revoked, as it is decided in item II hereof.

This decision is final in the administrative procedure.

One may initiate an administrative dispute against this decision by filing a claim to the Administrative Court within 30 (thirty) days after the receipt of the decision.

A fee for this decision shall be charged in accordance with the National Administrative Fees Act ("Serbian Official Gazette" no. 61/17).

Delivered to:

- "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)",
address: Belgrade-Čukarica, Bore Stankovića 2
- Records Management Office

MINISTER

Ass. Zlatibor Lončar, PhD, MD

(Signed)

(Round seal:

*Ministry of Health, Belgrade,
Republic of Serbia)*


.....the end of translation.....



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I, the undersigned sworn-in court translator, appointed by the decision of the Ministry of Justice of the Republic of Serbia no. 740-06-968/2000-04 of April 12, 2000, certify hereby that this translation into English is fully true to the original text written in the Serbian language. My commission is permanent.

In Belgrade, May 29, 2020
No. 3008/2020



The image shows a handwritten signature in blue ink, which appears to be 'Maja Popović'. The signature is written over a circular official stamp. The stamp contains the text 'SUDSKI PREVODILAC ZA ENGLJEŠKI JEZIK' around the top edge and '* BEOGRAD *' around the bottom edge. In the center of the stamp, the name 'Maja Popović' is printed in blue ink.

Maja Popović
Sworn-In Court Translator for English