LAW NO. 04/L-190

ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Assembly of Republic of Kosovo,

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

Approves

LAW ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

CHAPTER I
BASIC PROVISIONS

Article 1
Purpose

The purpose of this Law is to lay down the rules and procedures for manufacturing, quality control, classification, marketing authorization, registration, import, trading, pharmacovigilance, clinical trials, supervision of medicinal products and medical devices in the Republic of Kosovo, in order to provide citizens with safe, effective and qualitative medicinal products.

Article 2
Scope

This Law applies to all public authorities, public and private enterprises as well as legal and natural entities engaged in the manufacturing, trading and other activities that involve medicinal products and medical devices, products containing radioactive substances or dealing with the safety of using radioactive radiation, immunologic preparations and blood products, medicinal gas, vitaminose, herbal and mineral preparations, diet and cosmetic preparations with therapeutic action, raw material for manufacturing medicinal products, semi products of medicinal products.

Article 3
Definitions

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

1.1. **Medicinal product-** any substance or combination of substances that has properties for treating or preventing disease in human beings which may be used in human beings or administered to them either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

1.2. **Substance** - any matter irrespective of origin which may be: human, human blood and human blood products; animal, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products; obtained by chemical change or synthesis.

1.3. **Active substance (Active pharmaceutical ingredient) -** any substance or mixture of substances that when used in production of a medicinal product, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

1.4. **Excipient** - any constituent of a medicinal product other than the active substance and the packaging material.

1.5. **Immunological medicinal product** - any medicinal product consisting of vaccines, toxins, serums or allergen products:

1.5.1. vaccines, toxins and serums shall cover in particular:

1.5.1.1. agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

1.5.1.2. agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

1.5.1.3. agents used to produce passive immunity, such as diphtheria globulin, anti-smallpox globulin, antilymphocytic globulin.

1.6. A**llergen product -** any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

1.7. **Advanced therapy medicinal product -** any following medicinal products for human use:

1.7.1. a gene therapy medicinal product;

1.7.2. a somatic cell therapy medicinal product;

1.7.3. a tissue engineered product.

1.8. **Orphan Medicinal Products -** medicinal products for treatment of serious and rare cases, shall be classified the medicinal products for which, in the European Union, there is approved the statute of medicinal products for treatment of serious and rare diseases, in conformity with the conditions described in the European Union:

1.8.1. if it is used for a diagnosis, prevention and treatment from the diseases and dangerous life condition which lead to chronic weakness and affecting not more than five (5) persons in ten thousand (10.000) inhabitants, or

1.8.2. if it is used for diagnosis, prevention and treatment of diseases or dangerous life conditions, leading to chronic weakness, due to great extensions in the development of medicinal products, it is no possible that that products is placed on the market, or

1.8.3. if there does not exist satisfactory methods of the diagnosing, preventing and treatment of certain health conditions or if there exist such methods, but the medicinal products is documented as beneficiary to persons who have such a health condition.

1.9. **Herbal medicinal products -** any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

1.10. **Herbal preparations -** preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

1.11. **Herbal Substance -** all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system, such as: genus, species, variety and author.

1.12. **Traditional herbal medicinal product -** a herbal medicinal product that fulfils the following conditions**:**

1.12.1. have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner or for diagnostic purposes or for prescription or monitoring of treatment;

1.12.2. are exclusively for administration in accordance with a specified strength and posology;

1.12.3. are preparation for an oral, external and/or inhalation use;

1.12.4. have the period of traditional use at least thirty (30) years preceding of the date of application including at least fifteen (15) years in Europe;

1.12.5. the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of longstanding use and experience.

1.13. **Homeopathic medicinal product -** any medicinal product prepared from substances called primary homeopathic materials in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used in the Republic of Kosovo. A homeopathic medicinal product may contain a number of principles.

1.14. **Falsified products -** any medicinal product or medical device with a false representation of:

1.14.1. its juridical identity, including its packaging and labeling, its name as regards any of the including excipients and the strength of those ingredients;

1.14.2. its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization polder;

1.14.3. its history, including the records and document related to the distribution channels.

1.14.4. this definition does not include unintentional quality defects and does not prejudice other law violations or issues related to the right on intellectual property.

