Republika e Kosovës
Republika Kosovo-Republic of Kosovo
Kuvendi - Skupština - Assembly

Law No.03/L –188

ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Assembly of Republic of Kosovo,

Based on Article 65 (1) of the Constitution of Republic of Kosovo,

Approves:

LAW ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

GENERAL PROVISIONS

Article 1
Purpose

The purpose of this law is to determine the rules for manufacturing, quality control, registration, labeling, banderoles, import, export, trading, medical prescription, efficiency, safe use of medicinal products and medical devices in the Republic of Kosovo.

Article 2
Scope

This Law applies to all public authorities, natural and legal persons engaged in the manufacturing, trading of medicinal products and medical devices, products containing radioactive substances or dealing with the safety of using radioactive radiation,

immunologic preparations and blood products, vitaminose, herbal and mineral preparations, diet, cosmetic preparations, food for children which is given by doctor's recommendation, raw material for manufacturing medicinal products, semi-products of medicinal products and pricing of medicinal products.

Article 3
Definitions

1. The terms used in this Law shall have the following meaning:

1.1**. Medicinal product** - any substance or combination of substances for the purpose of treating, diagnosing or preventing diseases or correcting or modifying physiological functions in human beings.

1.2. **Substance**- any matter irrespective of origin which shall include any of the following:

- Human being, human blood and products of human blood;

-Animal matter, micro-organisms, whole animals, parts of organisms, animal secretion, toxins, extracts, blood products;

-Plant matter, micro-organisms, plants, parts of plants, plant secretion, extracts;

-Mineral matter, elements, natural substances and chemical products obtained by chemical change or synthesis; or

-Matter developed by means of biotechnological processes.

1.3**. Medicinal product**-for human use– a medicinal product intended exclusively for use in human beings.

1.4**. Active Substance-** a substance in a medicinal product having a pharmacological effect.

1.5. **Excipients-**have no pharmacological effect of drugs but they:

-assist in pharmaceutical medicinal product formulation;

-protect, support and/or improve stability, bioavailability or tolerance of medicinal product;

1.6. **Pharmaceutical Form–**the physical form of the medicinal product.

1.7.**Galenic Product-** any medicinal product prepared by a Galenic Laboratory of pharmacy with retail for the patient, pursuant to current EU pharmacopoeia standards, International Pharmacopeia-IntPh, USP or the form of magistral and official preparations for which no Marketing Authorization is required.

1.8. **Magistral Preparation -** any medicinal product prepared in a pharmacy's laboratory in accordance with medical prescription, for individual patient and for which no Marketing Authorization is required.

1.9.**Advanced Therapy Medicinal Product** -any medicinal product based on processes focused on various gene-transfer produced bio-molecules, biologically advanced therapeutic modified cells and tissues as active substances or part of active substances**.**

1.10.**Good Clinical Practice -**an international ethical and scientific system of quality control, planning, implementation, recording, controlling and reporting on clinical research in human beings providing for the credibility of data acquired through studies and the protection of rights and the safety of trial subjects pursuant to the Declaration of Helsinki and other relevant regulations,

1.11. **Good Laboratory control Practice-**a part of Good Manufacturing Practice which controls and ensures the quality of medicinal products.

1.12.**Good Laboratory Practice-**the system of quality dealing with organization process and conditions of planning, implementation, control, registration and reporting of non-clinical medicinal trials and environment studies;

1.13. **Good Manufacturing Practice-**the system for ensuring quality, providing for the consistent manufacture and control of products by qualitative criteria and conformity assessing criteria with intended purpose as required by the Marketing Authorization and specification of the product.

1.14. **Good Distribution Practice**- the qualitative system including the organization, implementation and supervision of storage, distribution, of medicinal products from the producer to the final user.

1.15. **Pharmacovigilance**– a process used for identifying, collecting, assessing and reporting of the adverse effects, adverse of medicinal products and other proofs regarding the security of medicinal products, measures taken to manage and reduce risks related to medicinal products.

1.16.**Adverse Effect -**the response to medicinal product which is harmful and unintended and which appears in therapeutic dosage used in human beings for prophylaxis, diagnosis or therapy of a disease or return, correction or modification of functions.

1.17**. Serious Adverse Effect –**an Adverse Effect which results in death, is life threatening, requires inpatient hospitalization or prolongation of current hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

1.18. **Medicinal Product Quality –**the characteristics of the medicinal product coming out of the qualitative analysis of all constituents, a quantitative analysis of all the active substances and all other tests or checks necessary to ensure the quality of a medicinal product in accordance with the requirements specified with international pharmacopeia standards.

1.19.**Manufacturer of Medicinal Products in terms of place of production -**a legal or natural person responsible for the development, manufacture, quality control, packaging and labeling of medicinal products as well as their safety and efficacy irrespective of whether medicinal products were manufactured by themselves or on their behalf by a third party.

1.20. **Official Laboratory for control of quality of Medicinal Products -**a laboratory for controlling the quality of medicinal products and medical devices, with the aim to verify, if the quality fulfils the international standards.

1.21. **Labeling -**all text and symbols on the immediate and outer packaging of a medicinal product or medical device.

1.22. **Sample of medicinal product -**the representative quantity of a medicinal product taken from a batch in order to determine the quality of corresponding series.

1.23. **Traceability of distribution canals of a Medicinal Product -**the documented distribution path from the manufacturer, the legal entity or natural person marketing the medicinal products from the either through pharmaceutics wholesaler, pharmacies to the final user.

1.24. **Prescription -**the legal obligation for prescription of medicinal product or medical device at human beings.

1.25. **Medical Device -**any instrument, equipment, application, material or other item, used either independently or in combination, including the software necessary for proper use intended by the manufacturer to be used in human beings for the purpose of:

-diagnosis, prevention, monitoring, treatment or alleviation of disease;

-diagnosis, monitoring, treatment, alleviation or compensation for an injury or defect;

-investigation, replacement of or modification of the anatomy or of the physiological process;

-control of conception;

-does not achieve its primary intended action, the principal of the purpose of action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means; and

-includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

1.26**. Active Implantable Medical Device -**a medical device which:

- relies on functioning on the other source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and

- is intended to be totally or partially introduced into use in the human body whether surgically or in a conservative medically manner, including the use through natural orifice and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is incorporated;

- even if it is intended to obtain a medicinal product or to incorporate as an integral part a substance which, if used separately, will be a medicinal product.

1.27**. In Vitro Diagnostic Medical Device-**means a medical device which:

- is a reagent, reagent product, calibrator, control material, test kit, instrument, apparatus, equipment or system, whether used alone or in combination;

- is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning:

-physiological or pathological state;

-congenital abnormality;

-determination of the safety and compatibility of donors, including

blood and tissue donations; or

-monitoring of therapeutic measures; and

-inclusion of specimen receptacles, but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

1.28. **Accessory Device -**any instrument, apparatus, device, material or other item regardless of whether it is a medical device or not, intended specifically by its manufacturer to be used with any particular medical device to enable it to be used as intended by the manufacturer.

1.29. **Custom-Made Device -**any medical device made in accordance with a medicinal prescription for a particular patient as determined by a specialist doctor and/or professional user. The prescription shall state the specific characteristics as to its design and intended use for a particular patient. Mass-produced devices needing to be adapted to the specific requirements of a qualified medical practitioner or professional user shall not be considered as custom-made devices.

1.30.**Single-use combination product -**a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable.

1.31**. Systems or Procedure Packs -**has the same meaning as in Article 12 of EU Directive 93/42.

1.32. **Harmonized Standard -**a technical specification adopted by the European Committee for Standardization or the European Committee for Electro technical Standardization, or by both of those bodies, an equivalent specification accepted internationally; or

-A monograph of the European Pharmacopoeia (in particular any monograph on surgical sutures and the interaction between medicinal products and materials used in medical devices containing medicinal products) or monograph from another recognized pharmacopoeia.

1.33. **Conformity Assessment Body -**synonymous with notifying body and means either a laboratory independent of a supplier, a certified body, controlling body or any other body involved in the conformity assessment procedure for medical devices.

1.34. **Technical Specifications -**a regulation defining the characteristics of a medical device or the procedure and method of its manufacture, that may only cover and regulate technical terms, symbols, packaging, and declaration and

labeling.

