Republika e Kosovës
Republika Kosova-Republic of Kosovo
Qeveria-Vlada-Government

REGULATION (OPM) NO. 04/2025 ON INTERNAL ORGANIZATION AND SYSTEMATIZATION OF JOBS IN KOSOVO MEDICINES AGENCY[1]

[1] Regulation (OPM) – No. 04/2025 on Internal Organization and Systematization of Jobs in Kosovo Medicines Agency, with Decision No.228/2025, dated 10.03.2025.

Prime Minister of the Republic of Kosovo,

Pursuant to Article 94, paragraph 3 of the Constitution of the Republic of Kosovo,based in article 9 Law no. 08/L-117 on Government of the Republic of Kosovo Article 28, paragraph 3 of Law No. 06/L-113 on Organization and Functioning of State Administration and Independent Agencies, Article 4, paragraph 3 of Law No. 04/L-190 on Medicinal Products and Medical Devices as well as Article 9, paragraph 7 of Regulation (GRK) No. 01/2020 on Standards for Internal Organization, Systematization of Jobs and Co-operation in State Administration Institutions and Independent Agencies:

Adopts the following:

REGULATION (OPM) NO. 04/2025 ON INTERNAL ORGANIZATION AND SYSTEMATIZATION OF JOBS IN KOSOVO MEDICINES AGENCY

CHAPTER I
GENERAL PROVISIONS

Article 1
Purpose

This Regulation aims to define the internal organization and systematization of jobs in Kosovo Medicines Agency (hereafter KMA).

Article 2
Scope

The Regulation applies to the Kosovo Medicines Agency.

CHAPTER II
INTERNAL ORGANIZATION OF THE KOSOVO MEDICINES AGENCY

Article 3
Mission of the Agency

The mission of the Kosovo Medicines Agency (KMA) is to ensure that medicinal products and medical devices are safe, effective and of high quality for use by citizens, by supervising and regulating the import, production, distribution and use of these products and devices in accordance with the standards and legislation in force.

Article 4
Organizational structure of the Agency

1. The organizational structure of the Kosovo Medicines Agency is as follows:

    1.1. Office of the Executive Director;

1.2. Departments;

1.3. Divisions.

2. The total number of employees in KMA is seventy-three (73).

Article 5
Office of the Executive Director

1. The office of the Executive Director of KMA consists of:

1.1. Executive Director;

1.2. Support staff.

2. The duties and responsibilities of the Executive Director of KMA are determined by Law No. 06/L-113 on Organization and Functioning of State Administration and Independent Agencies and Law No. 04/L-190 on Medicinal Products and Medical Devices as well as other relevant legislation.

3.The duties and responsibilities of the support staff of the Office of the Executive Director of KMA are defined according to the relevant legislation for public officials.

4.The professional and support civil servants within the Office of the Executive Director are as follows:

4.1. Senior Executive Officer;

4.2. Administrative Officer.

5.Another position that reports directly to the Executive Director is also:

5.1. Senior Certification Officer;

6.The number of employees in the Office of the Executive Director is four (4).

7.The Executive Director of KMA reports to the Minister of the Ministry of Health and informs the General Secretary.

Article 6
Departments and Divisions of the Agency

1.The Departments and Divisions of KMA are as follows:

1.1. Department for Laboratories of Quality Control;

1.1.1. Division for Physics-Chemistry;

1.1.2. Division for Microbiology;

1.1.3.Division for Biopharmaceutics.

1.2. Department for Marketing Authorization;

1.2.1. Division for Registration of Medicinal Products;

1.2.2. Division for Registration of Food Supplements;

1.2.3. Division for Variations and Renewals;

1.2.4.Division for Evaluation of Quality, Safety and Efficacy of Medicines;

1.2.5. Division for Registration of Veterinary Medicinal Products.

1.3. Department for Licensing and Import;

1.3.1. Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols;

1.3.2. Division for Import/Export of Medicinal Products;

1.3.3. Division for Import/Export of Medical Devices;

1.4. Department for Pharmacovigilance;

1.4.1. Division for Administration and Evaluation of Side Effects;

1.4.2. Division for Risk Management;

1.5. Division for Narcotics and Precursors;

1.6. Division for Human Resources;

1.7. Division for Common Services;

1.8. Budget and Finance Division;

1.9. Division for Procurement;

1.10. Legal Division.

Article 7
Department for Laboratories of Quality Control

1.The mission of the Department for Laboratories of Quality Control is to ensure the safety and effectiveness of medicines through laboratory tests and quality controls, in accordance with the standards and legislation in force to protect public health and ensure high quality pharmaceutical products.

2.The duties and responsibilities of the Department for Laboratories of Quality Control are:

2.1. Performs laboratory testing and quality control of medicines to identify potential defects;

2.2. Prepares the sampling plan on a periodic basis and as needed;

2.3. Ensures that the application and documentation for quality control is in accordance with the legislation in force;

2.4. Defines application review procedures;

2.5. Ensures that the application and the received file is reviewed within the specified time period;

2.6. Verifies whether quality control methods are submitted by the manufacturer;

2.7. Cooperates with the Kosovo Accreditation Directorate (KAD);

2.8. Develops and maintains the Quality Management System according to ISO/IEC 17025:2017;

2.9. Maintains the system of documents of environment, equipment, reagents, work procedures and personnel according to ISO/IEC 17025:2017.