1.15. **Magistral preparation -** any medicinal product prepared in a licensed pharmacy in accordance with a prescription for an individual patient for which are not required either a Manufacturing Authorization or a Marketing Authorization.

1.16. **Semi-product -** each partially processed medicinal products that serve for production which then shall be subject to further technologic processing in other phases in industrial ways up to the final pharmaceutical form which shall be packaged.

1.17. **Products ready for packing -** medicinal products for which it is needed Authorization for Marketing.

1.18. **Borderline Products -** products which are close to the border between medicinal products having a need for a marketing authorization and products such as food, cosmetic supplements, which do not need a marketing authorization. Their classification depends on the content or the manufacturer's statement, or both.

1.19. **Pharmacovigilance -** system of identification, collection, evaluation and reporting of side effects of medicinal products and other evidence concerning the safety of medicinal products, taking measures to manage and reduce risks associated with medicinal products.

1.20. **Pharmacovigilance System -** a system used by the marketing authorisation holder and by the Kosovo Medical Agency (KMA) to fulfill the tasks and responsibilities of pharmacovigilance and designed to monitor the safety of authorized medicinal products and detect any change to the risk benefit balance.

1.21. **Adverse Reaction -** a response to a medicinal product used in a therapeutical dosage which is noxious and unintended.

1.22. **Serious Adverse Reaction -** an adverse reaction which results in death; is life threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; or is a congenital anomaly/birth defect.

1.23. **Pharmaceutical form -** is the physical form of a medicinal product.

1.24. **Good clinical practice -** a set of internationally recognized ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve trial subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.

1.25. **Clinical trial -** any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal product(s), or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. This includes clinical trials carried out in either one site or multiple sites.

1.26. **Sponsor -** an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

1.27. **Ethics Committee -** an independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of the facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

1.28. **Good Manufacturing Practice GMP -** that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use.

1.29. **Manufacturer of medicinal products -** a legal entity 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 where manufactured by themselves or on their behalf by a third party and posses a manufacturing authorization which undergoes regular inspections from the Competent Authority.

1.30. **Manufacturing Authorization -** official written permission granted by the KMA for manufacturing medicinal products and medical devices in the Republic of Kosovo.

1.31. **Business License -** official written permission issued by the responsible competent authority.

1.32. **Good Laboratory Practice -** that part of the quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

1.33. **Good Distribution Practice -** that part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorization or product specification.

1.34. **Pharmaceutical wholesale distribution -** all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public.

1.35. **Wholesale Circulation for Medicinal Products and Medical Devices License -** official written permission issued by the KMA for the wholesale of medicinal products and/or medical devices in the Republic of Kosovo.

1.36. **Import of medicinal products -** any actions including the import of medicinal products and medical devices from abroad, including but not limited to the storage, quality control at batch release and distribution of such medicinal products.

1.37. **Importing Authorization -** official written permission issued by KMA for importing medicinal products and medical devices in the Republic of Kosovo.

1.38. **Import License -** official written permission issued by KMA to import a medicinal product in the Republic of Kosovo holding a marketing authorization granted by KMA.

1.39. **Qualified Person of manufacturer or importer -** employed person responsible for quality assurance. He possess diploma, certificate or other evidence of official qualification, gained after the completion of university studies in duration of at least four (4) year, of theoretical studies and practical studies in one of the following scientific fields: pharmacy, human medicine, chemistry, biology, chemical-pharmaceutical technology.

1.40. **Licensed Pharmacist -** pharmacist who has a license issued by the responsible competent authority.

1.41. **Professional Pharmacy License -** official written permission issued by the responsible competent authority.

1.42. **Pharmaceutical Inspection -** the control of manufacturing and import conditions of medicinal products and active and supplementary substances used as initial material, used for the manufacturing of medicinal products carried out by the pharmaceutical inspectors related to the supervision over pharmaceutical wholesalers and retailers and the quality of marketed medicinal products.

1.43. **Marketing authorization -** permission given by KMA for approval of the medicine on the market based on fulfillment of requests for quality, safety and efficiency for human use in therapeutic treatment.

1.44. **Marketing authorisation holder -** a legal entity who obtained the marketing authorisation for a medicinal product.

1.45. **Representative of the marketing authorization holder -** a legal entity, commonly known as local representative, designated by the marketing authorization holder to represent him in the Republic of Kosovo.