1.35.**Manufacturer of Medical Devices -**a natural or legal person responsible for the design, manufacturing, packaging and labeling of medical devices before placing them on the market under their own name, irrespective of whether they were manufactured by the manufacturer or by a third party.

1.36.**Authorized Supplier of Medical Devices -**a natural or legal person who, explicitly designated by the manufacturer, acts and may be managed by authorities and bodies instead of the manufacturer with respect to the latter's obligations under this Law and its pursuant sub-legal acts, including the requirement to provide a quality assurance system for the medical device concerned.

1.37.**Professional User -**either a health or social welfare institution licensed by the Ministry of Health of Republic of Kosovo or by the Ministry of Labor and Social Welfare that takes care for the position and rights of patients including mentally retarded patients;

-health professional authorized to use the medical device in the course of his/her duties;

-other natural or legal person supplying and/or providing the usage of medical devices without being a retailer or wholesaler.

1.38. **Intended Purpose -**the use for which a medical device is intended according to the data supplied by the manufacturer on the labeling, instructions for use or in promotional material.

1.39. **Placing on the Market -**the first placing is compensated in return for payment or free of charge for a medical device with a view to distribution or use in the Republic of Kosovo regardless of whether the device is new or refurbished. The use of a medical device for Clinical Investigation or for performance evaluation is not considered to be placing on the market.

1.40. **Putting into Service -**the stage at which a medical device has been made available to the final user as being ready for use for the first time in the Republic of Kosovo for a certain purpose.

1.41. **Authorizations and Licenses provided for by this Law shall be defined as follows:**

- certificate of Analysis-the certificate of medicinal product quality issued by the manufacturer or an official laboratory for quality control on compliance of medicinal product quality in conformity with accepted international standards;

- batch certificate of Analysis-the certificate of analysis of medicinal product for a certain series.

1.42. **License for Business -** official permission issued by the Ministry of Trade and Industry.

1.43. **Clinical Trial Authorization -** the official written permission issued by the Kosovo Medicines Agency KMA in the case of medicinal products and medical devices for human use and authorizing the sponsor and principle investigator of a proposed clinical research to conduct the clinical trial in accordance with the provisions of Article 20 of this Law and of additional acts, sub-legal acts issued pursuant to this Law.

1.44. **Declaration of Conformity** - synonymous with conformity certificate and report on testing and means the confirmation that a medical device meets essential requirements concerning conformity assessment procedures for medical devices as set out in this Law, its pursuant sub-legal acts and harmonized standards and the issuance of which shall be an absolute requirement before the placing on the market or putting into service of a medical device in the Republic of Kosovo.

1.45. **Galenic Laboratory License -**the official written permission issued by the KMA for pharmacy for the manufacturing of magistral and officinal products.

1.46. **License for Import/Export of Medicinal Products and Medical Devices-** written official permission issued by KMA for importing in, or exporting from Kosovo medicinal products and medical devices.

1.47. **Licensed pharmacist** -pharmacist who has a license issued by the competent body at the Ministry of Health.

1.48. **Manufacturing Authorization** -the official written permission issued by the KMA for manufacturers in the Republic of Kosovo.

1.49. **Marketing Authorization -** is synonymous (has the same meaning) with medicinal product license and authorized medicinal product to provide both documentation and physical evidence that the quality, safety and efficacy of a medicinal product placed into market in the Republic of Kosovo, meets the required standards stated in the sub-legal act issued pursuant to this Law.

1.50. **Professional Pharmacy License -** the official written permission issued by the KMA for the dispensation or retail of medicinal products and devices as specified in this Law and its sub-legal acts promulgated pursuant to this Law.

1.51. **Wholesale Pharmaceutical License** -the official written permission issued by the KMA for the wholesale trade of medicinal products and/or medical devices in the Republic of Kosovo pursuant to this Law and sub-legal acts promulgated

pursuant to this Law.

1.52. **Faked Medicinal product -**is considered the intentional untrue labeling regarding the identity, content or source of a final medical product, or its components during final manufacturing of medical product.
Faked products can comprise as follows: the products with the right components, but also with wrong components, or they are without active ingredients or fake packaging, are packed in such packages that confuse the patient; they can also contain various amounts, or various dirtiness which can be harmless but also toxic.

1.53. **Orphan Medicinal Products**- medicaments for curing severe and rare diseases, shall be classified those medicinal products whose medicinal products status have been approved in European Union for curing severe and rare diseases, pursuant to conditions described in European Union:

- if it is used for diagnosis, preventions and cure from disease or dangerous vital state, which shall bring the chronic weakening and such diseases is affecting more than five (5) persons in ten thousand (10.000) inhabitants in European Union or

- if it is used for diagnosis, prevention and cure from disease or dangerous vital state, which shall bring the chronic weakening, but because of the big expenses in development of medicinal product it is not possible to place that product in the market or

- if there are not satisfactory methods for diagnosis, prevention or cures of certain health states or if such methods exist but the medical product is proofed useful for persons that have such a health condition.

1.54. **Qualified Person in production** - possesses a diploma, certificate or other evidence of official qualifications, gained after completion of university studies in time duration of at least four (4) years, of theoretical or practical studies in one of the following scientific disciplines: pharmacy, humanitarian medicine, chemistry, biology, chemical-pharmaceutical technology.

1.55. **Quality Assurance** - planned and systematic activities necessary to achieve the confidence that the product or service shall meet the given requirements.

1.56. **Quality Control** - includes the verification of service or process to ensure its proper quality.

1.57. **Bioavailability** – the part of the absorbed substance reached in total circulation from the initial used dosage as well as the speed by which this process is achieved.

1.58. **Bioequivalence** – medicament which compared to the reference medicament has a comparable bioavailability and which reaches a plasmatic concentration for an approximate time. Medicaments which have a considerable difference in bioavailability are called bioequivalent.

1.59. **Officinal Products** -products prepared in a pharmacy according to pharmacopeia or certain guide, products which were included in pharmacopeia only after a long use which has proved their value.

1.60. **Magistral Products -** any medicinal product prepared in a pharmacy in accordance with a prescription of doctor for a certain patient and are immediately used by the patient.

1.61. **Pharmacopeia** – a summary book of standards and norms, with legal force, that determines preparation, quality control and storage of most important medicaments used in daily practice

1.62. **Semi-product** – any product that has undergone a partial processing and is used as raw material in a follow up industrial production step up to making the finished product.

1.63. **Herbal Medical Products** – any medical product which as active substance has one or more verbal substances, combined with herbal preparation, for which it is required a certain authorizing procedure for marketing.

1.64. **Herbal Substances** – part or the entirety of a plant, algae, fungus, likens in dry forms but sometimes fresh as well. Certain exudates which were not subject of any treatment may be considered herbal substances. Herbal substances are defined from plant part according to botanic name.

1.65. **Herbal preparation** – preparation made after treatments such as extracting, distillation, fractioning, purification, concentration or fermentation. This includes the herbal substances powdered, tinctures, extracts, essential oils, liquids and proceeded exudates.

Article 4
Kosovo Agency for Medicinal Products

1. The competent authority regarding medicinal products and medical devices for human use shall be the Kosovo Medicines Agency (hereinafter "KMA")

2. KMA shall have special legal personality and shall function within the Ministry of Health.

Article 5
KMA Bodies

1. Bodies of the KMA are:

1.1. Director;

1.2. Committee for assessment of Medicinal products and medical devices (CAMPMD);

1.3. Board of appeals;

1.4. Ethic Committee.

Article 6
Competencies of KMA

1. KMA, upon recommendation of CAMPMD shall issue:

1.1. general license for production of pharmaceutical products, after the assessment of technical and professional conditions for work at producing factory;

1.2. authorization for production of every medicinal product;

1.3. authorization for production of medical devices;

1.4. authorization for clinical investigations;

1.5. authorization for marketing for medicinal products;

1.6. license for circulation of medicinal products and medical devices;

1.7. permission for import and wholesale distribution of medicinal product and medical device;

1.8. permission for export of medicinal product.

2. KMA is also obliged to undertake the following activities:

2.1. technical classification and assessments of medicinal products and medical devices;

2.2. classification of ways of distribution of medicinal products and medical devices;

2.3. assessments of security of medicinal products and medical devices that are in Kosovo;

2.4. keeping the database regarding the persons, who are licensed, authorized and provided with various licenses;

2.5. preparation and keeping of statistics regarding the using of medicinal products and medical devices;

2.6. effective cooperation and communication with other institutions me purpose of advancing the rational and healthy use of medicinal products and medical devices;

2.7. integration to international information networks regarding the advance of medicinal products and medical devices;

2.8. functionalizing of Kosovo Laboratory for medicinal products and medical devices.