3.The Director of the Department for Laboratories of Quality Control reports to the Executive Director of KMA.

4.The following divisions are part of this Department:

4.1. Division for Physics-Chemistry;

4.2. Division for Microbiology;

4.3. Division for Biopharmaceutics

5.The number of employees in the Department for Laboratories of Quality Control is ten (10).

Article 8
Division for Physics-Chemistry

1.The duties and responsibilities of the Division for Physics-Chemistry are:

1.1. Conducting physical-chemical analysis of medicinal products.

1.2. Checking the packaging and organoleptic characteristics as well as verifying the identity and content of the active substance of the final products;

1.3. Identifying and quantifying the active substance and, as necessary, impurities of the final products;

1.4. Developing and validating instrumental analytical methods;

1.5. Verifying quality control methods submitted by the manufacturer and pharmacopoeial methods;

1.6. Preparing, compiling and implementing Standard Operating Procedures according to ISO/IEC 17025:2017 – for physical-chemical analysis.

2.The Head of the Division for Physics-Chemistry reports to the Director of the Department for Laboratories of Quality Control.

3.The number of employees in the Division for Physics-Chemistry is three (3).

Article 9
Division for Microbiology

1.The duties and responsibilities of the Division for Microbiology are:

1.1. Conducting microbiological /biological analysis and control of medicinal products;

1.2. Accepting, recording and preparing samples for microbiological controls;

1.3. Preparing, compiling and implementing Standard Operating Procedures according to ISO/IEC 17025:2017 – for microbiological analysis;

1.4. Preparing the sampling plan on a periodic basis and as needed in cooperation with other Divisions in LQC;

1.5. Checking the purity of medicinal products;

1.6. Verifying microbiological control methods submitted by the manufacturer and pharmacopoeial methods;
1.7. Reviewing, approving and forwarding final results;

2.The Head of the Division for Microbiology reports to the Director of the Department for Laboratories of Quality Control.

3.The number of employees in the Division for Microbiology is three (3).

Article 10
Division for Biopharmaceutics

1.The duties and responsibilities of the Division for Biopharmaceutics are:

1.1. Testing and evaluating the absorption, bioavailability, and bioequivalence of active substances in pharmaceutical products, ensuring that they meet standards for biopharmaceutical quality and safety;

1.2. Ensuring the compliance of biopharmaceutical products with regulatory standards by implementing quality controls that include biopharmaceutical aspects, such as content, stability and distribution of active substances;

1.3. Certifying biopharmaceutical products for use in the local market, based on criteria determined by public health authorities.

1.4. Monitoring laboratory processes for biopharmaceutical control of products by performing accurate analyses and tests to assess the pharmacokinetic effectiveness of medicines;

1.5. Ensuring the compliance of pharmaceutical products with local and international biopharmaceutical regulations and related quality controls;

1.6. Improving laboratory capacities through the use of advanced technology in the evaluation and control of the biopharmacy of medicines to ensure accurate results and compliance of pharmaceutical products with the highest quality standards;

1.7. Preparing and submitting reports on quality and effectiveness testing of pharmaceutical formulations by evaluating the biopharmacy of products in accordance with local and international standards;

2.The Head of the Division for Biopharmaceutics reports to the Director of the Department for Laboratories of Quality Control.

3.The number of employees in the Division for Biopharmaceutics is three (3).

Article 11
Department for Marketing Authorization

1.The mission of the Department for Marketing Authorization is to ensure that medicinal, medicinal-herbal, homeopathic and other products that have a therapeutic effect, nutritional supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations that are placed on the market of the Republic of Kosovo are qualitative, safe and effective.

2.The duties and responsibilities of the Department for Marketing Authorization are:

2.1. Receives and records applicants' documentation, ensures maintenance of data on the receipt database and their systematization;

2.2. Recieves applications to obtain marketing authorization for a medicinal product as well as changes and renews them;

2.3. Issues marketing authorization for relevant medicinal products, homoeopathic medicinal products and traditional herbal medicinal products;

2.4. Evaluates the necessary documentation for the registration of Biosimilar and Biorenuncim products;

2.5. Provides legal and procedural advice that must be applied for the registration of Medicinal Products and food supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;

2.6. Evaluates the complete scientific documentation of human medicinal, veterinary, herbal and similar products;

2.7. Reviews applications and documentation for changes and renewals of the Medicinal Product as well as reviews SmpC, Fip and Mock up;

2.8. Cooperates with CEMPD, Department for Pharmacovigilance, Pharmaceutical Inspectorate and LQC;

2.9. Maintains the Lists of Medicinal Products, veterinary medicinal products, food supplements registered in Kosovo and publishes them;

2.10. Suspends or cancels certificates for products for which registration or Marketing Authorization is required and registration certificates for food supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;

2.11. Approves the advertising of medicinal products that have a Marketing Authorization.

3.The Director of the Department for Marketing Authorization reports to the Executive Director of KMA.

4.The following divisions are within the Department for Marketing Authorization:

4.1. Division for Registration of Medicinal Products;

4.2. Division for Registration of Food Supplements;

4.3. Division for Variations and Renewals;

4.4. Division for Evaluation of Quality, Safety and Efficacy of Medicines;

4.5. Division for Registration of Veterinary Medicinal Products.

5.The number of employees in the Department for Marketing Authorization is eighteen (18).

