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BOSNIA AND HERZEGOVINA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICINAL DEVICES

[Coat of arms: BiH]

Number: 10-07.12-6-288-1/17

Date: July 31, 2017

The Agency for Medicinal Products and Medicinal Devices of BiH, pursuant to the Article 193 of the Law on Administrative Procedure ("Off. Gazette of BiH" No. 29/02, 12/04/, 88/07, 93/09, 41/13 and 53/16), Art. 8 and 109 of the Law on Medicinal Products and Medicinal Devices ("Off. Gazette of BiH", No. 58/08) and the Art. 7 of the Policy on production and wholesale of medical devices ("Off. Gazette of BiH", No. 71/12 and 64/13) upon the request of "Evropa Lijek Pharma" d.o.o. Sarajevo, enacts the following:

DECISION

1. "Evropa Lijek Pharma" d.o.o. Sarajevo, with a warehouse at Rogačići bb, Vlakovo, Blažuj Sarajevo, is approved to be entered in the Register of large-scale dispatchers of medical devices.
2. Based on the entry in the Register of large-scale dispatchers of medical devices, the holder of the approval may perform large-scale dispatch of class I, I-s, IIa and "in-vitro" (medical devices from List C – self-testing tests) medical devices.
3. Performing the circulation of medical devices at the facility of the large-scale dispatcher is the responsibility of Edita Šačić, a nurse-technician (person responsible for large-scale dispatching) and Namik Turković, a Stomatology Doctor (person responsible for monitoring adverse effects).
4. The Decision is issued on the time period of five years conclusive with July 30, 2022.
5. The owner of this Decision is obliged to inform this Agency on every alteration in conditions, based on with the Decision is enacted, in no more than 15 days after performing the alteration.

Elaboration

The legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo filed the Agency for Medicinal Products and Medicinal Devices of BiH on May 25, 2017 a request to renew the entry in the Register of large-scale dispatcher of medical devices.

According to the formally complete request, the Agency has determined, in the procedure of inspection monitoring that the legal entity "Evropa Lijek Pharma" d.o.o. Sarajevo, fulfils the conditions for renewal of entry in the Register of large-scale dispatchers of medical devices with a warehouse at Rogačići bb, Vlakovo, Blažuj Sarajevo, for large-scale dispatching of class I, I-s, IIa and "in-vitro" (medical devices from List C – self-testing tests) medical devices.

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I hereby certify that the above translation complies completely with the original text written in Bosnian.
Translation log: 979-17
Sarajevo, August 8, 2017
Dea Paljević
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Instruction on legal remedy: An appeal to the Appellate Chamber of the Council of Ministers of Bosnia and Herzegovina may be filed within 15 days after receiving the decision, in accordance with the Article 215(1) of the Law on Administrative Procedure.

An administrative fee is paid for the appeal in amount of 10.00 BAM, according to the tariff No. 2 of the Administrative Fees Tariff. The fee is paid for the purpose of "Administrative Fee", for the benefit of "JRT-Treasury BiH-taxes" account No. 3380002210018390 (UniCredit Bank), type of income 722102.

Delivered to:

1. The Requestor,
2. Department of Finances,
3. Inspectorate,
4. Case file,
5. a.a.

ACT. DIRECTOR

Dr. Aleksandar Zorlak

/Signature and seal: illegible/

Mladen Čančarević, Grad. Lawyer

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THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
BOSNIA AND HERZEGOVINA



No. 10-07.12-6-288-9/17

Date: January 13, 2020

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, acting upon the request submitted by „Evropa Lijek Pharma“ d.o.o. Sarajevo in the procedure of amending the previously issued Decision, pursuant to Articles 8 and 109 of the Law on Medicinal Products and Medical Devices (Official Gazette of BiH, no. 58/08), Article 7 of the Rulebook on Production and Wholesale of Medical Devices (Official Gazette of BiH, no. 71/12 and 64/13) and Article 193 of the Law on Administrative Procedure (Official Gazette of BiH, no. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16) adopts the following

DECISION
on Amendments to the Decision

1. **Item 1 of the operative part of the Decision issued by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina no. 10-07.12-6-288-1/17 dated July 31, 2017 is modified and it now reads:** Approval has been granted to „Evropa Lijek Pharma“ d.o.o. Sarajevo, with its head office in Vlakovo 252, Ilidža, Sarajevo, the entry in the Registry of Wholesalers of Medical Devices.
2. The remaining parts of the Decision 10-07.12-6-288-1/17 dated July 31, 2017 remain unchanged, and this Decision on Amendments to the Decision forms its integral part.