Article 7
Director of KMA

1. Director of KMA shall be a civil servant.

2. Director of KMA shall be appointed according to the procedures of the Law on Civil Service for senior managing positions.

Article 8
Committee for Assessment of Medicinal Products and Medical Devices (CAMPMD)

1. CAMPMD shall be responsible for giving technical advice to KMA, regarding the issuance and keeping the licenses, authorizations and permissions of medicinal products and medical devices. Recommendations of CAMPMD regarding the giving the licenses, authorizations and permissions of medicinal products and medical devices shall be mandatory for KMA. They may be contested by KMA only in case of procedural infringements.

2. CAMPMD shall consist of seven (7) members, three (3) pharmacists, two (2) bioengineers, one (1) dentist or engineer of stomatology and one (1) ad-hoc member specialist doctor of respective field. Members of CAMPMD shall be eminent professionals of the respective field and shall have at least ten (10) years work experience in the respective profession.

3. Members of CAMPMD shall be appointed by the Government of Kosovo, with a mandate of three (3) years, after the selection through a public and competitive competition organized by KMA.

4. CAMPMD will establish sub-committees for various products, such as herbal products, magistral products, narcotic products, medical devices, price policies, etc. Members of sub-committees shall be professionals with at least post-graduate studies. They, before every engagement, should sign a declaration of the lack of conflict of interest on the issue that they review.

Article 9
Board of appeals

1. Board of Appeals shall have the responsibility for review of every appeal submitted by a natural or legal person, regarding the decisions brought by KMA, based on this Law and sub-legal acts promulgated in compliance with this Law.

2. Board of Appeals shall consist of three (3) members and shall be established by the Government of Kosovo, with a mandate of four (4) years.

Article 10
Professional Committee of ethics

1. Professional Committee of ethics shall be responsible for ethic approval of clinical investigations of experimental medicinal products and medical devices.

2. Professional Committee of ethics shall be appointed by the Minister of Health, according to the procedures foreseen with sub-legal acts.

Article 11
Official Laboratory for Medicinal Products and Medical Devices (OLMPMD)

Official Laboratory for Control of quantity of medicinal products is a laboratory for control of quantity of medicinal products and medical devices with the purpose of verification whether the quantity of medicinal products meets the international standards, and the function will be regulated in a sub-legal act.

Article 12
Licensing manufacturers of medicinal products

1. Medicinal products in Republic of Kosovo are manufactured only by Pharmaceutical Manufacturers Licensed by KMA.

2. Technical conditions for licensing of pharmaceutical manufacturers are set by the sub-legal act promulgated in accordance with this Law.

3. Pharmaceutical Manufacturers must fulfill current conditions of Good Manufacture Practice - GMP.

4. Medicinal products in Kosovo must be produced and controlled according to the criteria of "European Pharmacopoeia" and other eventual supplementing conditions foreseen with sub-legal acts.

5. Notwithstanding paragraph 3 of this Article, the pharmaceutical manufacturers who currently do exercise this activity, have a timeframe of two (2) years from entering into force of this Law, to meet the standards of current GMP.

6. Manufacturers of Medicinal Products/ medicaments have the right to circulate manufactured medicinal products, without a need to be licensed as Pharmaceutical Wholesalers.

7. The licensed pharmaceutical manufacturers have the right to import the raw material and semi-products without an Authorization for Marketing by KMA. The manufacturers shall be granted with the permission for import preliminarily by KMA.

8. The License to Pharmaceutical Manufacturers is issued for an unlimited term, with annual renewal, except if is not suspended or revoked.

9. KMA is obliged to decide in relation to the request for licensing and renewal (annual renewal) from paragraph 8 of this Article, within sixty (60) days from the date of application.

Article 13
Manufacture of Medicinal Products

1. The authorization for manufacturing medicinal products intended to be placed in Kosovo is issued for medicinal products either prepared industrially or manufactured by a method involving an industrial process.

2. A Manufacturing Authorization holder of medicinal products in Kosovo, is obliged to provide manufacturing conditions which prove meeting of current international standards of Good Manufacturing Practice (hereinafter GMP) which shall be defined by a sub-legal act.

3. A Manufacturing Authorization holder in Kosovo is engaged in the manufacture of specific medicinal products, designated pharmaceutical forms or parts of the manufacturing process, or services to other manufacturers, in accordance with provisions laid down by the Manufacturing Authorization

4. A Manufacturing Authorization holder in Kosovo shall give a job to at least one qualified person to assure the manufacturing quality and a qualified person for quality control of medicinal products, qualified employees, facilities and equipment to produce medicinal products according to the terms of current GMP, GLP and GDP.

5. A Manufacturing Authorization holder in Kosovo shall keep detailed records of Standard Operation Procedures according to GMP, GLP and GDP and such details to be inspected by PIMPD at any time.

6. A Manufacturing Authorization for medicinal products issued in Kosovo is valid for a period of five (5) years provided that the payment of annual license fee is made except if it is suspended or revoked.

7. A Manufacturing Authorization issued in Kosovo can be amended either at the request of the manufacturer, or at the request of KMA with the purpose to harmonization with GMP standards and to the extent that such amendments do not exceed the provisions of this Law or sub-legal acts promulgated in compliance with this Law.

8. Any proposed change to the terms of the Manufacturing Authorization shall be notified to the KMA, and the Manufacturing Authorization amended on the basis that changes proposed by the authorization holder can not be in contradiction with provisions of this Law and its sub-legal acts.

Article 14
Import and export of medicinal products

1. Medicinal products may be imported into Kosovo only when a Batch Import License has been granted by the KMA for human use , the granting of which shall be after meeting the following terms:

1.1. import License, issued by KMA;

1.2. a Marketing Authorization for medicinal products, issued by KMA

1.3. a Wholesale Pharmaceutical License, issued by the KMA; and

1.4. a Batch certificate of Analysis for each batch of medicinal product imported.

2. An importer/exporter shall keep detailed records of all relevant activities as specified in the license, such records shall include full information on all medicinal products and batch traded their source and immediate destination. The KMA and PIMPD shall request regular reports about traded medicinal products and the volumes traded.

3. A license to import or export of medicinal products, unless suspended or withdrawn, shall be valid for six (6) months with a possibility of extension to maximum twelve (12) months by the competent authority.

4. Health professionals, health institutions having obtained a Clinical Investigation Authorization, may, through licensed wholesalers, import reasonable quantities of medicinal products which are required for such investigations, provided that the prior written approval for any specific importation is obtained from the KMA in accordance with this Law and its supplementing sub-legal acts.

5. Natural persons entering or exiting Kosovo may carry with them reasonable quantities of medicinal products required for one treatment for their personal use, proved by a medical report or doctor's prescription.

6. Applicants for a Marketing Authorization may import such samples of medicinal products as are required in the Marketing Authorization application procedure as defined in additional/sub-legal act pursuant of this Law.

7. The KMA may, upon the request of the Ministry of Health, directly import medicinal products, active substances, excipients and pharmacopoeia reference standards, as required for the purpose of quality control of medicinal products placed in Kosovo and in accordance with special import license conditions defined in sub-legal act pursuant of this Law.

8. The KMA may, upon the request of the Ministry of Health, directly export medicinal products, active substances, excipients and pharmacopoeia reference standards for the purpose of quality control of medicinal products placed in Kosovo and in accordance with special export license conditions defined in the subsequent sub-legal act of this Law.

9. The import of initial material, raw material and semi-products by the licensed pharmaceutics manufacturer shall be regulated with a sub-legal act.

10. KMA gives banderoles for the permitted amount at the occasion of obtaining the License for importing medicinal products as well as trading medicinal products manufactured in Kosovo

11. Procedures related to banderoles are regulated by a sub-legal act.

Article 15
Wholesale trade of medicinal products

1. Wholesale trade, import, export of medicinal products may only be undertaken by circulators who meet the following criteria:

1.1. enterprises registered in the Agency for Registration of Business;

1.2. enterprises engaged only with import, export and wholesale distribution of medicinal products and medical devices;

1.3. enterprises that shall be equipped with License for circulation of medicinal products and medical devices by KMA, attesting that they meet the technical and environmental conditions for deposition, keeping and transport of medicinal products and medical devices.