1.46. **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 by the Marketing Authorization and/or international pharmacopoeia standards.

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

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

1.49. **Labeling -** all texts and symbols on the inside and outer packaging of a medicinal product or medical device.

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

1.51. **Prescription –** any medical prescription issued by professional person qualified to do so.

1.52. **Bioavailability -** measurement of the rate and extent of the active therapeutic drug which is absorbed systematically.

1.53. **Bioequivalence -** two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailability in terms of rate after administration of the same molar dose under the same conditions are within preset acceptance limits.

1.54. **Medical Device -** any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for proper application intended by the manufacturer to be used for human beings for the purpose of:

1.54.1. diagnosis, prevention, monitoring, treatment or alleviation of disease;

1.54.2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

1.54.3. investigation, replacement of or modification of the anatomy or of a physiological process;

1.54.4. control of conception and control of pregnancy; which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means; the definition 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.

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

1.55.1. it is based on its functionality in another source of power or the source of other power from the ones directly generated by the human body and gravity, and

1.55.2. it is destined to be completely or partially entered for use in the human body either surgically or conservatively, including also the use through natural ways, which is destined to remain in the human body upon completion of the surgical or medicinal procedure during which it is incorporated;

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

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

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

1.56.2. 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 a physiological or pathological state; a congenital abnormality; the determination of the safety and compatibility of donors, including blood and tissue donations; or to monitor therapeutic measures;

1.56.3. the definitions include 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.

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1.57. **Accessory -** any instrument, apparatus, device, material or other article which, whilst not being a medical device, is, intended specifically by its manufacturer to be used with any particular medical device to enable it to be used as intended by the manufacturer. Accessories are treated as medical devices on their own right.

1.58. **Custom-Made Device -** any medical device specifically made in accordance with a medicinal prescription for a particular patient as determined by a duly qualified medical practitioner or health care professional. 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.

1.59. **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. Such products are treated as medicinal products. The relevant essential requirements for medical devices shall apply as far as safety and performance related device features are concerned.

1.60. **System or Procedure packs -** has the same meaning as in Article 12 of EU Directive 93/42.

1.61. **Harmonized Standard -** a standard adopted by the European Committee for Standardization or the European Committee for Electro technical Standardization, or by both of those bodies, or a monograph of the European Pharmacopoeia related to medical devices. The references to the harmonized standards that are published by relevant authorities in the Official Gazette.

1.62. **Conformity Assessment Body -** synonymous with notified body and means an independent laboratory or a certification body, involved in the conformity assessment procedure for medical devices, accredited and supervised by the respective competent authority.

1.63. **Technical Specification -** a description of a medical device in technical terms, including relevant characteristics, method of its manufacture, packaging, labeling and instructions for use.

1.64. **Manufacturer of Medical Devices -** a legal or natural 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 the devices were manufactured by the manufacturer or by a third party.

1.65. **Authorized Representative for Medical Devices -** an entity or a natural person who is, explicitly appointed by the manufacturer, to act on behalf of the manufacturer in the country and who is obliged to respect this Law and sub-legal act pursuant to this Law, including the requirements for the quality assurance requirements for medical devices.

1.66. **Professional User –** can be either;

1.66.1. a health or social welfare institution licensed by the Ministry of Health or Ministry of Labour and Social Welfare that provides for the position and rights of patients including mentally retarded patients;

1.66.2. an authorized health care professional using a medical device in the course of his duties;

1.66.3. another entity or natural person supplying and/or providing for the usage of medical devices without being a retailer or wholesaler.

1.67. **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.

1.68. **Placing on the Market -** the first making available in return for payment or free of charge of a medical device with a view to distribution or use in the Republic of Kosovo regardless of whether the device is new or fully refurbished. The use of a medical device for clinical trial or for performance evaluation is not considered to be placing on the market.

1.69. **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.

1.70. **Declaration of Conformity -** the confirmation by the manufacturer that a medical device meets the essential requirements based on conformity assessment procedures for medical devices as set out in this Law, supplementary sub-legal acts, and the harmonized standards, that have been followed.

