

BOSNIA AND HERZEGOVINA

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Number: 10-07.12-5-411-1/20

Date: 27 April 2020

The Agency for Medicinal Products and Medical Devices of BiH, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices (Official Gazette of BiH, 58/08), Articles 4 and 8 of the Rulebook on requirements for wholesale of medicinal products (Official Gazette of BiH, 49/14), acting in an administrative procedure at the request of „PHOENIX Pharma“ d.o.o. Bijeljina, BU „PHOENIX Pharma“ d.o.o. Sarajevo, pursuant to Article 193 of the Law on Administrative Procedure (Official Gazette of BiH, 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16), i s s u e d

**DECISION**

1. It is hereby approved to the legal person „PHOENIX Pharma“ d.o.o. Bijeljina, BU „PHOENIX Pharma“ d.o.o. Sarajevo, with the warehouse at Vlakovo 252, Ilidža, Sarajevo, to perform wholesale of medicinal products for activities of import, export, procurement, storage and supply of:
  - Medicinal products with controlled storage conditions at room temperature in accordance with the marketing authorisation for medicinal product.
  - Medicinal products with special storage conditions:
    - Narcotics;
    - Psychotropic substances;
    - Medicinal products from human blood and plasma;
    - Immunological medicines;
    - Medicinal products requiring cold storage chain;
    - Medicinal products form clinical research.
2. The Decision is issued for the period of 5 years, until 26 April 2025.
3. The person responsible for acceptance and discharge of medicinal products and review of documentation is mr ph. **Jasna Demirović**.
4. The person responsible for marketing of medicinal products and quality control of each imported batch of medicinal product is mr ph. **Sanja Lelić**.
5. The Decision holder is must inform this Agency of any change with reference to the name or system of quality within 15 days from the date of change.

**Justification**

The legal person „PHOENIX Pharma“ d.o.o. Bijeljina, BU „PHOENIX Pharma“ d.o.o. Sarajevo, at Vlakovo 252, Ilidža, Sarajevo, submitted to the Agency for Medicinal Products and Medical



Devices of BiH on 21 January 2020 the application for renewal of wholesale of medical products.

In accordance with the formally complete application and the Certificate of good distribution practice number: BH 1597/17 INS GDP 09-01/18 issued on 16 April 2018 by the Inspectorate of the Agency, and upon completed inspection, the Agency decided, in accordance with the submitted application and due to an extraordinary situation caused by the COVID-19 viral pandemics, to issue to the legal person „PHOENIX Pharma“ d.o.o. Bijeljina, BU „PHOENIX Pharma“ d.o.o. Sarajevo, the decision on compliance the requirements for renewal of licence for wholesale of medicinal products, import, export, procurement, storage and supply of medicinal products with controlled storage conditions in accordance with the marketing authorisation for medicinal product, and medicinal products with special storage conditions: narcotics, psychotropic substances, medicinal products from human blood and plasma, immunological medicines, medicinal products requiring cold storage chain and medicinal products form clinical research. After the emergency situation caused by the COVID-19 viral pandemics ends, a direct inspection of the legal person will be performed as soon as possible.

**Legal remedy:** This Decision is final in administrative procedure and it may not be appealed against, but an administrative dispute may be initiated by filing a suit to the Court of BiH within 60 days from the date of the decision receipt.

**DIRECTOR**

*/Round Stamp/ /Signature/*  
**Dr. Aleksandar Zolak**

**Copies to:**

1. Applicant,
2. Sector for financial assets
3. Inspectorate
4. Case file,
5. Archives.

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*I hereby certify that the above translation complies completely  
with the original text written in Bosnian.  
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Amira Dozo  
Certified Court Interpreter for English*