2. The terms and criteria for Licensing the Pharmaceutical Wholesale Enterprise shall be defined by a sub-legal act.

3. The holder of a Pharmaceutical Enterprise License shall employ a licensed pharmacist responsible for monitoring of all medicinal products and shall have necessary and qualified employees, storage facilities and security systems for this purpose.

4. A Pharmaceutical Enterprise License shall, unless suspended or withdrawn, be valid for a five (5) year period subject to payment of annual tax.

5. A Pharmaceutical Wholesale Enterprise of medicinal products shall keep detailed records of all business activities which shall be inspected by PIMPD.

Article 16
Pharmacies and dispensing of medicinal products

1. Medicinal products for human use may only be dispensed and retailed through pharmacies licensed by MoH.

2. Licensed pharmacies should possess a Business Certificate and a Professional Pharmacy Work License.

3. Conditions for exercising the community Pharmacy activity are determined by legal and sub-legal acts**.**

4. Conditions for exercising the hospital Pharmacy activity are determined by legal and sub-legal acts**.**

5. A pharmacy shall keep detailed records about trading, storage and dispensing of medicinal products and medical devices.

6. A licensed pharmacy has the right to prepare and dispense magistral and official pharmacy preparations

Article 17
Galenic laboratories

1. A galenic product is a product prepared in galenic laboratory of the pharmacy according to the current official pharmacopeia of EU, international American pharmacopeia, or in compliance with the forms of magistral and galenic preparation.

2. A magistral preparation is manufactured and dispensed only by the pharmacies, for individual patients, based on the prescription of licensed doctor.

3. The manufacturing quality of the galenic product should comply with current pharmacopeia standards of EU, USP and other pharmaceutical form for manufacturing such products and it doesn't require a Marketing Authorization

4. The work license for a Galenic Laboratory is issued by KMA;

5. The KMA, through CAMPMD, makes the classification of magisterial preparations or galenic products and differentiates them from medicinal product, according to sub-legal acts.

6. A Galenic Laboratory License shall, unless suspended or withdrawn, be valid for a five (5) year period annually renewable.

Article 18
Marketing authorization for medicinal products

1. A medicinal product is traded in the Republic of Kosovo having received a Marketing Authorization from the KMA.

2. Obtaining the Marketing Authorization for medicinal products, procedures and labeling shall be determined by sub-legal act.

3. Marketing Authorization for medicinal products shall not be required for:

3.1. magistral and official preparations;

3.2. Orphan products, list of which shall be formulated by KKEMP published by KMA.

3.3. radioactive pharmaceutical preparations manufactured before the time of use by a person or by an authorized institution, according to national legislation, to use such medicinal products in an approved health institution exclusively approved for authorized radionuclide generators, radionuclide kits or radionuclide precursors in accordance with the manufacturer's instructions;

3.4. medicinal products for which an appropriate authorization for use in clinical investigations has been granted;

3.5. medicinal products intended for treatment as a continuation of a process for medical treatment started abroad;

3.6. additional products of nutrition, mineral and oligo-mineral multivitamins, herbal substances (except the products that are classified as traditional herbal products) will be defined by KMA based on the recommendation of CAMPMD with a sub-legal act;

3.7. semi-products that shall be further processed in the licensed pharmaceutical manufacturers;

3.8. medicinal products to be used in research and development;

3.9. pure blood, plasma or blood cells of human origin, except for plasma which is prepared by a manufacturing method;

3.10. samples submitted for Marketing Authorization;

4. A Marketing Authorization can be subject to particular conditions, and when necessary be limited to certain experimental or not well established therapeutic indications, or granted for a limited period of time.

5. A Marketing Authorization, unless suspended or withdrawn, shall be valid for a five (5) year period and subject to ongoing review and/or renewal, the procedures and conditions for which shall be set out in the sub-legal act.

6. A Marketing Authorization holder shall inform the KMA of any new significant findings for quality, safety and efficacy of the authorized medicinal product in accordance with the provisions of this Law,

7. A Marketing Authorization and the determined conditions thereto may be modified at the request of the Marketing Authorization holder.

8. Every medicinal product for which the Marketing Authorization is issued, must have in its external part of packaging the data for medicament including even in Braille alphabet, as well as the instruction for use of medicament in official languages of the Republic of Kosovo.

9. The Minister of Health may conclude a bilateral and multilateral agreement with EU countries and other countries for unilateral recognition of Marketing Authorization by the Republic of Kosovo.

10. Ministry of Health, with a sub-legal act, regulates the simplification of procedures for registration of medicinal products which do not have parallels registered in the Republic of Kosovo.

11. For products which possess the certificate of Marketing Authorization issued by EMEA that are registered in the American Food and Drug Administration (FDA) the applicant does not need to submit CTD modules, he/she submits only the documents required by the competent authority specified by the sub-legal act.

12. The KMA provides confidentiality of documents for marketing authorization submitted by manufacturers.

Article 19
Description and dispensing of medicinal products

1. When a Marketing Authorization is granted, the KMA, takes into consideration the professional advice of the CAMPMD, for:

1.1. a medicinal product subject to medical prescription (Prescription Only Medicine-"POM"); and

1.2. a medicinal product not subject to medical prescription (Over The Counter - "OTC").

2. The KMA shall determine sub categories for medicinal products subject to medicinal prescription according to the following classification:

2.1. medicinal products which are object of renewable or non-renewable medicinal prescription;

2.2. medicinal products which are object of special medicinal prescription and prescription for narcotics.

3. Medicinal products shall be object of medical prescription where they:

3.1. are likely to present a risk to public health either directly or indirectly, even when used correctly, if utilized without medical supervision,

3.2. are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect risk to public health,

3.3. contain active substances, the adverse effects of which require further research;

3.4. are normally prescribed by a physician to be administered parenterally.

4. Where medicinal products are object of special medical prescription for narcotics, the following factors shall apply:

4.1. the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, namely the United Nations Conventions of 1961 and 1971; or

4.2. the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction.

5. The use of some medicinal products are strictly restricted and they shall be allowed only to those authorized health institutions licensed by the Ministry of Health according to the conditions required for obtaining a license and based on recommendations of KMA and CAMPMD.

6. Prescription and dispensing of Medicinal Products shall be determined by the sub-legal act.

Article 20
Clinical researches of medicinal products

1. Clinical trials on patients or healthy persons, of either unauthorized medicinal products or of authorized medicinal products within approved indications, for new indications and new dosage strengths, may only be conducted in accordance with the requirements of this Law and sub-legal act, requirements of Good Clinical Practice (hereinafter "GCP") in clinical trials, principles of medical ethics as well as the mandatory and guaranteed protection of personal data.

2. When a clinical trial of either an unauthorized medicinal product or an authorized medicinal product for new indications and new dosage strengths is proposed, the sponsor or the principal investigator of the trial shall submit to the KMA an application, including a comprehensive summary relating to the nature and properties of the medicinal product, the investigations which have been performed to define its pharmacological and toxicological properties, the clinical experience to date, the protocol of the proposed trial and a list of all clinicians and health institutions involved in the trial.

3. When a trial for an authorized medicinal product used according to the approved Summary of Product Characteristics (SmPC) is proposed, the sponsor or the investigator shall submit a notification, stating the medicinal product to be tested, the study design, the number of patients involved and participating medical personnel.

4. Prior to issuing a Clinical Trial Authorization by the KMA, the health institution and the investigator should:

4.1. hold a GCP license that shall be issued in accordance with the Administrative Instruction,

4.2. obtain the approval of the Ethics Committee and provide the Committee with a full account of documentation regarding trial results and declarations that are or will be provided in writing for the consent approved by the patients.

5. Clinical trials are conducted only after a Clinical Trial Authorization has been granted by the KMA following advice received from the CAMPMD, having regard to the trial's purpose, usefulness, possible risks and benefits to the trial subjects, the competence of the institutions and the investigators. Clinical trials are object of assessment and monitoring by the KMA in accordance with this Law, its supplementary/sub-legal acts, GCP requirements and the terms of the Clinical Trial Authorization.

6. The sponsor shall provide each individual investigator and health institution with documentation that was approved by KMA.