Article 12
Division for Registration of Medicinal Products

1.The duties and responsibilities of the Division for Registration of Medicinal Products are:

1.1. Receives the application in a hard copy for Module 1 and in online form for Modules 2, 3, 4 and 5;

1.2. Organizes the files for the relevant divisions and makes a preliminary assessment of the administrative documents included in Module 1;

1.3. Classifies the documentation whether it is a medicinal, biological, herbal, dietary, homeopathic product and, in controversial cases, submits it to the Commission for Classification and then a professional opinion is obtained;

1.4. Performs technical and professional control of SPC, FIP and Mock-up;

1.5. Approves the advertising of medicinal products that have a marketing authorization;

1.6. Coordinates with parties and provides legal and procedural recommendations that must be applied to the technical and professional control of SPC, FIP and Mock-up;

1.7. Reviews the complete scientific documentation of the generic or protected medicinal product;

1.8. Coordinates with parties and provides legal and procedural recommendations that must be applied for the registration of medicinal products;

1.9. Collaborates with the professional and support staff within the Department for Marketing Authorization, LQC and other Departments at KMA.

2.The Head of the Division for Registration of Medicinal Products reports to the Director of the Department for Marketing Authorization.

3.The number of employees in the Division for Registration of Medicinal Products is three (3).

Article 13
Division for Registration of Food Supplements

1.The duties and responsibilities of the Division for Food Supplements are:

1.1. eceives and examines applications for registration and change for food supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;

1.2. Makes the professional assessment of patient information leaflets and labels for nutritional supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;

1.3. Approves or rejects the application for food supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;
1.4. Maintains the register of certificates for food supplements, multivitamins, minerals and oligominerals, herbal substances and herbal preparations;

1.5. Cooperates with the professional and support staff within the Department for Marketing Authorization, LQC, CEMPD and other Departments of KMA;

1.6. Reviews the complete documentation for food supplements;

1.7. Coordinates with parties and provides legal and procedural recommendations that must be applied to the registration of food supplements;

2.The Head of the Division for Registration of Food Supplements reports to the Director of the Department for Marketing Authorization.

3.The number of employees in the Division for Registration of Food Supplements is three (3).

Article 14
Division for Variations and Renewals

1.The duties and responsibilities of the Division for Variations and Renewals are:

1.1 Reviews the complete scientific documentation of biological, dietary, homeopathic, herbal medicinal products and for variation and renewal;

1.2 Coordinates with parties and provides legal and procedural recommendations that must be applied to the registration of Medicinal Products.

1.3 Cooperates with the professional and support staff within the Department for Marketing Authorization, LQC and other Departments at the KMA.

1.4. Performs technical and professional control of SPC, FIP and Mock-up.

1.5. Approves advertising of medicinal products that have Marketing Authorization.

1.6. Coordinates with parties and provides legal and procedural recommendations that must be applied to the technical and professional control of SPC, FIP and Mock-up and the registration of Variations and Renewals of medicinal products.

1.7. Cooperates with the professional and support staff within the Department for Marketing Authorization, LQC, CEMPD and other Departments.

2.The Head of the Division for Variations and Renewals reports to the Director of the Department for Marketing Authorization.

3.The number of employees in the Division for Variations and Renewals is four (4).

Article 15
Division for Evaluation of Quality, Safety and Efficacy of Medicines

1. The duties and responsibilities of the Division for Evaluation of Quality, Safety and Efficacy of Medicines are:

1.1. Reviewing the scientific documentation in Modules 2 and 3 of the medicinal product CTD format by ensuring that the documentation meets the required international and national standards for safety and quality;

1.2. Providing procedural instructions and recommendations to parties applying for the evaluation of their applications at the DMA, including by providing technical advice on improving documentation and procedures to speed up the product authorization process;

1.3. Cooperating with the professional and support staff within the Department for Marketing Authorization, LQC and other departments at KMA to ensure that all medicines evaluations are in accordance with legal regulations and scientific standards;

1.4. Professionally assessing PKP, SPC, and FIP with the relevant modules by analysing their compatibility with scientific data and safety requirements defined for medicinal products;

1.5. Monitoring the progress of applications after the initial assessment by ensuring that the recommendations and comments made during the review are implemented and improvements are implemented within the established deadlines;

1.6. Preparing detailed reports and analyses on the quality and safety of medicinal and veterinary products, including assessments of their potential impacts on public health and the environment.

2.The Head of the Division for Evaluation of Quality, Safety and Efficacy of Medicines reports to the Director of the Department for Marketing Authorization.

3.The number of employees in the Division for Evaluation of Quality, Safety and Efficacy of Medicines is four (4).

Article 16
Division for Registration of Veterinary Medicinal Products

1.The duties and responsibilities of the Division for Registration of Veterinary Medicinal Products are:

1.1. Receiving applications in hard copies of the documentation for Module 1 and in online form for Modules 2, 3, 4 and 5 for veterinary medicinal products;

1.2. Organizing files and conducting preliminary assessment of administrative documents in Module 1, ensuring that all information is complete and correct;

1.3. Classifying the documentation to determine whether the product is medicinal veterinary, biological, herbal, dietary, homeopathic, and in controversial cases, sending the matter to the Commission for Classification for a professional opinion;

1.4. Conducting the technical and professional control of veterinary product documents, including SPC (Summary of Product Characteristics), FIP (Finished Product Specifications) and Mock-up;

1.5. Approving the advertising of veterinary medicinal products that have a marketing authorization;

1.6. Coordinating with parties and giving legal and procedural recommendations for technical and professional control of documents such as SPC, FIP and Mock-up;

1.7. Reviewing scientific documentation for generic or protected veterinary medicinal products;

1.8. Coordinating with parties and giving legal and procedural recommendations for the registration of veterinary medicinal products;

1.9. Cooperating with the professional and support staff within the Department of Marketing Authorization, the Commission for Classification and other relevant Departments to ensure compliance with legislation and procedures in force.

