



Decision No. 10-07.12-5-8981/16  
Date: 28 December, 2016

The Agency for Medicinal Products and Medical Devices Bosnia and Herzegovina, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices (Official Gazette of BiH, No. 58/08), Articles 4 and 8 of the Rulebook on the requirements for the marketing authorization for the wholesale of medicinal products (Official Gazette of BiH, No. 49/14), deciding on the request in the administrative procedure by **“Evropa Lijek Pharma” d.o.o. Sarajevo**, pursuant to Article 193 of the Law on Administrative Procedures (Official Gazette of BiH, No. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16), hereby renders the following

### DECISION

1. The legal entity **“Evropa Lijek Pharma” d.o.o. Sarajevo**, headquartered at Rogačići bb, Vlakovo, Ilidža, Sarajevo, is hereby approved to **conduct the wholesale of medicinal product** for the import, procurement, storage and supply of:
  - **medicinal products that require controlled storage conditions, in accordance with the marketing authorization;**
  - **medicinal products that require special storage conditions:**
    - Medicinal products containing psychotropic substances;
    - Immunological medicinal products;
    - Medicinal products that require cold storage chain;
    - Medicinal products for clinical examinations.
2. The Decision is issued for a period of five years, including 27 December, 2021
3. The responsible person for the receipt and issuance of medicinal products is **Alma Spahić, M. pharm.**
4. The person responsible for marketing the medicinal products or for the quality control of each imported batch of medicinal products is **Šejla Čatović-Jašarević, M. pharm.**
5. The authorization holder shall be obliged to notify this Agency of any change pertaining to the name or quality system, within 15 days following the change.

### Reasoning

On 30 September, 2016, “Evropa Lijek Pharma” d.o.o. Sarajevo filed with the Agency of Medicinal Products and Medical Devices of BiH, a request to renew the marketing authorization for the wholesale of medicinal products.

Pursuant to the formally complete request, the Agency assessed, in the inspection supervision procedure, that the legal entity “Evropa Lijek Pharma” d.o.o. Sarajevo meets the requirements for the marketing authorization for the wholesale of medicinal products for the import, procurement, storage and supply of medicinal products, in accordance with the marketing authorization for medicinal products and medicinal products that require special storage conditions – medicinal products containing psychotropic substances, immunological medicinal products, medicinal products that require cold storage chain and medicinal products



for clinical examinations, the Agency has decided as rendered in the operative part of the Decision.

**Legal Remedy:** An appeal may be filed against this Decision with the Council of Ministers of Bosnia and Herzegovina Appeals Commission within eight days following the day of receipt of the Decision, pursuant to Article 215 (1) of the Administrative Procedure Act.

The administrative fee in the amount of BAM 10.00 shall be charged in acc. with tariff no. 2 of the Law on Administrative Fees. Payment shall be made to the current account no. 3380002210018390 (UniCredit Bank), stating "Administrative Fee" as the reference, "JRT-Trezor BiH – takse" as the beneficiary and 722102 as income type.

**Delivered to:**

1. Applicant
2. Finance Department
3. Inspectorate
4. Case file
5. a/a

ACTING DIRECTOR  
dr. Aleksandar Zolak  
*/stamp and signature affixed/*

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*I hereby confirm that this document is a true translation of the original written in  
Bosnian/Croatian/Serbian language  
Reg. No. 15/2017  
Sarajevo, 4 January 2017  
Tihana Puzić, Certified Court Interpreter for English Language*



Number: 10-07.12-5-8781-2/16  
Date: September 5, 2019

The Agency for Medicinal Products and Medicinal Devices of BiH, resolving upon the request of "Evropa Lijek Pharma" d.o.o. Sarajevo, in the procedure of amending the decision, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medicinal Devices ("Official Gazette of BiH", num. 58/08), Art. 8 of the Policy on conditions for performing wholesale of medicinal products ("Off. Gazette of BiH", num. 49/14) and Art. 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 (3) of the ruling of the decision made by the Agency for Medicinal Products and Medicinal Devices of BiH number: 10-07.12-5-8981/16 of December 28, 2016 as follows: the person accountable for reception and issuance of medicinal products and overview of documentation is mr ph. Aida Pavlović.
2. Other parts of the decision number: 10-07.12-5-8981/16 of December 28, 2016, stay the same and this decision on amending the decision is included with the decision.