7. Patients who participate in trial shall be offered a reasonable reimbursement for their expenses, but shall not be induced to participate because of any high financial compensation or in excess of this compensation.

8. All participating subjects in a trial shall be fully informed, in a manner appropriate to their understanding, for the purpose, nature and possible risks of the trial. Their participation shall be dependent on their consent, given freely and without duress considering this information. Where the participating subjects are not legally competent to give such consent such informed consent may be sought from a parent or legally recognized guardian. Consent is given in written form and may be withdrawn at any time.

9. The sponsor of a trial shall ensure that all participating subjects are fully insured against any loss or injury resulting from their taking part in the trial, and shall further bear ultimate liability for all such losses or injury.

10. If any serious adverse effect, accident or other untoward event occurs in the course of the trial, the KMA and the Ethics Committee shall be notified immediately.

11. Medicinal products supplied by the sponsor for the purpose of the clinical trials shall be clearly labeled “For clinical trial”

12. In order to protect public health, the KMA may order temporary or permanent cessation of a clinical trial.

Article 21
Advertising and promotion of medicinal products

1. Based on this Law, any information about a medicinal product provided by its manufacturer, or marketing authorization holder or organization financially supported by either of the former is considered to be advertising or promotion.

2. Advertising and promotion of a medicinal product without Marketing Authorization is prohibited.

3. Advertising and promotion of a medicinal product, and all information provided on it to health professionals and the public, whether printed, oral, or in any other form, shall be consistent with the conditions of its Marketing Authorization, in particular its approved Summary of Medicinal Product Characteristics (SmPC).

4. Advertising and promotion of a medicinal product shall encourage the rational use of the medicinal product by presenting it objectively and its properties, and shall be in accordance with pharmaceutical industry codes of ethical marketing practice.

5. Where printed or electronic advertising or promotional material is presented to health professionals, the full text of the SmPC shall be attached to the promoting material, unless a specific exemption has been granted by the KMA.

6. Sellers of medicinal products or their representatives shall carry with them and present on request, the full SmPC of any medicinal product that they intend to promote.

7. A manufacturer or a holder of a Marketing Authorization or any of their representatives shall not offer or provide any person qualified for prescribing and dispensing of medicinal products, bribery of every kind whether financial, material or other inducements of any significant value.

8. Notwithstanding the provisions of paragraph 7 of this Article, a manufacturer or a holder of a Marketing Authorization or their representatives may enable persons qualified for prescribing and dispensing of medicinal products to acquire additional knowledge of new medicinal products. Training through which such additional knowledge is acquired must stay within professional and scientific objectives. Its sole purpose must be the acquisition of knowledge and it may be made available only to qualified persons.

9. Distribution of free samples of medicinal products for marketing purposes shall only be done by holders of a Marketing Authorization and only to persons qualified to prescribe the product. Distribution shall be limited to one pack of the smallest size and clearly labeled ‘Free sample - not for sale.

10. Health professionals shall have access to neutral and objective source of information about authorized medicinal products that are provided by the MoH - KMA and relevant bodies.

11. Advertising to the general public of those medicinal products, which are classified by the MoH, KMA and products subject to medical prescription or contain narcotic or psychotropic substances as listed in the United Nations Conventions of 1961 and 1971 is prohibited with the exception of:

11.1. vaccination campaigns carried out by the pharmaceutical industries and approved by the KMA;

11.2. the interest of the public health with a view to preventing an epidemic, an epizootic, or in case of a natural disaster or in other similar emergencies, the MoH can allow advertising and promotion of certain medicinal products via the mass media.

Article 22
Quality assurance of medicinal products

1. Quality assurance of medicinal products concerns the establishment by the KMA by means of satisfactory documentary and existing physical evidence that a medicinal product meets the foreseen quality standard requirements for placement in or export from Kosovo in order to protect public health.

2. The KMA, via OLMPMD shall through assessment of documentation; inspections and laboratory quality control, assure that all medicinal products imported and manufactured in Kosovo or exported from Kosovo are in conformity with international standards.

3. The OLMPMD shall provide quality assurance of all medicinal products placed on the Kosovo market and for export from Kosovo in accordance with the following internationally defined quality standards:

3.1. reference standards set by the European Pharmacopoeia, other Pharmacopoeias recognized by the KMA or other validated methods of analysis;

3.2. Good Control Laboratory Practice (herein after GLP).

4. In order to assure the quality of medicinal products imported and manufactured in Kosovo, OLMPMD shall be obliged to perform the following tasks:

4.1. quality assessment of an application for a medicinal product Marketing Authorization;

4.2. batch release control that shall be obligatory for vaccines, sera and blood products manufactured in Kosovo;

4.3. control measures applied to medicinal products imported and manufactured in Kosovo such as random sampling, testing of sensitive medicinal products (i.e.

products where quality is critical to safety and efficacy of usage), solving of suspected and identified product quality problems, control of the first imported batch of authorized medicinal product, identification of counterfeit medicines and other measures related to such matters;

4.4. re-testing of medicinal products that already have a Batch Certificate of Analysis in the case where internationally recognized GMP standards are suspected to be not in place;

4.5. methodology validation for quality control in accordance with accepted internationally standards;

4.6. International co-operation in development of medicinal product quality assurance procedures and standards of medicinal products including pharmacopoeia standards;

4.7. other quality assurance tasks that may be deemed necessary in accordance with supplementary act, sub-legal act pursuant to this Law.

5. The KMA based on the recommendation of OLMPMD shall be entitled to perform any quality assurance procedure it considers that is appropriate for any given medicinal product in order to protect public health.

6. In the case that a medicinal product does not meet the defined and applied quality standards, remedial action shall be taken as defined by the sub-legal act supplementing this Law, including the provision for a complete removal of the concerned product from the Kosovo market.

Article 23
Quality assurance of immunological medicinal products and medicinal products derived from human blood or plasma

1**.** In the interest of public health, the KMA requires from a holder of a Marketing Authorization for immunological medicinal products to meet the criteria set out in sub-paragraph 1.1 of this paragraph, to act in compliance with specified procedures and fulfils conditions as stated in sub-paragraph 1.2. of this paragraph as follows:

1.1 live vaccines, immunological medicinal products used in the primary immunization of infants or of other groups at risk, immunological medicinal products used in public health immunization programs, immunological medicinal products manufactured using types of advanced technology (advanced therapy medicinal products) or a new type for a particular manufacturer, medicinal products derived from human blood or human plasma;

1.2 Submit samples from each batch of the bulk and/or the medicinal product for examination before release on to the Kosovo market notwithstanding a mutual recognition procedure for batch release determined between the KMA and the competent authorities of EU Member and EU Accessing States. The time frame for batch analysis shall be defined by sub-legal act of this Law.

2. With respect to the use of human blood or human plasma as a raw material for the manufacture of medicinal products, manufacturers of such products shall take all known necessary measures to prevent the transmission of infectious diseases in accordance with international standards.

3. Measures set out in paragraph 2 of this Article shall be included in the monographs of the European Pharmacopoeia regarding blood and plasma and measures recommended by the World Health Organization (WHO) and the European Council, particularly with reference to the selection and testing of blood and plasma donors.

4. The safety measures set out in paragraph 2 of this Article must also be evidenced by importers and exporters of medicinal products derived from human blood or human plasma with reference to relevant international standards.

5. The production within and importation into Kosovo of medicinal products derived from human blood and human plasma shall be subject of control in terms of quality, safety and efficacy by the KMA.

6. Usage of authorized medicinal products derived from human blood and human plasma shall be allowed to health institutions which have licenses for their use, issued by the Ministry of Health.

7. The KMA shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, and prevents the absence of specific viral contaminations.

8. With respect to the provisions of paragraph 7 of this Article above, manufacturers shall notify the KMA of the method used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma and the KMA may submit samples of the bulk and/or the medicinal product for testing by the OLMPMD, either during the examination of the Marketing Authorization or at anytime after the Marketing Authorization has been granted.

Article 24
Pharmacovigilance

1. The KMA establishes a pharmacovigilance system with regard to information obtained related to possible adverse effects and interactions of medicinal products for human use and ensure that this information is conveyed to health professionals and when necessary also to the general public.

2. Taking account of such data, it may be required either to supplement-amend the terms of the Marketing Authorization for specified medicinal products, or revoke/suspend the Marketing Authorization or to order withdrawal of specified medicinal products from the market.