2.Head of the Division for Registration of Veterinary Medicinal Products reports to the Director of the Department for Marketing Authorization.

3.The number of employees in the Division for Registration of Veterinary Medicinal Products is three (3).

Article 17
Department for Licensing and Import

1.The mission of the Department for Licensing and Import is to ensure that each batch of medicinal, herbal-medicinal, homeopathic and other products with therapeutic action, as well as medical devices that are produced, imported, distributed for placing on the market in the Republic of Kosovo is qualitative, safe and effective, in accordance with the conditions and criteria defined by the legislation in force.

2. The duties and responsibilities of the Department for Licensing and Import are:

2.1. Licensing the activity for production, wholesale and retail circulation of medicinal products and medical devices, based on the legislation in force;

2.2. Assessing the fulfilment of the conditions and criteria for conducting the activity under subparagraph 2.1 of this Article, defined by the legislation in force.

2.3. Keeping records and updating lists of activities and publishing them at least once a month on the official website of KMA;

2.4. Evaluating the fulfillment of the criteria for good manufacturing and distribution practice of activities inside and outside the country and issuing a certificate for positive evaluations;
2.5. Providing advice to parties before the application and during the process of review and assessment for the completion of the documentation and the fulfillment of the basic conditions and criteria for the good manufacturing and distribution practice;

2.6. Examining applications for the import of each batch of medicinal products and medical devices under paragraph 1 of this Article, based on the legislation in force.

3.The Director of the Department for Licensing and Import reports to the Executive Director of KMA.

4.The following divisions are part of the Department for Licensing and Import:

4.1. Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols;

4.2. Division for Import/Export of Medicinal Products;

4.3. Division for Import/Export of Medical Devices;

5.The number of employees in the Department for Licensing and Import is thirteen (13).

Article 18
Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols

1.The duties and responsibilities of the Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols are:

1.1. Evaluates the conditions and criteria for good manufacturing and distribution practice (hereinafter GMDP), ensuring that the production, storage and distribution of medicinal products and medical devices is done in accordance with the legislation in force, with the aim of protecting public health;

1.2. Receives and examines the application with accompanying documentation for manufacturers of medicinal products and/or medical devices, including galenic products;

1.3. Assesses compliance with the conditions and requirements of Good Manufacturing Practice (referred to by law and administrative instruction as ("GMP" standards - the part of quality assurance that ensures that products are produced in a consistent and controlled manner in accordance with the standards of quality in compliance with the purpose of their use). The audit evaluation includes the place(s) of production / quality control, or service production for other manufacturers, the spaces and equipment of the entire or even partial manufacturing operations, as well as for the different processes of separation, packaging, packing of medicinal products and specific pharmaceutical forms;

1.4. At the request of KMA - or the manufacturer / person authorized by him, it makes an assessment and audit of the conditions and requirements of good manufacturing practice (GMP) in manufacturers outside the country who have registered or are in the process of registering their products in KMA;

1.5. Issues a detailed report on the fulfillment of the requirements under sub-paragraphs 1.1, 1.2 and 1.3 of this Article, based on which the KMA issues the authorization for manufacturing and the certificate for GMP, if the recommendation from the report is positive;

1.6. After the authorization of the manufacturing, on the basis of the risk based on the authorized operations of the manufacturing, conducts the periodic audit of the maintenance of the standard of the Good Manufacturing Practice by the manufacturer and his operation in compliance with the authorization of the manufacturing and the marketing authorization;

1.7. Receives and examines the application and accompanying documentation for wholesale distributors of medicinal products and medical devices;

1.8. Evaluates the fulfilment of the conditions and requirements for exercising the activity as a wholesale pharmaceutical distributor;

1.9. Assesses compliance with the conditions and requirements of good distribution practice (referred to by law as GDP standards - the part of quality assurance that ensures that products are stored and transported consistently and under appropriate conditions as required by the Marketing Authorization or product specification).

1.10. Evaluates the fulfillment of the conditions of spaces and equipment for storage and distribution of medicinal products and medical devices, in accordance with the legislation in force;

1.11. On the basis of the positive evaluation under subparagraphs 1.7 and 1.8 of this Article, KMA issues the permit for the activity of wholesale circulation of medicinal products and medical devices, namely the certificate for GDP;

1.12. Receives and examines the application and accompanying documentation for retail distributors of medicinal products and medical devices;

1.13. Assesses the fulfillment of the basic conditions of spaces and equipment for storage of medicinal products and medical devices, in accordance with the legislation in force;

1.14. Based on the positive evaluation under subparagraphs 1.10 and 1.11 of this Article, the KMA issues the permit for the activity of retail circulation of medicinal products and medical devices;

1.15. Keeps the records and updates the lists of activities and publishes the lists at least once a month on the official website of the KMA.

2.The Head of the Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols reports to the Director of the Department for Licensing and Import.

3.The number of employees in the Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderols is five (5).

