

The Agency for Medicines and Medical Equipment, pursuant to Article 77 paragraph 1, and in connection with Article 74 paragraph 1 line 5 of the Law on Medicines and Medical Devices ("Official Gazette of the Republic of Macedonia" no. 106/07, 88/2010, 36/11, 53/11, 136/11, 11/12, 147/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18 and 245/18) and "Official Gazette of the Republic of North Macedonia" no. 28/21, 122/21 and 60/23), deciding on the request no. UPI 20-135 of December 11, 2024 of the Company for production, trade and services EUROPA LEK PHARMA DOOEL Skopje for obtaining a decision to supplement the activity for the wholesale trade in medicines and medical devices, adopted the following

DECISION

The Company for production, trade and services EUROPA LEK PHARMA DOOEL, located at str. Jadranska Magistrala, no.51, Skopje, Butel, meets the requirements for supplementing the activity for performing wholesale trade in medicines and medical devices, including storage and keeping of biological medicines and immunological medicines (vaccines, toxins, serums or allergens) under a specially declared temperature regime for storage, from 2 to 8°C in the warehouse space located at str. Jadranska Magistrala no.31, Skopje.

The amendments regarding the supplement to the activity from paragraph 1 of this Decision refer to the Decision by the Agency for Medicines no.15-10700/4 of January 29, 2015.

The founder shall enter the changes, determined with this Decision, in the Central Registry of the Republic of North Macedonia.

Explanation

The Company for production, trade and services EUROPA LEK PHARMA DOOEL Skopje located at str. Jadranska Magistrala no.31, Skopje, Butel submitted a request to this authority, no. UPI 20-135 of December 11, 2024 for obtaining a Decision to supplement the activity performing wholesale trade in medicines and medical devices, including storage and keeping of biological medicines and immunological medicines (vaccines, toxins, serums or allergens) under a specially declared temperature regime for storage, from 2 to 8°C in the warehouse space located at str. Jadranska Magistrala no.31, Skopje.

The following documents are submitted to the request: proof of paid administration fees, a copy of the Decision by the Agency for Medicines no.15-10700/4 from January 29, 2015, a copy of the Decision by the Agency for Medicines and Medical Equipment no. UPI 20-41 of July 17, 2023, a certificate for performed calibration of the cold chamber, a report from performed qualification with technical features of a cold chamber, a certificate for performed calibration of cold vehicle, a report from performed qualification with technical features of cold vehicle, technical features of diesel electric aggregate (backup power supply), report for the last servicing of the diesel electric aggregate, notices for the employed professional staff, a certificate of proper functioning of the cold chain system for storage and transport of medicines No. 18-12899/2 of November 27, 2024, Decision on commissioning technical equipment by the State Inspectorate for Technical Inspection and registration documents for the vehicle CITROEN JUMPER SK 7618 AF.

This authority has reviewed the request with the attached evidence, and after inspecting the warehouse space at str. Jadranska Magistrala no.31, Skopje for the wholesale trade in medicines and medical equipment, the authorized persons from the Agency for Medicines and Medical Equipment have determined, with minutes no. UPI 20-135 from January 15, 2025 that the same is in accordance with the provisions of the Law on Medicines and Medical Equipment ("Official Gazette of RM", no. 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 141/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18 and 245/18), and "Official Gazette of the Republic of North Macedonia" no. 28/21, 122/31 and 60/23), the Rulebook on the content of the request and the more detailed requirements regarding the size, equipment and staff for obtaining approval for wholesale trade in medicines ("Official Gazette of RM", no.151/08) and the Rulebook on the requirements for



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AGENCY FOR MEDICINES AND MEDICAL EQUIPMENT
Skopje

space, equipment and staff, the documentation for registration in the Registry of legal entities for wholesale trade in medical equipment ("Official Gazette of the Republic of Macedonia No. 220/16"), the Company for production, trade and services EUROPA LEK PHARMA DOOEL Skopje meets the conditions for supplementing the approval for wholesale trade in medicines and medical devices in terms of space, equipment for storage, storage and distribution of biological medicines and immunological medicines (vaccines, toxins, serums or allergens) under a specially declared temperature regime for storage from 2 to 8°C in a secured cold chamber with a capacity of 201 m³, an aggregate and 1 special purpose vehicle. The responsible persons Gabriela Stavreska - Bogojevska, a graduate pharmacist, and master of pharmacy Sofija Kostoska remain unchanged.

The fee for this decision is charged according to tariff number 3 of the Law on Administrative Fees ("Official Gazette of the Republic of Macedonia" no. 17/93, 20/96, 7/98, 13/01 ... and 23/16) and ("Official Gazette of the Republic of Macedonia" no. 151/21).

INSTRUCTION FOR LEGAL REMEDY: An administrative dispute may be filed against this decision before the Administrative Court - Skopje within 30 days from the date of receipt of this decision.

Resolved in the Agency for Medicines and Medical Devices under No. UPI 20-135 on January 30, 2025.

ACTING DIRECTOR

Sefedin JONUZI

/personal signature, affixed/

/round seal, Agency for Medicines and Medical Equipment, Skopje/

Prepared by: B. Prentovska, advisor /personal signature, affixed/

Checked by: J.A. Shakjiri, department manager /personal signature, affixed/

Approved by: M. Doncheva, sector manager /personal signature, affixed/

Submitted to

- The applicant
- Archive



Даниела Трајчо Тодосова - Јевтиќ, овластен судски преведувач, со Решение за овластен преведувач Бр. 08/1-714/2000-2, потврдувам дека извршив правилен превод на оригиналниот документ од македонски јазик на англиски јазик.

Скопје, _____

I, Daniela Trajcho Todosova - Jevtikj, Authorized Court Translator, with a Decision for authorized translator No. 08/1-714/2000-2, solemnly declare that I have faithfully and accurately translated the content of the original document from Macedonian language into English language.

Skopje, _____