3. In its assessment of the adverse effects of medicinal products, and in all cases leading to an administrative decision related to the Marketing Authorization, the KMA shall consult the CAMPMD or relevant sub-committee thereof.

4. The KMA shall request and encourage the submission of reports from health professionals on suspected known or unknown adverse effects of medicinal products, examine relevant data appearing in the relevant literature or data submitted by the manufacturer or extracted from international databases, and shall maintain international collaboration with other agencies and institutions to arrive at best possible conclusions about the safe and effective use of medicinal products.

5. The KMA shall define specific requirements on health professionals with respect to the reporting of suspected adverse effects of medicinal products in sub-legal act of this Law.

6. In case the medicinal product causes adverse effects due to suspected quality, the KMA shall take samples for testing by OLMPMD.

7. Holders of a Marketing Authorization shall have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance who shall be responsible for the proactive reporting to the KMA of adverse effects of medicinal products placed on the Kosovo market by the holder of a Marketing Authorization.

8. A holder of a Marketing Authorization shall be required to maintain detailed records of all reported known or suspected adverse effects related to an authorized medicinal product placed in Kosovo. Such adverse effects occurring either within or outside Kosovo shall be issue of KMA.

Article 25
Medicinal product disposal

1. Medicinal products without either an Import License or Marketing Authorization, notwithstanding the provisions of Article 18 paragraph 3 of this Law of suspected quality,

with an expiry term, or stored or prepared in contradiction with stipulated conditions according to the requirements of Good Distribution Practice (GDP), or obviously damaged or not completely consumed, hereinafter "unusable medicinal products", must be disposed of, including their packaging, so as to prevent a threat to life and health of humans or animals or to the environment.

2. The procedures for disposal of unusable medicinal products shall be set out in sub-legal acts of this Law and in coordination with the Ministry of Environmental Protection and Spatial Planning, Ministry of Internal affairs, Ministry of Agriculture, Forestry and Rural Development.

3. Disposal of unusable medicinal products shall be performed by authorized legal entities in Kosovo on the basis of permit granted by the relevant authority in the case of radiopharmaceuticals, by the authority responsible for radiation safety.

4. Information that consent has been granted for disposal shall be provided by the authorities priory authorized by MoH and KMA for a medicinal product for human use.

5. Legal bodies authorized to dispose of unusable medicinal products (which, based on definition, exclude: unusable whole human blood, plasma or blood cells of human origin, the disposal of which shall be determined based on procedures set out by sub-legal act) will be determined by the Ministry of Environment and Spatial Planning..

6. Authorized authorities in Kosovo to dispose of unusable medicinal products shall be obliged to maintain and keep records of disposed unusable medicinal products in accordance with waste recording procedures set out by the Ministry of Environmental Protection and Spatial Planning.

7. Manufacturers, wholesalers and retailers of medicinal products and health institutions located in Kosovo are obliged to submit unusable medicinal products to the location specified by competent authorities pursuant to legal and sub-legal acts.

8. A pharmacy is obliged to accept unusable medicinal products surrendered by natural persons. The costs incurred by the pharmacy in connection with the submission by natural persons of unusable medicinal products to the legal entities specified in paragraph 7 of this Article and with their disposal by such legal entities shall be covered by the relevant authority in Kosovo.

9. The cost of disposal of unusable medicinal products, with the exception of those specified in paragraph 8 of this Article, shall be borne by the manufacture, pharmaceutical wholesaler and retailer, or other health institution.

Article 26
Pharmaceutical inspectorate for medicinal products and medical devices

1. The pharmaceutical inspectorate for medicinal products and medical devices (hereinafter PIMPMD) is an executive administrative body of KMA, which exercises outside supervision of pharmaceutical wholesalers and retailers, of medicinal products and devices and pharmaceutical manufacturers as well as the corresponding personnel at working place.

2. PIMPMD consists of the Chief inspector, Pharmacy Inspectors and Inspectors of Medicinal Products, who are selected by a public competition

3 The Chief inspector and the Inspectors for medicinal products and medical devices should at have the adequate professional qualification, for carrying out the activity in compliance with the regulations and directives of EU.

4. Duties and responsibilities of PIMPMD and division of sub-categories of inspections of GMP, GCP, GDP, GLP and other Practices of Pharmacy, shall be regulated by a sub-legal act by Ministry of Health.

5. Upon the request of KMA, the inspectorate is obliged to undertake activities, and to act according to their obligations, defined by the provisions of this Law.

Article 27
Classification of medical devices

1. Medical devices shall be classified into:

1.1. general medical devices;

1.2. active implantable medical devices; and

1.3. *in vitro* diagnostic medical devices

2. In terms of risk to their users, general medical devices shall be classified in accordance with the classification criteria set out in Annex IX of EC Directive 93/42 into:

2.1. class I-medical devices constituting a low risk potential for users;

2.2. class IIa-medical devices constituting higher risk potential for users;

2.3. class IIb-medical devices constituting a high risk potential for users; and

2.4. class III-medical devices constituting the highest risk potential for users.

3. Taking into account the nature, source of power and other characteristics, medical devices shall be further classified into:

3.1. non-invasive;

3.2. invasive; and

3.3. active.

4. According to their purpose and risk potential for the user, medical devices shall be:

4.1. used exclusively in human or veterinary health care;

4.2. dispensed on prescription or without prescription in pharmacies;

4.3. dispensed on prescription or without prescription in specialized shops;

5. The KMA shall determine in greater detail the classification of medical devices and the manner of their dispensation in sub-legal act pursuant to this Law.

6. Dependently whether the article should be a combination of a medicinal product and medical device or a combination of a medical device that is in a free sale, it will be classified according to its primary purpose as declared by the manufacturer in accordance with classification criteria laid down by the KMA.

7. In the event a classification is either ambiguous or disputed, the matter shall be decided by the KMA taking into consideration the technical advice of the Kosovo Medical Devices Committee.

Article 28
Placing on the market and putting into service of medical devices

1. The KMA shall take all necessary steps to ensure that medical devices to be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.

2. Before a medical device can either be placed on the market or put into service in Kosovo, the manufacturer or his supplier shall submit to the KMA the registration file. Taking into account the class of medical device, format, content and procedure for the registration, it shall be defined in sub-legal act pursuant to this Law.

3. Subject to a satisfactory evaluation of the notification submitted by the manufacturer of a medical device or his designated supplier, the KMA shall issue an authorization for placing on the market or putting into service of a medical device.

4. Manufacturers of custom-made devices and devices intended for clinical trial shall be obliged to present all details about the medical device to the KMA.

5. In the case that the device is determined by the KMA, to be of importance for the protection of public health in Kosovo, based on technical advice of the Kosovo Medical Devices Committee, KMA, having processed the application, may issue permission for placing on the market or putting into service an individual medical device, despite the fact that no conformity assessment has been carried out according to the provisions of this Law and its supplementary sub-legal acts.

6. The KMA may prohibit the placing on the market or putting into service of a medical device or a product group or impose conditions on the use or availability if necessary for the protection of public health and safety.

Article 29
Essential requirements for medical devices

1. Before a medical device can be placed on the market or put into service in Kosovo, it shall be necessary for a medical device to satisfy essential requirements which apply to them, taking account the intended purpose of the devices concerned:

1.1. they must be designed, manufactured, installed, maintained and applied in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety;

1.2 any health risks associated with use of the device must be investigated during its design and manufacture and users must be informed about any risks that cannot be eliminated;

1.3 devices are classified by the KMA in accordance with provisions of Article 27 of this Law;

1.4 their manufacturers shall apply the quality system approved for the design and construction of the medical device in accordance with harmonized standards;

1.5 special prescribed requirements concerning the purpose of the device are met in accordance with the type of medical device;

1.6 in demonstrating the conformity of a medical device in accordance with relevant essential requirements and in the related approval, the manufacturer must

apply tests and inspections carried out by a conformity assessment body approved by the KMA.

2. A medical devices will meet essential requirements if it has been designed, manufactured and fitted with appropriate equipment in accordance with standards adopted pursuant to harmonized standards.

3. The KMA shall give detailed instructions on the quality assurance procedures to be followed in the cleaning, sterilization, calibration, maintenance and other measures taken to ensure the reliability of medical devices.