Article 19
Division for Import/Export of Medicinal Products

1.The duties and responsibilities of the Division for Import/Export of Medical Products are:

1.1 Reviewing the application and accompanying documentation of the products under paragraph 1 of this Article to check whether they are in accordance with the legislation in force for trading in the Republic of Kosovo;

1.2 Assessing whether the batch of medicinal product to be imported is in accordance with the authorization for placing on the market;

1.3 Assessing whether the data in the quality control certificate is consistent with the data in the application;

1.4 Assessing whether the expiration date is in accordance with the legislation in force;

1.5 Assessing whether the applicant is authorized by the marketing authorization certificate holder to import and distribute the medicinal product in the Republic of Kosovo;

1.6 Contacting the applicant regarding any irregularities and/or for additional information;

1.7 Informing the supervisor about the difficulties or ambiguities encountered during the examination of the application and accompanying documentation;

1.8 For requests for export of the medicinal product, evaluating the relevant documentation to check whether the medicinal product is placed on the market of the Republic of Kosovo in accordance with the legislation in force.

1.9 Based on the positive evaluation, the KMA issues the permit for import or export of the products under paragraph 1 of this Article.

2.The Head of the Division for Import/Export of Medicinal Products reports to the Director of the Department for Licensing and Import.

3.The number of employees in the Division for Import/Export of Medicinal Products is four (4).

Article 20
Division for Import/Export of Medical Devices

1.The duties and responsibilities of the Division for Import/Export of Medical Devices are:

1.1 Reviewing the application and accompanying documentation to check whether they are in accordance with the legislation in force for trading and use in the Republic of Kosovo;

1.2. Assessing whether the medical device to be imported is registered for placement on the European Union market;

1.3. Assessing whether the EC certificate issued by the Notifying Body or the EC declaration of conformity issued by the manufacturer is in accordance with the legislation in force of the European Union and is valid;

1.4. Assessing whether the data in the EC certificate issued by the Notifying Body or in the EC declaration of conformity issued by the manufacturer are consistent with the data in the application;

1.5. For manufacturers of medical devices that are not members of the EU, Schengen countries or the USA, verifying or requesting verification from the Notifying Body for the validity of the EC certificate;

1.6. If the medical devices are Class I, non-sterile and non-measuring, manufactured by manufacturers of medical devices that are not members of the EU, Schengen countries or the USA, verifying or requesting verification from the Notifying Body for the validity of

the ISO certificate for the manufacturing of medical devices in accordance with harmonized EU standards;

1.7. Contacting the applicant regarding any irregularities and/or for additional information;

1.8. Informing the supervisor about the difficulties or ambiguities encountered during the examination of the application and accompanying documentation;

1.9. For requests for the export of medical devices, evaluating the relevant documentation to check whether the medical device has been placed on the market of the Republic of Kosovo in accordance with the legislation in force;

1.10. Based on the positive evaluation, the KMA issues a permit for import or export of medical devices.

2.The Head of the Division for Import/Export of Medical Devices reports to the Director of the Department for Licensing and Import.

3.The number of employees in the Division for Import/Export of Medical Devices is three (3).

Article 21
Department for Pharmacovigilance

1. The mission of the Department for Pharmacovigilance is to undertake a series of activities related to the detection, assessment, prevention and action in case of side effects of medicinal products, as well as to provide new knowledge about the risks of harmful effects during the use of medicinal products.

2. The duties and responsibilities of the Department for Pharmacovigilance are:

2.1. Participating in compilation of strategies, policies and procedures related to pharmacovigilance;

2.2. Developing pharmacovigilance system to collect information on the risks of medicinal products in relation to patients or public health;

2.3. Confirming the responsible person according to the authorization by the marketing authorization holder;

2.4. Evaluating and identifying signals and response to risks from the use of human medicinal products, from their interactions with other products or substances, and informing health professionals;

2.5. Checking and evaluating the latest Periodic Safety Update Reports submitted by pharmaceutical companies;

2.6. Checking and evaluating CIOMS Reports (any suspected side effect on the patient or animal) submitted by pharmaceutical companies;

2.7. Monitoring the implementation of the pharmacovigilance system by pharmaceutical companies;

2.8. Inspecting and implementing procedures and obligations according to the legislation in force for pharmacovigilance;

2.9. Planning and implementing risk management measures;

2.10. Cooperating and exchanging information with the UMC/WHO monitoring center, the European Medicines Agency (EMA), and any relevant national and international health institution;

2.11. In special events (pandemic, epidemic, etc.) announced by local and international state authorities, performing all activities in the field of pharmacovigilance.

3.The Director of the Department for Pharmacovigilance reports to the Executive Directorof KMA.

4.The following divisions are within the Department for Pharmacovigilance:

4.1. Division for Administration and Evaluation of Side Effects.

4.2. Division for Risk Management.

5.The number of employees in the Department for Pharmacovigilance is seven (7).

Article 22
Division for Administration and Evaluation of Side Effects

1.The duties and responsibilities of the Division for Administration and Evaluation of Side Effects are:

1.1. Receiving reports (CIOMS) of side effects, analysing and evaluating side effects;

1.2. Classifying side effects;

1.3. Monitoring and storing data of side effects in the database;

1.4. Following the latest international standards of the pharmacovigilance system, informing the relevant parties about the latest information from pharmacovigilance and making decisions.