**Elaboration**

The legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo, with central office at Rogačići bb, Vlakovo, Ilidža, Sarajevo, filed to the Agency for Medicinal Products and Medicinal Devices of BiH, on August 29, 2019, the request for amending the decision (changing the accountable person).

Under formally complete request, the Agency established that the legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo fulfils conditions for amending the decision (changing the accountable person).

**Legal remedy:** This decision is final in the administrative procedure and no appeal may be filed against it, but an administrative proceeding may be filed via a lawsuit with the authorized court, within 60 days, counting from the date of receiving the decision.

ACCORDING TO THE AUTHORIZATION OF THE DIRECTOR  
Assistant Director of Legal and General Affairs Department  
/Signature: illegible/  
Mladen Čančarević, Grad. lur.  
/Seal: BOSNIA AND HERZEGOVINA  
AGENCY FOR MEDICINAL PRODUCTS AND MEDICINAL DEVICES  
BANJA LUKA/

**Deliver to:**

1. The requestor,
2. Sector for financial affairs,
3. Inspectorate,
4. Case files,
5. a.a.



*I hereby certify that the above translation complies completely with the original text written in Bosnian.*  
Translation log: 2091-19  
Sarajevo, September 10, 2019  
Dea Paljević  
Certified Court Interpreter for English

BOSNIA AND HERZEGOVINA  
AGENCY FOR MEDICINAL PRODUCTS  
AND MEDICAL DEVICES

Number: 10-07.12-5-8981-2/16

Date: 14 May 2020

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, acting at the request of „Evropa Lijek Pharma“ d.o.o. Sarajevo in the procedure for modification of decision, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices (Official Gazette of BiH, 58/08), Article 8 of the Rulebook on requirements for wholesale of medicinal products (Official Gazette of BiH, 49/14), and 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), hereby issues

DECISION  
on Modification of Decision

1. This is to modify point 1 of the operative part of the decision of the Agency for Medicinal Products and Medical Devices of BiH, number: 10- 07.12-5-8981/16 of 28 December 2016 as follows: This is to approve to „Evropa Lijek Pharma“ d.o.o. Sarajevo, with a warehouse at Vlakovo br. 252, Ilidža, Sarajevo, to perform activities of wholesale form import, procurement, storage and supply of:
  - Medicinal products with controlled storage conditions at room temperature in accordance with the marketing authorisation.
  - Medicinal products with special storage conditions:
    - Medicinal products containing psychotropic substances;
    - Medicinal products from human blood and plasma;
    - Immunological medicines;
    - Medicinal products requiring cold storage chain;
    - Medicinal products for clinical research.
2. Other parts of the decision number: 10-07.12-5-8981/16 of 28 December 2016 remain unchanged, and this Decision on modification of decision constitutes an integral part thereof.

Justification

The legal person „Evropa Lijek Pharma“ d.o.o. Sarajevo, submitted to the Agency for Medicinal Products and Medical Devices of BiH on 25 December 2019 the application for modification of the decision (change of warehouse address and addition of activities).

In accordance with the formally complete application, the Agency decided that the legal person „Evropa Lijek Pharma“ d.o.o. Sarajevo, with the warehouse at Vlakovo br. 252, Ilidža, Sarajevo, met the requirements for modification of the decision (change of warehouse address and addition of activities).

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.

Copies to:

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

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

*I hereby certify that the above translation complies completely with the original text written in Bosnian.*

*Translation log: 217-20*

*Sarajevo, 29 May 2020*

*Amira Dozo*

*Certified Court Interpreter for English*





Decision No. 10-07.12-5-8981-4/16

Date: 20 November, 2020

The Agency for Medicinal Products and Medical Devices Bosnia and Herzegovina deciding on the request regarding the decision amendment procedure filed by “**Evropa Lijek Pharma**” d.o.o. Sarajevo, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices (Official Gazette of BiH, No. 58/08), Article 8 of the Rulebook on the requirements for the marketing authorization for the wholesale of medicinal products (Official Gazette of BiH, No. 49/14), pursuant to Article 193 of the Law on Administrative Procedures (Official Gazette of BiH, No. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16), hereby renders the following

**DECISION**  
**on amendments to the decision**

1. **Item 1 of the operative part of the Decision on amendments to the Decision issued by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina no. 10-07.12-5-8981-2-16 dated May 9, 2019 is modified and it now reads: the person responsible for acceptance and issuing of medicinal products, as well as for documentation review is Berina Tatlić, Mr. Ph.**
2. The remaining parts of the Decision **10-07.12-5-8981/16** dated December 28, 2016 remain unchanged, and this Decision on Amendments to the Decision forms its integral part.

