Republika e Kosovës
Republika Kosova-Republic of Kosovo
Qeveria - Vlada-Government
Ministria e Shëndetësisë / Ministarstvo Zdravstva / Ministry of Health

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ADMINISTRATIVE INSTRUCTION (Health) NO. 05/2026 ON SUPPLEMENTATION AND AMENDMENT OF ADMINISTRATIVE INSTRUCTION (Health) NO.01/2022 FOR SIMPLIFYING THE PROCEDURES FOR REGISTRATION AND IMPORT OF MEDICINAL PRODUCTS WHICH ARE NOT REGISTERED IN THE REPUBLIC OF KOSOVO

Acting Minister of the Ministry of Health,

Pursuant to Article 16, paragraph 11 of Law No. 04/L -190 on Medicinal Products and Medical Devices (Official Gazette of the Republic of Kosovo/no. 27/25 April 2014), Article 11, paragraph 1, subparagraph 1.5 of Law No. 08/l-117 on Government of the Republic of Kosovo, Article 9 paragraph 2 of the Regulation No. 17/2024 of Rules and Procedures of the Government of the Republic of Kosovo ,

Issues the following:

Administrative Instruction (Health) No. 05 /2026 on Amendment and Supplementation Of Administrative Instruction (Health) No.01/2022 for Simplifying the Procedures for Registration And Import Of Medicinal Products which are not registered in the Republic Of Kosovo

Article 1
Purpose

The purpose of this Instruction shall be to amend and supplement Administrative Instruction (Health) No. 01/2022 for Simplifying the Procedures for Registration and Import of Medicinal Products Which Are Not Registered in the Republic of Kosovo.

Article 2

1. Subparagraph 1.2 of paragraph 1 of Article 2 of the basic Administrative Instruction shall be and amended supplemented as follows:

> 1.2. **Limited Authorization for Marketing** — Marketing Authorization granted for a medicinal product that is not registered in the market, limited in terms of time to a period of 1 year from the issuance of the first authorization, with possibility of extension for one more year.

Article 3

1. Paragraph 3 of Article 3 of the basic Administrative Instruction shall be deleted in its entirety.

Article 4

1. Subparagraph 3.2 of paragraph 3 of Article 4 of the basic administrative instruction shall be amended and supplemented as follows:

> 3.2. Two representatives from the Ministry of Health;

2. Subparagraph 3.3 of paragraph 3 of Article 4 of the basic Administrative Instruction shall be deleted in its entirety.

3. Subparagraph 6.3 of paragraph 6 of Article 4 of the basic administrative instruction shall be amended and supplemented as follows:

> 6.3. To assess and decide on the issuance of a Limited Marketing Authorization for the medicinal product.

4. After subparagraph 6.6 of paragraph 6 of Article 4 of the basic Administrative Instruction, a new subparagraph under the ordinal number 6.7 shall be added as follows:

6.7. To verify the status of authorization of the Wholesale Pharmaceutical Distributor or Certificate of Good Distribution Practice in one of the EU countries, at the following link:

https://eudragmdp.ema.europa.eu

Article 5

1. Subparagraph 1.1 of paragraph 1 of Article 5 of the basic Administrative Instruction shall be amended and supplemented as follows:

1.1 Copy of the authorization of the Wholesale Pharmaceutical Distributor or Certificate of Good Distribution Practice in one of the EU countries.

2. Subparagraph 1.2 of paragraph 1 of Article 5 of the Basic Administrative Instruction shall be amended and supplemented as follows:

1.2. The patient information leaflet translated into the official languages of the Republic of Kosovo to be specific for each product for which the application is made.

3. After subparagraph 1.3 of paragraph 1 of Article 5 of the Basic Administrative Instruction, the following paragraphs 1.4, 1.5 and 1.6 are added:

1.4. Evidence that the medicinal product for which the application is submitted is authorized for marketing and is legally placed on the market in one of the EU countries. The evidence shall refer to the medicinal product, the active substance, the pharmaceutical form, the dose, and the respective packaging, and shall not be older than 6 months.

1.5. Physical invoice - fee in the amount of 1,500 Euros at the AKPPM.

1.6. For re-application, the applicant is obliged to pay the physical invoice of 750 Euros to the AKPPM.

2. After paragraph 1 of Article 5 of the basic Administrative Instruction, three new paragraphs under the ordinal numbers 2, 3 and 4 shall be added as follows:

2. For the registration of the same medicinal product with limited authorization, the pharmaceutical wholesaler may submit no more than two applications to the AKPPM. The second application is considered a re-application and is subject to the same procedure and criteria as the first application.

3. The pharmaceutical wholesaler must reapply for the renewal of the limited authorization 30 working days prior to the expiration of the limited authorization; otherwise, it forfeits the right to reapply.

4. Following the submission of the second application, the submission of any other application for the registration of the same medicinal product with limited authorization is not permitted.

Article 6

1. Paragraph 2 of Article 6 of the basic administrative instruction shall be amended and supplemented as follows:

> 2. Limited Authorization for Marketing for imports of medicinal products shall be issued for a period of 1 year.

Article 7

1. Subparagraph 1.2 of paragraph 1 of Article 7 shall be deleted in its entirety.

2. After subparagraph 1.2 of paragraph 1 of Article 7, a new paragraph under ordinal number 1.3 shall be added follows:

> 1.3. Proof that the batch of the medicinal product for the import of which the application is made has been circulating in one of the EU countries, which may not be older than 6 months.

Article 8
Transitional Provisions

Article 8 of the Basic Administrative Instruction is supplemented and amended as follows:

1. The provisions, conditions and procedures of this Administrative Instruction apply to all applications that are in process.

Article 9
Entry into force

This Administrative Instruction shall enter into force on the date of its publication in the Official Gazette of the Republic of Kosovo.

Prishtina 24.07.2026

Dr. Arben Vitia
Acting Minister of Health