Reasoning

On December 25, 2019 the legal subject „Evropa Lijek Pharma“ d.o.o. Sarajevo submitted the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina a request to amend the Decision (change of the warehouse address).

Based on the formally complete request, the Agency established that the legal subject „Evropa Lijek Pharma“ d.o.o. Sarajevo, at the address Vlakovo 252, Ilidža, Sarajevo, meets the requirements necessary to amend the Decision (change of the warehouse address).

Legal remedy: Pursuant to Article 215, Paragraph 1 of the Law on Administrative Procedure, an appeal can be submitted against this Decision to the Appeals Council of the Council of Ministers of Bosnia and Herzegovina no later than 15 days from the day of the reception of the Decision.

An administrative fee amounting to BAM 10.00, under tariff no. 2 Authority Fees applies to this appeal. The purpose of the fee is „Administrative Fee“, paid to JRT Trezor-takse (unique treasury account – fees), to the account no. 3380002210018390 (UniCredit Bank), type of revenue 722102. One copy of the payment order is submitted with the appeal.

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Delivered to:

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

DIRECTOR
Aleksandar Zorlak, Dr
/signature affixed/

I hereby confirm that this document is a true translation of the original written in Bosnian/ Croatian/ Serbian language
Reg. No. 163/2020
Sarajevo, 7 February 2020
Tihana Puzić, Certified Court Interpreter for English Language



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THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

No.: 10-07.12-6-288-11/17

Date: 17.06.2020.

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, acting upon the request submitted by „Evropa Lijek Pharma“ d.o.o. Sarajevo in the procedure of amending the previously issued decision, pursuant to Articles 8 and 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 Production and Wholesale of Medical Devices (Official Gazette of Bosnia and Herzegovina, no. 71/12 and 64/13) and Article 193 of the Law on Administrative Procedure (Official Gazette of Bosnia and Herzegovina, no. 29/02, 12/04, 88/07, 93/09, 41/13 and 53/16) adopts the following

DECISION
on Amendments to the Decision

1. **Item 2 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. 10-07.12-6-288-5/17 dated March 14, 2018, is modified and now reads:** For performing marketing of medical devices in the wholesale facility, the responsible persons are: **Edita Bašić**, nurse (person responsible for wholesale trade), and **Zerina Zorlak**, Master of Pharmacy (responsible person for monitoring of adverse effects).
2. The remaining parts of the Decision 10-07.12-6-288-1/17 dated July 31, 2017, as well as the Decision on Amendments to the Decision no.: 10-07.12-6-288-9/17 dated January 13, 2020, remain unchanged and this Decision on Amendments to the Decision forms its integral part.

Reasoning

On June 9, 2020 the legal subject „Evropa Lijek Pharma“ d.o.o. Sarajevo submitted the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina a request to amend the Decision (change of responsible person).

Based on the formally complete request, during the inspection visit procedure the Agency established that the legal subject „Evropa Lijek Pharma“ d.o.o. Sarajevo, at the address Vlakovo 252, Ilidža, Sarajevo, meets the requirements necessary to amend the Decision (change of responsible person).

Legal remedy: Pursuant to Article 215, Paragraph 1 of the Law on Administrative Procedure, an appeal can be submitted against this Decision to the Appeals Council of the Council of Ministers


Tinana Puzić

of Bosnia and Herzegovina no later than 15 days from the day of the reception of the Decision. An administrative fee amounting to BAM 10.00, under tariff no. 2 Authority Fees applies to this appeal. The purpose of the fee is „Administrative Fee“, paid to JRT Trezor BiH-takse (unique treasury account – fees), to the account no. 3380002210018390 (UniCredit Bank), type of revenue 722102. One copy of the payment order is submitted with the appeal.

Delivered to:

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3. Inspectorate
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5. Ad acta

BY AUTHORIZATION OF THE DIRECTOR
Assistant Director in the Sector for Legal and General Affairs
/round stamp affixed/ **Mladen Čančarević, lawyer**
/signature affixed/

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Reg. No. 847/2020
Sarajevo, 25 June 2020
Tihana Puzić, Certified Court Interpreter for English Language

