



*Gjelković*

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BOSNIA AND HERZEGOVINA  
Agency for Medicines and Medical Resources BaH

No.: 10-07.12-6-11220-1/18

Date: 11 March 2019

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, business unit "PHOENIX Pharma" d.o.o. Sarajevo , brings the following

### DECISION

1. This is to approve to legal entity " PHOENIX Pharma " d.o.o. Bijeljina, business unit " PHOENIX Pharma " d.o.o. Sarajevo, with the address in Rogacici bb, Sarajevo, 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**, as well as **"in vitro" 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's premises , responsible employees are : Azra Ridjanovic, BA in Veterinary Medicine ( responsible person for whole trade ) and Ajla Turalic, Master of S.D. in Pharmacy, ( responsible person for estimating the side effects) .
4. License is issued on the period of 5 years, until 10 March, 2024.
5. License holder is obliged to report to the Agency within 15 days from the very day of any changes made, changes concerning the staff, premises and equipment.

### RATIONALE

" PHOENIX PHARMA " d.o.o. Bijeljina, Business unit " PHOENIX Pharma " d.o.o. Sarajevo, on 31 December, 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, Business unit " PHOENIX Pharma " d.o.o. Sarajevo, meets the conditions for renewal of entry into Register of Whole Traders of Medical Resources at the address Rogacici bb, Sarajevo. 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 Lists A, B, C, as well as D, and medical resources requesting cold chain conditions of storage .

**Legal remedy:** An appeal can be lodged against this decision to Appeal 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 Proceeding.

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

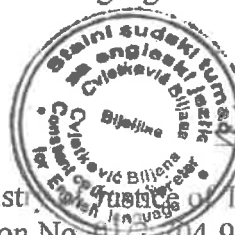
SEAL OF THE AGENCY

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 Cvjetković*

Appointed by Minister of Justice of The Republic of Srpska  
Decision No. 01/1704-9/02

Bijeljina, 16 March, 2019  
Bosnia and Herzegovina

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

Transl. No. 62/19

BOSNIA AND HERZEGOVINA

[Logo]

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

[Coat of arms]

Number: 10-07.12-6-11220-3/18

Date: January 16, 2020

Agency for Medicinal Products and Medical Devices of BiH, resolving upon the request of "PHOENIX Pharma" d.o.o. Bijeljina, Business Unit "PHOENIX Pharma" Sarajevo, in the procedure of amending the decision, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices ("Official Gazette of BiH", num. 58/08), Article 8 of the Policy on conditions for wholesale in medicinal products ("Official Gazette of BiH", num. 49/14) and Article 193 of the Law on Administrative Procedure ("Official Gazette of BiH", num. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16), makes the following

**DECISION**  
on amending the decision

1. To amend point (1) of the dispositive of the decision on amending the decision of the Agency for Medicinal Products and Medical Devices of BiH number: 10-07.12-6-11220-1/18 of March 11, 2019 as follows: "PHOENIX Pharma" d.o.o. Bijeljina, Business Unit "PHOENIX Pharma" d.o.o. Sarajevo with storage at Vlakovo num. 252, Ildža, Sarajevo, registered in the Register of Wholesalers of Medical Devices of BiH.
2. Other parts in the decision number: 10-07.12-6-11220-1/18 of March 11, 2019 remain the same and this decision on amending the decision is included as its part.

**Elaboration**

The legal entity "PHOENIX Pharma" d.o.o. Bijeljina, Business Unit Sarajevo, filed a request to amend the decision (amending the address of the storage) to the Agency for Medicinal Products and Medical Devices of BiH on December 31, 2019.

According to the formally complete request, the Agency determined that the legal entity "PHOENIX Pharma" d.o.o. Bijeljina, Business Unit Sarajevo, with storage at Vlakovo num. 252, Ildža, Sarajevo, fulfils the conditions for amending the decision (changing the address of storage).

**Legal remedy:** An appeal may be filed against this decision to the Appellation Council with the Council of Ministers of Bosnia and Herzegovina within 15 days from the date of receiving the decision, pursuant to Article 215(1) of the Law on Administrative Procedure.

The appeal is charged with administrative fee in amount of BAM 10.00 under the tariff number 2. of the Tariff of administrative fees. The fee is paid for the purpose of "Administrative fee" for the benefit of "JRT-Treasury of BiH-fees" gyro account number 3380002210018390 (UniCredit Bank), type of income 722102. One copy of the deposit slip has to be delivered with the appeal.

**Deliver to:**

1. Requester,
2. Financial Affairs Sector
3. Inspectorate,
4. Case file,
5. a/a

[Seal: BOSNIA AND HERZEGOVINA; AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES BANJA LUKA]



I hereby certify that the above translation complies completely with the original text written in Bosnian.  
Translation log: 131-20  
Sarajevo, January 27, 2020  
Dea Paljević  
Certified Court Interpreter for English