

Coat of Arms of the Republic of Serbia

Republic of Serbia

MINISTRY OF HEALTH

Number: 515-04-02984/2014-11

Date: 28 July 2014

Belgrade, no. 22 – 26, Nemanjina Street

Tel. no. 011/311-4949

ZN

The Minister of Health of the Republic of Serbia, deciding on the request by "PHOENIX PHARMA", d.o.o., Belgrade, no. 2, Bore Stankovica Street, for supplementing the marketing authorisation for the wholesale trade of medicines and medical devices, pursuant to Article 212 paragraph 6 of the Law on Medicines and Medical Devices ("Official Gazette of RS" no. 30/2010 and 107/2012) and Article 192 paragraph 1 of the Law on the General Administrative Procedure ("Official Gazette of FRY" no. 33/97 and 31/01), passes the following

DECISION

I MARKETING AUTHORISATION IS HEREBY ISSUED TO "PHOENIX PHARMA", doo Belgrade, no. 2, Bore Stankovica Street, for the wholesale trade – import, export, supply, storage and distribution in the territory of the Republic of Serbia from the warehouse premises with the total surface area of 3391.63 m² in Novi Sad, no. 2, Privrednikova Street, of:

1. Medicines for human consumption of all groups according to the ATC (Anatomical Therapeutic Chemical) classification:

- A – Alimentary tract and metabolism
 - B – Blood and blood forming organs
 - C – Cardiovascular system
 - D – Dermatologicals
 - G – Genito-urinary system and sex hormones
 - H – Systemic hormonal preparations, excl. sex hormones and insulins
 - 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 (other than the medicines from the major therapy groups V09 and V10)
2. Herbal medicines,
3. Traditional medicines,
4. Homeopathic medicines
5. Medical devices, classified as follows:



Class I

- category 02** – Anesthetic and respiratory devices
- category 03** – Dental devices
- category 04** – Electromechanical medical devices
- category 05** – Hospital hardware
- category 08** – Ophthalmic and optical devices
- category 09** – Reusable devices
- category 10** - Single use devices
- category 11** – Assistive products for persons with disability

Class Is

- category 02** – Anesthetic and respiratory devices
- category 03** – Dental devices
- category 05** – Hospital hardware
- category 08** – Ophthalmic and optical devices
- category 09** – Reusable devices
- category 10** - Single use devices
- category 11** – Assistive products for persons with disability

Class Im

- category 04** – Electromechanical medical devices
- category 05** – Hospital hardware
- category 09** – Reusable devices

Class IIa

- category 02** – Anesthetic and respiratory devices
- category 03** – Dental devices
- category 04** – Electromechanical medical devices
- category 05** – Hospital hardware
- category 07** – Non-active implantable devices
- category 08** – Ophthalmic and optical devices
- category 09** – Reusable devices
- category 10** - Single use devices
- category 11** – Assistive products for persons with disability
- category 12** – Diagnostic and therapeutic radiation devices

Class IIb

- category 02** – Anesthetic and respiratory devices
- category 03** – Dental devices
- category 04** – Electromechanical medical devices
- category 05** – Hospital hardware
- category 07** – Non-active implantable devices
- category 08** – Ophthalmic and optical devices
- category 09** – Reusable devices
- category 10** - Single use devices
- category 12** – Diagnostic and therapeutic radiation devices

Class III

- category 02** – Anesthetic and respiratory devices
- category 03** – Dental devices
- category 04** – Electromechanical medical devices
- category 07** – Non-active implantable devices



category 08 – Ophthalmic and optical devices

category 09 – Reusable devices

category 10 - Single use devices

category 12 – Diagnostic and therapeutic radiation devices

Class: List A, List B, Self-testing devices, Other diagnostic devices

category 06 - *In vitro* diagnostic devices

Class AIMD

category 01 – Active implantable devices

6. **Pharmaceutical chemicals** in the **original** packaging

Explanation

“PHOENIX PHARMA” doo Belgrade, no. 2, Bore Stankovica Street, submitted the request on 11 June 2014 for the issuance of the marketing authorisation for the trade of medicines and medical devices, as well as pharmaceutical chemicals in the original packaging in its business premises in Novi Sad, no. 2, Privrednikova Street.

Acting in accordance with the submitted request, pursuant to Article 208, paragraph 3 item 2, an inspector for medicines and medical devices has performed the review of the submitted documentation, as well as the inspection of the warehouse with the surface area of 3391.63 m² in Novi Sad, no. 2, Privrednikova Street and determined that the prescribed requirements for performing the activity of marketing of medicines and medical devices listed in the wording of the decision, as well as the pharmaceutical chemicals in the original packaging were met, as he/she recorded in the minutes dated 30 June and 16 July 2014, in accordance with Articles 120 – 123, 193, 194 of the Law on Medicines and Medical Devices (“Official Gazette of RS”, no. 30/10) and Articles 3, 10, 11, 13, 15, 21, 22 and 30 of the Rule Book on the requirements for the wholesale of medicines and medical devices, data entered into the Registered of the marketing authorizations issued for wholesale trade of medicines and medical devices, as well as the method of registration (“Official Gazette of RS”, no. 10/12).

Based on the foregoing, it has been decided as stated in the wording of the decision.

This decision is final in the administrative procedure.

Administrative proceedings before the competent court may be initiated against this decision within 30 (thirty) days from the date of receipt of this decision.

The fee for this decision was charged in accordance with the Law on the State Administrative Fees (“Official Gazette of RS” no. 70/11 and 47/13).

MINISTER

Ass. dr Zlatibor Loncar

- Duly signed -



Translation into English from the Serbian language

Seal: REPUBLIC OF SERBIA, MINISTRY OF HEALTH,
BELGRADE, CCCXXI

Delivered to:

- "PHOENIX PHARMA" doo, Belgrade, No. 2, Bore Stankovica Street
- Record Office

..... (End of translation).....

I, the undersigned sworn-in court translator according to the Decision of the Ministry of Justice No.760-06-197/2002-04 from 02 October 2002, certify hereby that this translation into English is fully true to the original text written in the Serbian language. Belgrade, April 2016, Milena Kovačević), B.A., sworn- in Court translator for English, Swedish and Slovenian