4. Ministry of Health shall determine in details the essential requirements for medical devices with sub-legal acts pursuant to this Law.

Article 30
Conformity assessment Procedures and labeling of medical devices

1. Conformity assessment procedure is a procedure based on which it is directly or indirectly assessed whether medical devices fulfill the requirements referred to in Article 29 of this Law.

2. A medical device's conformity with prescribed conditions shall be established by a Declaration of Conformity.

3. The procedure for assessing the conformity of medical devices with prescribed essential requirements shall depend on the classification of devices in view of the risk for their users, namely:

3.1. for medical devices of class I the manufacturers themselves shall establish conformity with prescribed essential requirements and draw up a conformity declaration on their own responsibility, the exceptions being measuring mechanisms and sterile products of class I, treated as if belonging to class II or III;

3.2. The conformity of medical devices of classes IIa, IIb and III with the prescribed essential requirements shall be established and the quality assurance system supervised by CAMPMD of conformity for performing this activity by the KMA.

4. Ministry of Health shall, through a supplementary sublegal act of this Law, will determine in details the conditions to be fulfilled, the appointment procedure by KCAMP for conformity assessment, conformity assessment procedures in accordance with the prescribed essential requirements, discharge and scope of reference.

5. The Declaration of Conformity and the conformity marking of medical devices, issued abroad, shall be valid in Kosovo, if issued in compliance with harmonized standards on medical devices recognized by Kosovo.

6. Notwithstanding the provisions of the paragraph above, the KMA shall acknowledge the validity of a Declaration of Conformity and the conformity markings of medical devices which were issued abroad, on condition that they demonstrate conformity with technical specifications, which are considered equivalent to the requirements regarding medical devices laid down by this Law and its pursuant sub-legal acts, and on condition that the qualification of the bodies involved in conformity assessment procedures of medical devices was established with equivalent procedure and assessed against the requirements as prescribed for such bodies by this Law and its pursuant sub-legal act.

7. Based on the Declaration of Conformity, the manufacturer must label its products with the prescribed conformity marking.

8. Ministry of Health shall prescribe the contents of the Declaration of Conformity and conformity marking requirements in sublegal act pursuant to this Law.

9. Notwithstanding the provisions of the previous paragraph of this article, medical devices intended for investigation and for individual use are not subject to registration procedures in accordance with this Law.

10. It is prohibited to mark a medical device with a marking contrary to the provisions of this Law.

Article 31
Manufacture of medical devices

1. For the purposes of this Law, manufacture of medical devices concerns both industrial manufacture and manufacture by Kosovo health institutions or their representatives either for placing on the market or putting into service of medical devices.

2. A manufacturer of medical devices or his authorized supplier is responsible for the design, manufacture, packaging and labeling of a medical device either placed on the market or put into service in Kosovo.

3. Manufacturers shall observe prescribed technical specifications in the process of manufacturing medical devices and in assuring their quality.

4. Technical specifications may determine that a medical device is considered to be in conformity with technical specification requirements, if it complies with the requirements of non-mandatory standards to which such technical specifications refer.

5. Manufacturers of medical devices or their authorized supplier must provide a Declaration of Conformity for each of their products, pursuant to the procedures determined in Article 30 of this Law.

6. Manufacturers or their authorized supplier must report to the KMA and designated conformity assessment body on all changes related to a medical device.

7. Manufacturers of medical devices in Kosovo or an authorized supplier, in the case that the medical device is manufactured outside Kosovo, must also satisfy the following conditions:

7.1. notify the KMA of their business;

7.2. provide evidence that they perform their business in such a way as to ensure the protection of public health;

7.3. employ an appropriately qualified person as defined by the KMA in normative act pursuant to this Law;

7.4. take up liability insurance for any possible damage caused to the user or third person.

8. Ministry of Health shall prescribe the license conditions for manufacturing of medical devices in Kosovo in a sub-legal act pursuant to this Law.

Article 32
Import, export, wholesale, retail and dispensing of medical devices

1. Legal or natural persons shall be authorized specifically for the import, export, wholesale and retail and dispensing of medical devices.

2. For the import of medical devices into Kosovo there shall be required:

2.1. an Import License issued by KMA;

2.2. pharmaceutical wholesaler license for medicinal products and devices.

3. The requirement to obtain an Import License for a medical device shall be waived according to the classification status of the medical device as defined by sub-legal act.

4. Medical devices may only be placed on the market or put into service if they comply with essential requirements, if their conformity was established according to prescribed procedures and if they are labeled in compliance with standards set out in the sub-legal act pursuant to this Law.

5. The KMA shall keep a register of wholesalers and retailers/dispensers of medical devices and a register of medical devices which may be marketed in Kosovo.

6. Legal or natural persons either conducting wholesale or dispensing of medical devices must satisfy license conditions prescribed by the KMA in accordance with sub-legal act pursuant to this Law.

7. The dispensation of certain medical devices may require a medicinal prescription as defined in the sub-legal act of this Law.

Article 33
Professional use of medical devices

1. A professional user shall take the necessary measures to ensure:

1.1. the condition of a medical device is maintained to a level as required by this Law;

1.2. the place of use, the components and structures affecting the safe use and devices, articles and equipment relating to the medical device do not compromise its performance or the health or safety of a patient, user or other person; and

1.3. the instructions and procedures concerning the use which are appropriate.

2. Medical devices may be installed, serviced and repaired only by expert persons and persons with the necessary professional skills.

3. A person using a medical device shall have adequate user training and experience and ensure that the necessary labeling and instructions for the safe use of the device are provided on or with the device.

4. A medical device must only be used in accordance with the intended purpose stated for the device.

5. A professional user shall ensure that the device is placed, calibrated, maintained and serviced appropriately to ensure it remains in working order.

6. A professional user shall keep a list of medical devices used or hired out by him or in his possession or introduced into a patient.

Article 34
Clinical trials of medical devices

1. If a manufacturer intends to conduct a clinical trial to verify the performance or to determine and assess the adverse effects of a medical device prior to placing on the market or putting into service of the device, the investigating institution or sponsor shall make a written notification to KMA before commencing a clinical trial.

2. The notification related to intended clinical trials shall be mandatory for Class III devices, implantable devices and Class IIa or IIb long-term invasive devices.

3. A clinical trial notification shall also be required concerning the investigation of a new purpose of a medical device regardless of whether the device has been placed on the market or put into service.

4. The investigating institution and sponsor of the clinical trial must prior to the commencement of the trial take up liability insurance for any possible damage resulting from the trial and obtain permission from the Ethics Committee.

5. The manufacturer of the medical device under investigation must ensure the investigator against any possible damage caused during the investigation of medical device.

6. The KMA may order a clinical trial to be discontinued if this is considered necessary due to public health reasons.

7. The detailed requirements and procedures for conducting clinical trials of medical devices in Kosovo shall be set out in sub-legal act pursuant to this Law.

Article 35
Monitoring of adverse effects of medical devices

1. A manufacturer of a medical device or his supplier must inform the KMA about any malfunction or deterioration in the characteristics or performance of a medical device or any inadequacy in the labeling or instructions for use which have or are suspected to have led to either an adverse effect or serious adverse effect in a patient, user or other person.

2. The manufacturer must inform the KMA about any technical or medical reason relating to the characteristics or performance of a medical device that leads to systematic recall of the device from the market by the manufacturer.

3. Manufacturer, supplier, dispenser and professional user of medical devices who discover or suspect any adverse effect to a medical device, must report such adverse effects to the KMA.

4. The KMA shall determine the requirements to be satisfied by legal and natural persons with respect to the assessment, monitoring and reporting of adverse effects to medical devices.

5. The KMA reserves the right to order the withdrawal of a medical device from circulation and service in Kosovo in order to protect public health.

6. Adverse effects to medical devices shall be recorded in an adverse effect register and monitored by the KMA in accordance with procedures set out in sub-legal act pursuant to this Law.

Article 36
Advertising and promotion of medical devices

1. It is prohibited to advertise and promote medical devices publicly which are used by legal persons or natural persons providing health care to humans.

2. Notwithstanding the above, the KMA may, based on the technical advice of CAMPMD, may allow public advertising and promotion of medical devices which are classified as of not a high risk to users.

3. Advertising and promotion of medical devices must not be inappropriate or include exaggerated or erroneous representations of the composition or efficacy of the device.