2.The Head of the Division for Administration and Evaluation of Side Effects reports to the Director of the Department for Pharmacovigilance.

3.The number of employees in the Division for Administration and Evaluation of Side Effects is three (3).

Article 23
Division for the Implementation of Risk Management and Post Marketing Measures

1.The duties and responsibilities of the Division for the Implementation of Risk Management and Post Marketing Measures are:

1.1. Planning and implementing risk management measures;

1.2. Communicating the latest information on the safety of medicinal products to health professionals and, when necessary, to the general public;

1.3. Communicating and cooperating with pharmaceutical companies on risk management measures.

1.4. Supervising the implementation of the pharmacovigilance system by pharmaceutical companies and of the measures taken to minimize risks.

1.5. Organizing the 'ad hoc' working group to solve problems and issues in the evaluation of data in the field of pharmacovigilance;

1.6. Inspecting the marketing authorization holder related to the pharmacovigilance system for medicinal products in the market of the Republic of Kosovo.

2.The Head of the Division for the Implementation of Risk Management and Post Marketing Measures reports to the Director of the Department for Pharmacovigilance.

3.The number of employees in the Division for the Implementation of Risk Management and Post Marketing Measures is three (3).

Article 24
Division for Narcotics and Precursors

1.The mission of the Division for Narcotics and Precursors is to ensure the effective management and control of narcotics and precursors in accordance with national law and international conventions, through the registration and monitoring of operators, analysis and reporting of turnover and consumption, as well as cooperation with local and international authorities to prevent misuse and promote public health and safety.

2.The main duties and responsibilities of the Division for Narcotics and Precursors are:

2.1. Registration of operators for narcotics and precursors who meet the criteria under the national law on narcotics and precursors;

2.2. Creation of a database for operators and publishing it on the official website of KMA;

2.3. Receipt and review of requests from operators for the import / export of narcotic drugs, psychotropic drugs, active substances, standards, reagents, samples and precursors, if they are in accordance with national law and international conventions;

2.4. Preparation of import/export permit based on international trading criteria which is approved by KMA;

2.5. Confirmation for the authorities of the exporting country that the import has been carried out in accordance with the issued permit;

2.6. Receipt of quarterly reports from operators for narcotic and psychotropic drugs, analysing them in order to evaluate circulation and consumption in the Republic of Kosovo;

2.7. Preparation of quarterly reports based on the data available with the KMA and the data from sub-paragraph 2.6 of paragraph 2 of this Article for the Ministry of Internal Affairs and the Commission for the evaluation of the fulfillment of the requirements according to the action plan issued by the National Strategy against Narcotics;

2.8. Supervision of the supply of health institutions with "Prescription for narcotics" in cooperation with the Ministry of Health;

2.9. Following trends and initiation of amendment/supplementation of legislation on narcotics and precursors.

2.10. Reporting related to the updating of legislation for strengthening the safeguards for prevention of the misuse of narcotics and precursors in the meetings with the Western Balkan states organized by the European Union;

2.11. Close cooperation with the Inter-institutional Commission for Narcotics Control and local institutions dealing with narcotics and precursors, especially with the Kosovo Customs, the Kosovo Police, the Pharmaceutical Inspectorate and the Ministry of Internal Affairs;

2.12. Close cooperation with other international institutions and organizations dealing with monitoring and combating the misuse of narcotics and precursors, such as the Narcotics Control Board (INCB), the European Monitoring Center for Drugs and Drug Addiction (EMCDDA), the World Health Organization (WHO), the competent authorities of the exporting countries in the Republic of Kosovo and the countries of the region.

3.The Head of the Division for Narcotics and Precursors reports to the Executive Director;

4. The number of employees in the Division for Narcotics and Precursors is three (3).

Article 25
Division for Human Resources

1.The mission of the Division for Human Resources is to manage human resources processes efficiently, including recruitment, capacity building, performance evaluation and compensation to ensure that employees can contribute effectively.

2.The duties and responsibilities of the Division for Human Resources are:

2.1. Ensuring the implementation of legislation on public officials, salaries and compensation, as well as guaranteeing the implementation of standards and best practices in human resource management.

2.2. Management and organization of all stages of recruitment, including the preliminary evaluation of candidates, transfer procedures, as well as the support of the Admission Committee in the development of the electronic test and interviews with candidates;

2.3. Support of organizational units in the development of individual job descriptions, human resources management, evaluation of work performance results and participation in the evaluation of civil servants.

2.4. Administration of vacations, trainings and work attendance system as well as the support of the Disciplinary Committee;

2.5. Administration of staff files and their management through the Human Resources Management Information System (HRMIS) in accordance with the legislation on public officials and that of privacy;

2.6. Administration of employee compensation, including salaries, allowances, bonuses and other benefits as well as management of employee retirement and leave policies;

2.7. Identification of training needs and organization of relevant training programs, development of training materials and resources for improving employee skills and career development;

2.8. Mediation and conflict resolution between employees, addressing their complaints and concerns and promoting a positive and inclusive work environment as well as supporting disciplinary and grievance committees;

2.9. Management of policies and practices of occupational health and safety of workers at workplace in compliance with relevant legislation;

2.10. Drafting of the annual plan and the mid-term staff plan, in accordance with the annual budget planning process of the Agency as well as the annual report on the state of the civil service in the Agency.

3.The Division for Human Resources is headed by the Head of the Division, who reports to the Executive Director.

