

Pursuant to Article 76 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 20-129 dated 16.11.2017 of the Company for Production, Trade and Services **EVROPA LEK FARMA DOOEL** from Skopje on adopting a decision on amending the work permit due to change of data referring to change in the area of warehouse space of the Company for Production, Trade and Services, located on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje, hereby adopted

DECISION

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 warehouse space 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 warehouse space located on Str. Jadranska magistrala No. 31, Municipality of Butel, Skopje is changed and the data now reading: 1061 m² shall be amended in **1273 m²**.
2. Amendments determined by this decision shall be performed by the founder in the Central Register of Republic of Macedonia.

Rationale

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 20-129 dated 16.11.2017 on amending a data in the decision No. UP1 20-4 dated 25.01.2017 due to change in the area of warehouse space of the Company for Production, Trade and Services, thus the area of the warehouse space shall be amended from area of 1061 m² into area of 1273 m². The staff remains the same (holder of activity – MA in Pharmacy Monika Naumovski and Bachelor of Pharmacy Julijana Ivanova).

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, title deed for the building, lease agreement for the building, building layout, SITE MASTER FILE v2 and statement on amending the area of the warehouse space.

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 warehouse space and minutes of the inspection performed No. UP1 20-129 dated 07.12.2017 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 20-129 on 15-12-2017.

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
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//round wet stamp of the Agency for Medicines and Medical Devices//