



Crjetkovic

AND HERZEGOVINA
for Medicines and Medical Resources BaH

No.: 10-07.12-2-7145-3/18

Date: 14 November, 2018

This is to certify that Agency for Medicines and Medical Resources BaH, pursuant to Article 193 of the Law on Administrative Proceedings ("BaH Official Gazette " No. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16) , as well as articles 8 and 109 of the Law on Medicines and Medical Resources ("BaH Official Gazette " No. 58/8) , and Article 7 of the Book of Rules on Production and Whole trade of Medical Resources ("BaH Official Gazette " No. 71/12 and 64/13) , acting at the request of " PHOENIX PHARMA " d.o.o. Bijeljina , 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 the entry into the Register of Whole Traders of Medical Resources .
2. In line with entry into the Register of Whole Traders of Medical Resources, license holder can perform whole trade of medical resources of class I, IIa, IIb, III, and "in vitro" diagnostic medical resources of List A , List B, List C as well as List D, and medical resources requesting cold chain conditions of storage .
3. For doing trade of medical resources in the whole trader' premises , responsible employees are : Radmila Jovic , pharmaceutical technician (responsible persor for whole trade) and Ajla Turalic Jovic, Master of S.D. in Pharmacy, (responsible for estimating the side effects) .
4. License is issued on the period of 5 years, until 13 November, 2023.
5. License holder is obliged to report to the Agency within 15 days from the very day of changes made , any change concerning the staff, premises and equipment.

RATIONALE

" PHOENIX PHARMA " d.o.o. Bijeljina on 5 September, 2018 submitted a request to Agency for Medicines and Medical Resources BaH . The request was for renewal of entry into Register of Whole Traders of Medical resources.

Having ensured that the formal request was complete, the Agency in the procedure of inspection supervision established that legal entity " PHOENIX PHARMA " d.o.o. Bijeljina meets the conditions for renewal of entry into Register of Whole Traders of Medical Resources at the address Bijeljina, Stefana Decanskog Street bb . They also meet the conditions for performing whole trade of medical resources of class I, IIa, IIb, III, and "in vitro" diagnostic medical resources of List A , List B, List C, as well as List D, and medical resources requesting cold chain conditions of storage

Legal remedy: An appeal can be lodged against this decision to Appellation Council of Council of Ministers of Bosnia and Herzegovina within 15 days from the very reception

of this decision , in line with article 215 paragraph (1) of the Law on Administrative Proceedings .

Administrative tax for Appeal of 10,00 BAM is paid , pursuant to tariff number 2 of the Tariffs of Administrative Taxes. Tax is paid in purpose of "Administrative tax " on behalf of "JRT- Treasury BaH – Taxes " , gyro account No. 3380002210018390 (UniCredit bank) , type of income 722102.

DELIVERED TO :

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

SEAL OF THE AGENCY

SIGNATURE : Director Dr Aleksandar Zolak

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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, 21 November, 2018
 Bosnia and Herzegovina

99387-65 / 955 047
 99387-55 / 205 59

Transl. No. 156/18

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH

BOSNIA AND HERZEGOVINA THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Number: 10-07.12-2-7145-5/18

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 8 and Article 109 of the Law on Medicinal Products and Medical Devices (Official Gazette of Bosnia and Herzegovina No. 58/08), Article 7 of the Rulebook on Manufacture and Wholesale of Medical Devices (Official Gazette of Bosnia and Herzegovina No. 71.12 and 64/13), 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

1. **Item 1 of the wording of Decision of The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina is amended, Decision No. 10-07.12-2-7145-3/18 of 14 November 2018, which reads: registration in the Register of Wholesale of Medical Devices of Bosnia and Herzegovina for "PHOENIX Pharma" d.o.o. Bijeljina, seat at Donja Ljeljenca 015B, Ljeljenca, Bijeljina, is approved.**
2. The remaining sections of Decision No. 10-07.12-2-7145-3/18 of 14 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 warehouse address) 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 for Medicinal Products and Medical Devices of Bosnia and Herzegovina 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 warehouse address).

Legal remedy: An appeal can be filed against this Decision to the Appeals Chamber of Council of Ministers of BiH within 15 days since the date of its receipt, in accordance with Article 215 Paragraph (1) of the Law on Administrative Procedure.

The appeal is charged BAM 10.00 as an administrative fee pursuant to Tariff No. 2 of the Tariff on Administrative Fees, The purpose of payment is "Administrative fee" to the account "JRT-Trezor BiH-



takse". account No. 338002210018390 (UniCredit Bank), revenue type 7221002. One pay-in slip is to be given together with the appeal.

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