4.The number of employees in the Division for Human Resources is three (3).

Article 26
Division for Budget and Finance

1.The mission of the Division for Budget and Finance is to ensure the efficient and responsible management of the agency's financial resources, by planning, administering and controlling the budget and finances in accordance with applicable laws and regulations, to support the achievement of the agency's strategic objectives.

2.The duties and responsibilities of the Division for Budget and Finance are:

2.1. Budget planning in coordination with the relevant units within the Agency and the preparation of the Mid-term Expenditure Framework, in harmony with the requirements of the budget units;

2.2. Coordination with the Ministry of Health, regarding the Agency's budget and revenues, as well as the registration of revenues and various donations and their incorporation into the budget according to the relevant legislation;

2.3. Preparation of budget analyses and reports on budget expenditures and monitoring the implementation of projects that are related to the Agency's budget;

2.4. Preparation of the cash flow plan in accordance with the legislation and established rules as well as ensuring that the commitments and expenses are made in accordance with the financial rules;

2.5. Budget impact estimates for the project and strategic documents from the scope of the Agency;

2.6. Allocation of funds for the realization of payments for projects/activities and management of the linking of allocated funds, those spent and allocated during the fiscal year;

2.7. Drafting financial statements together with budget units within the Agency and ensuring internal financial control based on accountability principles;

3. The Head of the Division for Budget and Finance reports to the Executive Director.

4.The number of employees in the Division for Budget and Finance is four (4).

Article 27
Division for Shared Services

1.The duties and responsibilities of the Division for Shared Services are:

1.1.Provision of administrative support and logistic services for the Agency;

1.2. Management of data, documents and archives, official correspondence, and other important administrative data;

1.3. Overseeing the maintenance, repair and use of the Agency's facilities and assets, including ensuring that the facilities and assets are maintained as per procedures set forth;

1.4. Ensuring the implementation of procedures for the management, maintenance and servicing of vehicle;

1.5. Management of the warehouse and supply of materials, inventory and provision of necessary equipment for the Agency;

1.6. Provision and management of IT infrastructure and services for the Agency including maintenance of computer systems, networks, software applications and cyber security measures.

2.The Head of the Division for Shared Services reports to the Executive Director.

3.The number of employees in the Division for Shared Services is four (4).

Article 28
Legal Division

1.The mission of the Legal Division is to provide legal advice, ensure compliance with laws, and protect the interests of the Agency, including providing legal advice, participating in the drafting and review of legislation, and advocating for the Agency's legal rights.

2.The duties and responsibilities of the Legal Division are:

2.1. Provide legal support in the drafting of strategic and legislative documents from the scope of KMA;

2.2. Provide assistance in the drafting of primary and secondary legislation from the scope of the KMA;

2.3. Ensure compliance with the techniques and standards of drafting legislation from the scope of the KMA;

2.4. Ensure the alignment of the legislation of the KMA with the legislation of the European Union (acquis communautaire) as well as with the applicable laws in Kosovo;

2.5. Provide legal advice from the scope of KMA upon request;

2.6. Cooperation with the Ministry of Justice for the representation of KMA in court disputes.

3.The Head of the Legal Division reports to the Executive Director.

4.The number of employees in the Legal Division is three (3).

Article 29
Division for Procurement

1.The mission of the Division for Procurement is to ensure the efficient and cost-effective procurement of necessary goods and services while respecting fairness, transparency and compliance with relevant laws, regulations and policies as well as ethical standards.

2.The duties and responsibilities of the Division for Procurement are:

2.1 Preparation, coordination and implementation of the Agency's annual plan in the field of public procurement, in accordance with the legislation in force;

2.2. Ensuring that all procurement requests are prepared in accordance with procurement rules and procedures;

2.3. Determination of procurement methodology for tender and price evaluation procedures.

2.4. Providing advice and assisting management in making decisions regarding disputes that may arise in cases of the execution of the contract.

2.5. Ensuring that all procurement activities comply with legal and regulatory requirements as well as managing documents and records for procurement processes for audit purposes;

2.6. Implementation of best, ethical and transparent procurement practices to prevent corruption and favouritism, reduce costs and increase overall effectiveness

3.The Head of the Division for Procurement reports to the Executive Director.

4.The number of employees in the Division for Procurement is three (3).

Article 30
Transitional and final provisions

1.The amendment and supplementation of this Regulation shall be done according to the same procedure as the approval of this Regulation.

2. The internal audit function is exercised by the Internal Audit Unit of the Ministry of Health.

3.The increase or decrease in the number of staff in accordance with the Law on Budget does not create a need to supplement-amend this Regulation, except in cases where organizational units are created and/or extinguished.

4.Part of this Regulation is Annex I, which contains the organizational structure and the total number of all employees, and the specific number in each unit in the Kosovo Medicines Agency, and Annex No. 2, which contains the organizational chart.

Article 31
Repeal

Upon the entry into force of this Regulation, the "Structural Organizational Chart of KMA: 2005-2006" (protocol 504/18.10.2005) shall be repealed.

Article 32
Entry into force

This Regulation shall enter into force seven (7) days after publication in the Official Gazette of the Republic of Kosovo.

