

Milica Borlja-Gluvacevic, B.A.
Court Appointed translator for
English and Spanish,
Belgrade, Kneginje Zorke 50/IV
Phone: + 381 11 245 62 98
E-mail: borlja@Eunet.rs

CERTIFIED TRANSLATION
FROM SERBIAN INTO ENGLISH

(Coat of Arms)
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-01023/2014-11
Date: 26 May 2014
Belgrade, Nemanjina 22-26
Phone: 011 311 4949

The Minister of Health of the Republic of Serbia, deciding on the application filed by "PHOENIX PHARMA" d.o.o. company, Belgrade, Bore Stankovica St., No. 2, for authorization of wholesale of medicines and medical devices, and pursuant to Article 212, paragraph 6 of the Law on Medicines and Medical Devices ("Official Gazette RS" No. 30/2010) and Article 192, paragraph 1 of the Law on General Administrative Procedure ("FRY Official Gazette" numbers 33/97 and 31/01, "RS Official Gazette" No. 30/10), hereby passes the following

DECISION

I "PHOENIX PHARMA" d.o.o. company, Belgrade, Bore Stankovica St., No. 2, **IS GRANTED AUTHORIZATION for wholesale – import, export, acquisition, storage and distribution of medicines and medical devices** on the territory of the Republic of Serbia, at business storage facility with a total area of **4,231.47 m²**, in Belgrade, Bore Stankovica St., No. 2, of the following:

1. **Medicines for human use of all treatment groups according to ATC (Anatomic Therapeutic Chemical) classification, excluding group V09 – diagnostic radiopharmaceuticals and V10 – therapeutic radiopharmaceuticals,**
2. **Herbal preparations,**
3. **Traditional medicines,**
4. **Homeopathic medicines,**
5. **Medical devices of all classes and categories,**
6. **Starting substances for manufacturing, or preparing galenic and magistral preparations in the original packaging of the manufacturer.**

II The Decision of the Ministry of Health of the Republic of Serbia number 515-04-00911/2011-04 of 09 March 2011 **IS NULLIFIED.**

Reasons for the Decision

The Decision of the Ministry of Health of the Republic of Serbia number 515-04-00911/2011-04 of 09 March 2011 determines that "PHOENIX PHARMA" d.o.o. company, Belgrade, Bore Stankovica St. number 2, fulfills the conditions for wholesale – import, export, acquisition, storage and distribution on the territory of the Republic of Serbia, of medicines for human use of all treatment groups according to ATC (Anatomic Therapeutic Chemical) classification, excluding groups V09 and V10, herbal medicines, traditional medicines, homeopathic medicines and medical devices of all classes and categories from the business facility with a total area of 3,367.97 m², in Belgrade, Bore Stankovica St, No. 2.

On 25 February 2014, "PHOENIX PHARMA" d.o.o. company, Belgrade, Bore Stankovica St., No. 2, filed an application for wholesale – import, export, acquisition, storage and distribution - on the territory of the Republic of Serbia also of starting substances for manufacturing, or preparing galenic and magistral preparations in the original packaging of the manufacturer to be marketed from the storage facility in Belgrade, Bore Stankovica St., No. 2, with a total area of 4,231.47 m².

Acting upon the submitted application, the inspector for medicines and medical devices reviewed the submitted documentation, inspected the facility and equipment for storage and safeguarding of medicines and medical devices, inspected transport vehicles and verified the fulfillment of the conditions regarding the education of employees, as it is determined in the inspector's record number 515-04-01023/2014-11 of 22 May 2014.

On the basis of the inspector's record and submitted documentation, it was determined that the conditions prescribed for performing wholesale of medicines and medical devices referred to in Articles 193, 194 and 198 of the Law on Medicines and Medical Devices ("RS 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 Regulation on the Conditions for Wholesale of Medicines and Medical Devices, Information Entered into Registry of Authorizations Issued for Wholesale of Medicines and Medical Devices, as well as the Manner of Registering ("RS Official Gazette" No. 10/12) are met.

Based on the above, it has been decided as formulated in paragraph I of the text of this Decision.

Taking into consideration that this Decision includes medicines and medical devices for whose marketing the decision No. 515-04-00911/2011-04 of 09 March 2011 has been granted, the named decision is nullified, as decided in paragraph II of the text of this Decision.

This Decision is final in the administrative procedure.

This Decision can be contested by instituting an administrative dispute with the Administrative Court within 30 (thirty) days, starting from the date of receiving this Decision.

Duty was collected pursuant to the Law on Republic Administrative Duties ("RS Official Gazette" No. 47/13).

Delivered to:

- "PHOENIX PHARMA" d.o.o. Belgrade,
2 Bore Stankovica St.,
- Record office

MINISTER

(Sgd.) Ass. Prof. Zlatibor Loncar, PhD

(Seal: REPUBLIC OF SERBIA, MINISTRY OF HEALTH, BELGRADE)

..... (End of translation)

I, the undersigned court appointed translator, certify hereby that this translation into English is fully true to the original text written in the Serbian language.

Belgrade, 17 December 2015

No. 664/2015



Milica Borlja-Gluvacevic

Milica BORLIJA-GLUVACEVIC, B.A. (Phil.),
Court appointed translator for English and
Spanish, Belgrade, Kneginje Zorke 50/IV