CHAPTER II
COMPETENT AUTHORITY AND ESSENTIAL BODIES

Article 4
Kosovo Medicines Agency

1. The competent authority of the Republic of Kosovo for medicinal products and medical devices for human use shall be the Kosovo Medicines Agency (referred to in this Law as, KMA).

2. KMA is a legal entity and independent executive authority within the portfolio of the Ministry of Health that has legal responsibilities to decide on scientific and technical issues related to medicinal products and medical devices for human use.

3. Organization, authorizations, and competencies of KMA, shall be determined by the sub-legal act approved by the Government.

Article 5
Pharmaceutical Inspectorate

1. The Pharmaceutical Inspectorate exercises outside supervision of manufacturers, importers, wholesalers and retailers of medicinal products and medical devices by the means of performance repeated, follow-up, ad-hoc and on-request inspections.

2. Pharmaceutical Inspectorate is organizational structure of the Health Inspectorate, in accordance with the law.

3. Organization, authorizations and competencies of Pharmaceutical Inspectorate, shall be determined by special law.

4. Inspector for control of medicinal products and medical devices must be qualified person according to Article 49 of Directive 2001/83

Article 6
Official Laboratory for the Control of the Quality of Medicinal Products and Medical Devices (“The Quality Control Laboratory”)

1. The Quality Control Laboratory is organizational structure of the KMA that shall provide supervision over quality of all medicinal products placed on the market of the Republic of Kosovo and for export from the Republic of Kosovo in accordance with Marketing Authorisation and reference standards set by the European Pharmacopoeia, other Pharmacopoeias recognized by the KMA or other validated methods of analysis.

2. The Quality Control Laboratory shall also be charged for the control of technical characteristics and the performance of medical devices that are imported, if considered necessary by KMA.

3. The working procedures of the Quality Control Laboratory shall be determined by sub-legal act pursuant to this Law, issued by the Ministry.

Article 7
Commission for the Evaluation of Medicinal Products and Medical Devices ("The Commission")

1. The Commission is responsible to provide technical and scientific advice to KMA related to the issuance and maintenance of marketing authorization of medicinal products and the performance and safety of medical devices. Opinions of the Commission are recommending to the KMA.

2. Commission shall be constituted by seven (7) members with postgraduate degree: three (3) pharmacists, one (1) doctor of medicine, one (1) doctor of dentistry, one (1) clinical pharmacologist and one (1) professional from the specific field (chemistry, biology, biochemistry, etc.).

3. Members of the Commission shall be selected with an open competition, proposed by the Chief Executive Officer of the KMA and nominated by the Minister of Health for the mandate of three (3) years.

4. Based on the needs, KMA shall establish sub-commissions for specific products, like herbal products, galenic products, orphan medicinal products, narcotics, medical devices etc. Members of the sub-commission should have postgraduate degree.

5. Organization, authorizations, and competencies of the Commission, shall be determined by the sub-legal act approved by the Ministry.

Article 8
Board of Appeals

1. The Board of Appeals has the responsibility to review any appeal filed by any entity or natural person, related to the decisions issued by KMA, based on this Law and sub-legal act pursuant to this Law.

2. Board of Appeals is constituted by three (3) members appointed by the Minister of Health for three (3) year mandate.

3. Organization, authorizations, and competencies of the Board of Appeals, shall be determined by the sub-legal act approved by the Ministry.

Article 9
Ethics Committee

1. The Ethics Committee is responsible for issuing the ethical opinion of clinical trials of medicinal products and medical devices.

2. The Ethics Committee shall be constituted by three (3) members proposed by the Chief Executive Officer of the KMA and nominated by the Minister of Health for a mandate of three (3) years.

3. Organization, authorizations, and competencies of the Ethics Committee shall be determined by the sub-legal act approved by the Ministry.

CHAPTER III
MEDICINAL PRODUCTS

Article 10
Manufacturing of Medicinal Products

1. Manufacturing medicinal products either prepared industrially or by a method involving an industrial process requires a Manufacturing Authorisation, granted:

1.1. for medicinal products manufactured by a pharmaceutical manufacturer in the Republic of Kosovo by KMA, and

1.2. for medicinal products imported into the Republic of Kosovo by the responsible competent authority of the country in which the medicinal product was manufactured.