Albin Kurti

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Prime Minister of the Republic of Kosovo

10/March/ 2025

1: Classification and systematization of jobs (organic)

Structure/Job position	Category & Class	Group of job positions	Number of executors
1 Office of the Chief Executive Officer			**Total: 4**
Chief Executive Officer	Senior Manager		1
Senior Executive Officer	Professional 1	63. General administration group	1
Administrative Officer	Professional 2	64. General administration group	1
Jobs subordinate to the Chief Executive Officer			
Senior Certification Officer		Budget and finance group	1
Structures subordinate to the Chief Executive Officer			
1.1 Division for Narcotics			**Total: 3**
Head of the Division for Narcotics	Low-level Manager		1
Senior Narcotics Officer	Specialist	Pharmaceutical group	2
1.2 Division for Shared Services			**Total: 4**
Head of the Division for Shared Services	Low-level Manager		1
Senior Information Technology Officer	Professional 1	Information technology group	1
Archives Officer	Professional 2	63. General administration group	1
Receptionist	Professional 3	63. General administration group	1
1.3 Division for Human Resources			**Total: 3**
Head of the Division for Human Resources	Low-level Manager		1
Senior Human Resources Officer	Professional 1	Human resources group	1
Human Resources Officer	Professional 2	Human resources group	1
1.4 Division for Budget and Finance			**Total: 4**
Head of the Division for Budget and Finance	Low-level Manager		1

Senior Budget and Finance Officer	Professional 1	Budget and finance group	1
Property Registration Officer	Professional 2	Social Science Group	1
Expenditure Officer	Professional 2	Budget and finance group	1
1.5 Division for Public Procurement			**Total: 3**
Head of the Division for Public Procurement	Low-level Manager		1
Senior Procurement Officer	Professional 1	Public procurement group	1
Procurement Officer	Professional 2	Public procurement group	1
1.6 Legal Division			**Total: 3**
Head of the Legal Division	Low-level Manager		1
Senior Legal Officer	Professional 1	Legal Group	1
Legal Officer	Professional 2	Legal Group	1
2. Department for Laboratories of Quality Control			**Total: 10**
Director of the Department for Laboratories of Quality Control	Middle-level manager		1
2.1 Division for Physics-Chemistry			**Total: 3**
Head of the Division for Physics-Chemistry	Low-level Manager		1
Senior Quality Assurance Officer	Specialist	Pharmaceutical group	2
2.2 Division for Microbiology			**Total: 3**
Head of the Division for Microbiology	Low-level Manager		1
Senior Quality Assurance Officer	Specialist	Pharmaceutical group	2
2.3 Division for Biopharmaceutics			**Total: 3**
Head of the Division for Biopharmaceutics	Low-level Manager		1
Senior Biopharmaceutical Officer	Specialist	Pharmaceutical group	2
3. Department for Marketing Authorization			**Total: 18**
Director of Department for Marketing Authorization	Middle-level manager		1
3.1 Division for Registration of Medicinal Products			**Total: 3**

Head of the Division for Registration of Medicinal Products	Low-level Manager		1
Senior Officer for Medicinal Products	Specialist	Pharmaceutical group	2
3.2 Division for Registration of Food Supplements			**Total: 3**
Head of the Division for Registration of Food Supplements	Low-level Manager		1
Senior Officer for Food Supplements	Specialist	Pharmaceutical group	2
3.3 Division for Variations and Renewals			**Total: 4**
Head of the Division for Variations and Renewals	Low-level Manager		1
Senior Variations and Renewals Officer	Specialist	Pharmaceutical group	3
3.4 Division for Safety, Quality and Efficacy of Medicines			**Total: 4**
Head of the Division for Safety, Quality and Efficacy of Medicines	Low-level Manager		1
Senior Medicines Evaluation Officer	Specialist	Pharmaceutical group	3
3.5 Division for Registration of Veterinary Medicinal Products			**Total: 3**
Head of the Division for Registration of Veterinary Medicinal Products	Low-level Manager		1
Senior Officer for Registration of Veterinary Medicinal Products	Specialist	Pharmaceutical group	2
4. Department for Licensing and Import			**Total: 13**
Director of the Department for Licensing and Import	Middle-level manager		1
4.1 Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderoles			**Total: 5**
Head of the Division for Licensing Activities for Medicinal Products and Medical Devices as well as Banderoles	Low-level Manager		1
Senior Licensing Officer	Specialist	Pharmaceutical group	3

Officer for Banderoles	Professional 3	64. General administration group	1
4.2 Division for Import/Export of Mediccinal Products			**Total: 4**
Head of the Division for Import/Export of Medicinal Products	Low-level Manager		1
Senior Officer for Import/Export of Medicinal Products	Specialist	Pharmaceutical group	3
4.3 Division for Import/Export of Medical Devices			**Total: 3**
Head of the Division for Import/Export of Medical Devices	Low-level Manager		1
Senior Officer for Import/Export of Medical Devices	Specialist	Pharmaceutical group	2
5. Department for Pharmacovigilance			**Total: 7**
Director of the Department for Pharmacovigilance	Middle-level manager		1
5.1 Division for Administration and Evaluation of Side Effects			**Total: 3**
Head of the Division for Administration and Evaluation of Side Effects	Low-level Manager		1
Senior Officer for Administration and Evaluation of Side Effects	Specialist	Pharmaceutical group	2
5.2 Division for Risk Management			**Total: 3**
Head of the Division for the Implementation of Risk Management and Post Marketing Measures	Low-level Manager		1
Senior Risk Assessment Officer	Specialist	Pharmaceutical group	2

Annex No. 2: Organogram of KMA