



BOSNIA AND HERZEGOVINA
Agency for Medicines and Medical Resources BaH

No.: 10-07.12-5-6413-1/18

Date: 6 November, 2018

This is to certify that Agency for Medicines and Medical Resources BaH, pursuant to Articles 7, 64 and 65 of the Law on Medicines and Medical Resources ("BaH Official Gazette " No. 58/8), as well as Articles 4 and 8 of the Book of Rules on Conditions for Doing Whole Trade of Medicines ("BaH Official Gazette " No. 49/14), acting in administrative proceedings at the request of " PHOENIX PHARMA " d.o.o. Bijeljina , in line with Article 193 of the Law on Administrative Proceedings ("BaH Official Gazette " No. 29/ , 12/04,88/07,93/09,41/13 and 53/16) , brings the following

DECISION

1. This is to approve to legal entity " PHOENIX PHARMA " d.o.o. Bijeljina with the address in Bijeljina, Stefana Decanskog Street bb , to perform business activities of whole trade of medicines for import, procurement , storage and supply of :

- **Medicines with controlled conditions of keeping at room temperature in line with license for putting medicine into trade**
- **Medicines with specific conditions of storage**
 1. narcotics
 2. medicines containing psychotropic substances
 3. medicines from human blood and plasma
 4. immunology medicines
 5. medicines requesting cold chain of keeping
 6. medicines for clinical researches

2. License is issued on the period of 5 years, until 5 November , 2023.

3. A person responsible for acceptance and generation of prescriptions , as well as examination of the documents is master of pharmacy Ankica Rudic.

4. A person responsible for putting medicines into trade as well as quality control of each imported series of medicines is master of pharmacy Natasa Draganic.

5. License holder is obliged to report to the Agency within 15 days from the very day of changes made , any change concerning the name or system of quality .

RATIONALE

" PHOENIX PHARMA " d.o.o. Bijeljina with its approved warehouse set in Bijeljina, Stefana Decanskog Street bb , submitted a request to Agency for Medicines and Medical Resources BaH on 9 August, 2018 . The request was for issuing the license for whole trade of medicines.

After ensuring that the formal request was complete, the Agency in the procedure of inspection supervision established that whole trader "PHOENIX PHARMA" d.o.o. Bijeljina meets the conditions to perform whole trade of medicines for import, procurement, storage and supply of medicines with controlled conditions of keeping in line with license for putting medicine into trade, as well as medicines with specific conditions of storage: narcotics, medicines containing psychotropic substances, medicines from human blood and plasma, immunology medicines, medicines requesting cold chain of keeping, medicines for clinical researches, as written in the decision.

Legal remedy: This Decision is final in administrative procedure and an appeal cannot be lodged against it, whereas an administrative lawsuit can be started with the charges submitted to the Court BiH, within 60 days starting from the very day of reception of this Decision.

DELIVERED TO :

1. Request applicant
2. Financial Department
3. Inspectorate
4. Case documentation
5. Archives

SEAL OF THE AGENCY

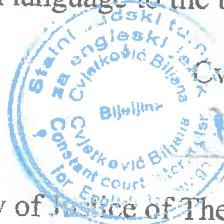
SIGNATURE : Authorised by Director
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The end of translation

I, Cvjetković Biljana, constant court interpreter for English language, solemnly declare that this translation is true to its original in Serbian language to the best of my knowledge and belief.

Cvjetkovic Biljana
Biljana Cvjetkovic



Appointed by Ministry of Justice of The Republic of Srpska
Decision No. 01/2-704-9/02

Bijeljina, 11 November, 2018
Bosnia and Herzegovina

99387-65 / 955 047
99387-55 / 205 459

Transl. No. 151e/18

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH

BOSNIA AND HERZEGOVINA THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Number: 10-07.12-5-6413-3/18

Date: 13 December 2019

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, acting upon the request of company "PHOENIX Pharma" d.o.o. Bijeljina in the procedure of amendment to a decision, pursuant to Article 7, 64 and 65 of the Law on Medicinal Products and Medical Devices (Official Gazette of Bosnia and Herzegovina No. 58/08), Article 87 of the Rulebook on Conditions to Conduct Wholesale of Medicinal Products (Official Gazette of Bosnia and Herzegovina No. 49/14) and Article 193 of the Law Administrative Procedure (Official Gazette of Bosnia and Herzegovina No. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16) hereby issues the following:

DECISION

On Amendment to Decision

- Item 1 of the wording of Decision of The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina is amended, Decision No. 10-07.12-5-6413-1/18 of 6 November 2018, which reads: legal entity "PHOENIX Pharma" d.o.o. Bijeljina, seat at Donja Ljeljenca 015B, Ljeljenca, Bijeljina, is approved to conduct wholesale activities of medicinal products, which include the activities of import, procurement, storage and supply of the following:**
 - **Medicinal products with controlled storage conditions at room temperature in accordance with the licence to put the medicinal product on the market;**
 - **Medicinal products with special storage conditions:**
 - Narcotics,
 - Medicinal products containing psychotropic substances,
 - Medicinal products from human blood and plasma,
 - Immunological medicinal products,
 - Medicinal products that require cold storage,
 - Medicinal products for clinical trials.
2. The remaining sections of Decision No. 10-07.12-5-6413-1/18 of 6 November 2018 remain unchanged, and this Decision on Amendment to Decision constitutes its integral part.

Explanation:

Legal entity "PHOENIX Pharma" d.o.o. Bijeljina submitted a request for the amendment of a decision (the change of company seat) to The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina on 19 November 2019.

Since the request was formally right, The Agency determined that the above stated legal entity "PHOENIX Pharma" d.o.o. Bijeljina, whose seat is at Donja Ljeljenca 015B, Ljeljenca, Bijeljina, fulfills all requirements for the amendment to the decision (the change of company seat).



Legal remedy: This Decision is final in a non-judicial procedure and therefore, an appeal cannot be filed against it, but an administrative dispute can be made at the competent court within 60 days since the date of the receipt of Decision.

Delivered to:

1. Applicant,
2. Financial Department,
3. Inspectorate,
4. Case files,
5. a/a.

Director:
Dr Aleksandar Zolak [signed]

Round seal of The Agency

_____ end of translation _____

I, Vladimir Novaković, a permanent court interpreter for the English language, appointed by the Ministry of Justice of the Republic of Srpska by Decision No. 08.020/704-70/12, dated 29 November 2012, certify that the above translation fully corresponds to the original in Serbian.

Bijeljina, 24 January 2020
Registry Book No: 1F/2020



Vladimir Novaković

Vladimir Novaković

Court interpreter for English