**Reasoning**

On November 2, 2020 the legal entity „Evropa Lijek Pharma“ d.o.o. Sarajevo with head office at the address Vlakovo 252, Ilidža, Sarajevo, submitted to the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina a request to amend the Decision (change of the responsible person).

Based on the formally complete request, the Agency established that the legal subject „Evropa Lijek Pharma“ d.o.o. Sarajevo, meets the requirements necessary to amend the Decision (change of the responsible person).

**Legal remedy:** This decision is final in the administrative procedure and it cannot be appealed, but an administrative dispute can be instigated, by filing a complaint with the competent court within 60 days from the day of receiving the decision

**Delivered to:**

1. Applicant
2. Financial Affairs Sector
3. Inspectorate
4. Case file */round stamp affixed/*
5. Ad acta

**DIRECTOR**

**Aleksandar Zoriak, Dr**

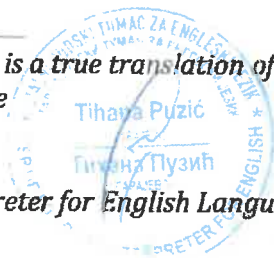
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Bosnian/Croatian/Serbian language  
Reg. No. 1796/2020  
Sarajevo, 3 December 2020  
Tihana Puzić, Certified Court Interpreter for English Language*



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**BOSNIA AND HERZEGOVINA**  
**The Agency for Medicinal Products and Medical Devices of B&H**

/handwritten text and date/

/B&H coat of arms/

Number: 10-07.12-5-8981-6/16

Date: 11.01.2021

Deciding upon the request of "Evropa Lijek Pharma" d.o.o. Sarajevo in the procedure of the change of Decision, pursuant to Articles 7, 64 and 65 of the Law on Medicinal Products and Medical Devices ("Official Gazette of B&H", no. 58/08) and Article 8 of the Rulebook on production and wholesale marketing of medical devices ("Official Gazette of B&H", no. 49/14) and Article 193 of the Law on Administrative Procedure ("Official Gazette of B&H", no. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16), the Agency for Medicinal Products and Medical Devices of B&H renders the following

**DECISION**  
on the change of decision

1. **Item 4 of the operative part of the Decision of the Agency for Medicinal Products and Medical Devices of B&H number 10-07.12-5-8981/16 dated 28 December 2016 is hereby changed to read as follows: For performing marketing of medical devices in the wholesale facility, the responsible person is: mr. ph. Naida Bilalagić-Pihura**
2. Other parts of the Decision number 10-07.12-5-8981/16 dated 28 December 2016, remain the same, and this Decision on the change of decision constitutes its integral part.

**Explanation**

On December 10, 2020, the legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo, with headquarters at Vlakovo br. 252, Blažuj, Sarajevo, addressed to the Agency for Medicinal Products and Medical Devices B&H a request for the change of the Decision (change of the responsible person).

Taking into consideration the formally complete request, the Agency determined that the legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo, fulfils the conditions for the change of decision (change of the responsible person).

**Instruction on legal remedy:** This decision is final in the administrative procedure and no appeal can be filed against it, but an administrative dispute can be initiated, by filing a lawsuit with the competent court within 60 days, counting from the day the decision was received.

Delivered to:

1. Applicant,
2. Finance Department
3. Inspectorate
4. Case file
5. a/a

**ACTING DIRECTOR**

**Dr. Aleksandar Zolak**

*/signature and round stamp affixed/*

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*Reg. No. 307/2021*

*Sarajevo, 25 February 2021*

*Tihana Puzić, Certified Court Interpreter for English Language*

