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AGENCY FOR MEDICINES
AND MEDICAL DEVICES

Pursuant to Article 77, Article 104 paragraph 1 and Article 129 of the Law on Medicines and Medical Devices (Official Gazette of Republic of Macedonia No. 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16 and 53/16) the Agency for Medicines and Medical Devices deciding upon the Request No. UP1 20-141 dated 12.12.2017 of the **Company for Production, Trade and Services EVROPA LEK FARMA DOOEL** from Skopje on adopting a decision on amending the decision on wholesale of medicines, narcotic and psychotropic substances and entering into the register of legal entities for wholesale of medical devices (temporary storage in public Customs warehouse) due to amendment of data referring to change in the area of the Customs warehouse of the Company for Production, Trade and Services, located on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje, hereby adopted

D E C I S I O N

1. An amendment to the decision of the Agency for Medicines and Medical Devices No. UP1 20-4 dated 25.01.2017 shall be performed due to change in the data referring to change in the area of Customs warehouse of the **Company for Production, Trade and Services EVROPA LEK FARMA DOOEL** from Skopje, headquartered on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje, where the data referring to the area of the Customs warehouse located on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje is changed and the data now reading: 331.8 m^2 shall be amended in **206 m^2**.

2. Amendments determined by this decision shall be performed by the founder in the Central Register of Republic of Macedonia.

R a t i o n a l e

The **Company for Production, Trade and Services EVROPA LEK FARMA DOOEL** from Skopje, headquartered on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje, with Company Registration No. 6714706 submitted a request to the Agency for Medicines and Medical Devices No. UP1 20-141 dated 12.12.2017 on amending a data in the decision No. UP1 20-4 dated 25.01.2017 due to change in the area of Customs warehouse of the Company for Production, Trade and Services, thus the area of the warehouse space shall be amended from area of 331.8 m^2 into area of 206 m^2.

In addition to the request the following documents were given: evidence of paid administrative costs, decision issued by the Central Register of Republic of Macedonia, decision on the work permit no. UP1 20-4 dated 25.01.2017 issued by the Agency for Medicines and Medical Devices, amendment of decision issued by the Customs Administration dated 07.11.2017, title deed for the building, sublease agreement for the building, building layout, SITE MASTER FILE v2 and statement on amending the area of the Customs warehouse.

Agency for Medicines and Medical Devices of Republic of Macedonia
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In case of amendment in the data contained in the work permit, at the request of the Company for Production, Trade and Services, there shall be an amendment in the work permit performed based on the documentation that proves that amendment.

After considering the aforementioned request, and based on the documentation submitted for amending the area of Customs warehouse and minutes of the inspection performed No. UP1 20-141 dated 18.12.2017 of the **Company for Production, Trade and Services EVROPA LEK FARMA DOOEL** from Skopje, the Agency for Medicines and Medical Devices determined that there are no legal obstacles for not acting upon the request and adopted a decision as in the wording.

INSTRUCTION ON LEGAL REMEDY: Administrative dispute may be initiated against this decision before the Administrative Court – Skopje within 30 days from the reception of this decision.

Decided in the Agency for Medicines and Medical Devices under no. UP1 20-141 on 21-12-2017.

Prepared by: Biljana Prentovska, counselor *//illegible handwritten signature//*
Controlled by: Marijana Doncheva, Head of Department *//illegible handwritten signature//*

Delivered to:
- requestor
- archives

ACTING DIRECTOR,
MA Pharm. Robert Bekiroski
//illegible handwritten signature//
//round wet stamp of the Agency for Medicines and Medical Devices//

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