4. The detailed conditions for advertising and promotion of medical devices shall be determined by sub-legal acts of this Law.

Article 37
Inspection and supervision of medical devices

1. The PIMPMD, by the supervisory measures stated in this article, ensures that the legal requirements concerning medical devices and pursuant sub-legal acts issued on the basis of this law should be fully fulfilled.

2. Supervisory measures shall be performed by inspection of manufacturers, wholesalers, dispensers/retailers and professional users of medical devices to certify that the requirements of this Law and its pursuant sub-legal acts are being met.

3. The PIMPMD inspectorate shall be authorized to carry out the following supervisory measures:

3.1. request all necessary information from the manufacturer and/or supplier including issued Declarations of Conformity and related technical documentation;

3.2. order execution of appropriate tests and checks of medical devices in order to assess their conformity with requirements also after such devices have either been placed on the market or put into service;

3.3. collect sample medical devices and submit them for conformity assessment;

3.4. prohibit the issuance of the Declaration of Conformity in case that the medical device is considered to be non-conforming with conformity conditions;

3.5. order the elimination of the established non-conformities;

3.6. request that medical devices are marked with prescribed markings or order the elimination of non-prescribed markings;

3.7. prohibit marketing, limit marketing or order withdrawal from the market of non-conforming medical devices and take additional measures to ensure that such prohibitions are observed;

3.8. prohibit the use, limit the use or order the cessation of use of non-conforming medical devices, and take additional measures to ensure that this prohibition is observed;

3.9. in the period required for carrying out required tests, temporarily prohibit any supply, supply offer or presentation of medical devices, if there exists a reasonable doubt that a medical device is not in conformity with requirements;

3.10. order the destruction of non-conforming medical devices, if necessary for the protection of public health and safety,

3.11. temporarily confiscate and seal medical devices until the reasons for the precautionary measure of confiscation have been eliminated;

3.12. suspension of licenses in the case of breech of license conditions;

3.13. monitoring of the functioning of Conformity Assessment Bodies in accordance with requirements defined in sub-legal act pursuant to this Law.

4. The PIMPMD can order a legal entity or natural person to bring their operations concerning medicinal devices in line within a defined period of time in compliance with pursuant sub-legal act issued by this Law.

5. KMA shall suspend an authorization or license in case of concrete breech of the provisions of this Law, its pursuant sub-legal acts and the terms of the authorization or license until the infringement is avoided.

6. Revocation of an authorization or license shall occur in the case of a material breech of the provisions of this Law, its sub-legal acts.

7. Any appeals issued against the orders of PIMPMD for the implementation of supervisory measures stated in this Article shall be submitted to the PIMPMD.

8. The Kosovo Customs Service must not permit the customs clearance for the release of medical devices shipments to the market without evidence of an Import License issued by the KMA notwithstanding exceptions that may be made taking into consideration the class of the medical device.

9. Custom Service allows entrance of medical devices given by the donors without any condition only if it is suspected that those devices are not in compliance with the said Articles of this Law.

10. The KMA, in compliance with the relevant Ministry, reserves the right to order other supervisory measures concerning medical devices necessary for the implementation of this Law and its pursuant sub-legal acts.

11. At the request of the competent inspector, the bodies in charge of Kosovo for internal affairs must participate in the enforcement of the supervisory measures stated in this article within the scope of their rights and obligations.

Article 38
Fees

1. A license fee shall be paid by applicants to the KMA for obtaining and maintaining of the authorizations and licenses stated in this Law, fees for which shall be stated in sub-legal acts of this Law.

1.1. applications for medicinal product and medical device authorizations and licenses as stated in this Law;

2. An inspection fee shall be applied by the KMA in order to ensure the correct implementation of this Law and its pursuant sub-legal acts.

2.1. inspection of legal entities or natural persons that infringe authorization and license conditions stated in this Law.

3. An inspection fee shall also include the costs of the inspection procedure including daily expenses allowances, travel allowances and testing costs shall be paid by the legal entity or natural person that is the subject of the inspection.

4. In accordance with fee procedures applied by OLMPMD in EU Member States and EU Accessing States, the costs of providing medicinal product quality assurance by

OLMPMD with respect to the provisions of Articles 20 and 21 of this Law shall be covered by:

4.1. Marketing Authorization applicants and holders for quality assurance related to a new application or maintenance/updating of an existing authorization respectively; or

4.2. in the case where testing relates to a suspected breech of the conditions of the authorizations and licenses stated in this Law, the cost shall be covered by the legal entity or natural person concerned for whom the offence is proven; or

4.3. in the case of testing of unauthorized medicinal products placed in Kosovo, the cost shall be covered by the legal entity or natural person responsible for placing the unauthorized product in Kosovo; or

4.4. KMA concerning medicinal product testing for reasons other than those stated above in this paragraph.

5. The costs of testing and withdrawal from the market or the destruction of a medicinal product or medical device in breech of the provisions of this Law and its pursuant sub-legal acts shall be paid by the legal entities or natural persons who have manufactured or imported the medicinal product or medical device in question.

6. Professional services provided by the KMA to other authorities in Kosovo with respect to the sub-legal acts of this Law shall incur a service fee.

7. The fees and costs specified in this Law shall be approved by the Ministry of Finance and Economy and shall be published and shall be payable to the Budget of Republic of Kosovo.

Article 39
Penalties

1. Violation of the provisions of this Law, its pursuant sub-legal acts and the terms of authorizations and licenses issued according to this Law shall be the subject of penalties and punishments.

2 The inspectorate with a self-initiation or upon the request of KMA, will initiate a civil procedure, economical or penal delicts for the unlawful activities of natural and legal persons in contradiction with this Law.

3. For the activities without license, authorization or license of natural or legal person, except the penal responsibility there will be applied the absolute stopping for operation in the field that this Law covers for next twenty (20) years.

4. Other activities, except penal responsibility will be fined from one thousand and five hundred (1.500) euro to one hundred thousand (100.000) euro, depending on the responsibility of the person and potential damages caused on humans health.

Article 40
Regulation of medicaments price

The price regulation for medicinal products and margin determination for medicinal products and medical devices shall be regulated by the Ministry of Health in cooperation with other Ministries of the Government of Republic of Kosovo set out pursuant to sub-legal acts.

Article 41
Transitory agreements

Until promulgation of new sub-legal acts, there shall apply the acts in power if they are not in contradiction with this law until the promulgation of sub-legal acts pursuant to this law, which shall be promulgated within the timeframe of six (6) months.

Article 42
Emergency situations

1. In the case of acute emergency, catastrophic situations, such as epidemies, big natural disasters, or emergency situations, KMA with the approval of the Government can issue import license, for a certain amount and type of medicinal products and for a defined term, without marketing authorization. KMA can issue import license only for medicinal products that do not have any essentially similar product, registered in the Republic of Kosovo. Regarding the amount, type, quality and the timeframe, the professional working group assigned by KMA, proposes to the Director to apply the special measures.

2. The Director of KMA, according to the working group proposal and the approval of Minister undertakes the special measure.

Article 43

1. The responsible authority for issuance of sub-legal acts is the Ministry of Health.

2. Procedures for election of the director of KMA shall be initiated at latest two (2) months from the entry into force of this Law.

3. Ministry of Health shall initiate the procedures for appointment of the director of KMA without delay, with the aim of respecting the term from paragraph 2 of this Article.

4. Members of the CAMPMD shall be elected within the term of three (3) months from the date of entry into force of this Law. KMA without any delay shall initiate the procedure for selection of members of KMA.

5. Ethic Committee shall be elected within the term of six (6) months from the entry into force of this Law.

6. Board of appeals shall be elected within the term of two (2) months from the entry into force of this Law.

7. LCMPMD shall be functionalized within the term of twelve (12) months from the entry into force of this Law.

8. Till the issuance of new sub-legal acts, there will be applied the acts in force, if they are not in contradiction with this Law, issuance of which will be done within the period of one (1) year, if is not foreseen otherwise by this Law

Article 44
Applicable laws

With the entry into force of this Law, there will cease to be applied the Law on Medicinal Products and Medical Devices 2003/26.

Article 40
Entry into force

This Law shall enter into force fifteen (15) days after its publication in the Official Gazette of Republic of Kosovo.

Law No.03/L –188
30 September 2010

Member of Presidency of the Assembly

Xhavit Haliti