2. The Manufacturing Authorisation shall be required for both total and partial manufacturing, and for the various processes of dividing up, packaging or presentation for specific, medicinal products and pharmaceutical forms, and also the place where they are to be manufactured and/or controlled, or service production to other manufacturers, in accordance with provisions laid down by the Manufacturing Authorisation.

3. A Manufacturing Authorization Holder shall provide evidence of meeting internationally recognized standards of Good Manufacturing Practice (referred in this Law as “GMP” standards) or GMP standards defined in sub-legal act pursuant to this Law.

4. A Manufacturing Authorization Holder in the Republic of Kosovo shall have permanently and continuously at his disposal at least one Qualified Person responsible for manufacturing and one person for quality assurance of each manufactured batch, and qualified staff, facilities and equipment to produce medicinal products according to the terms of GMP standards as referred to in paragraph 3. of this Article.

5. The responsible Qualified Person for placing the batch in the market shall be responsible for the results and certification of any batch of medicinal products manufactured and controlled in the Republic of Kosovo.

6. In all cases, and in particular when the batch of the medicinal product was placed in the market, the Qualified Person should certify that each manufactured batch fulfils the requirements defined under paragraph 3. of this Article.

7. Detailed conditions for applying for and granting a Manufacturing Authorisation shall be defined in sub-legal act pursuant to this Law.

8. A Manufacturing Authorisation Holder in the Republic of Kosovo shall hold a Business License issued by the responsible Competent Authority.

9. A Manufacturing Authorisation holder who is currently operating in the Republic of Kosovo shall start to implement the GMP standards referred to in paragraph 3. of this Article sixty (60) days after this Law comes into force.

10. Manufacturing authorization holder shall inform the KMA and the Marketing Authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorization are falsified, or are suspected of being falsified, irrespective of whether those medicinal products were distributed within the legal supply chain or by illegal means, including illegal sell by means of information society services.

11. Manufacturing Authorisation Holder shall verify the authenticity and quality of the active substances and the excipients intended to use for manufacturing of medicinal products.

12. A Manufacturing Authorization holder:

12.1. shall keep detailed records of Standard Operation Procedures according to GMP standards, and such details to be inspected by the Inspectorate at any time.

12.2. sale of the manufactured medicinal products to an entrepreneur manufacturing medicinal products or conducting wholesale trade in medicinal products,, and to hospitals and similar institutions as related to medicinal products used at granting healthcare services performed under agreements entered into with the healthcare financial institutions in compliance with the law.

13. A Manufacturing Authorization granted by KMA is valid for a period of five (5) years if it is not suspended or withdrawn.

14. A Manufacturing Authorization granted by KMA can be amended at the request of either the pharmaceutical manufacturer or the KMA subject to compliance with GMP standards as referred to in paragraph 3. of this Article and to the extent that such amendments do not exceed the provisions of this Law or sub-legal act pursuant to this Law. Any proposed change to the terms of the Manufacturing Authorization shall be notified to the KMA; the amendment of the Manufacturing Authorization based on the changes proposed by the Manufacturing Authorization Holder cannot be in contradiction with provisions of this Law and sub -legal act pursuant to this Law.

15. The format of the Manufacturing Authorisation shall be described within sub-legal act pursuant to this Law.

16. The Manufacturing Authorisation Holder has the right to import the initial material, the raw material and semi-products without a marketing authorisation by KMA but with an import license issued by the KMA.

17. The request for the import license of initial material, raw material and semi-products shall be associated with the documentation including the Analysis Certificate, Certificate of Origin and GMP certificate of the manufacturer.

18. KMA may request additional documents based on EU Regulations and Directives for the verification of quality of the imported substances in cases when blood products, narcotics, psychotropic products, products derives by human being, hormones, genetically modified substances or other substances dealing with special manufacturing characteristics are concerned.

Article 11
Veterinary Medicinal Products

1. Registration, supervision and pharmacology of veterinary medicinal products shall be carried out by Kosovo Medicines Agency.

2. KMA in cooperation with Food and Veterinary Agency shall propose the committee for evaluation of veterinary medicinal products, which shall be appointed by the Minister of Health.

3. Quality control of veterinary medicinal products shall be carried out in the official laboratory of quality control of the Kosovo Medicines Agency.

4. Ministry of Health in consultation s with Food and Veterinary Agency shall draft the sub-legal act by which shall be defined the registration, supervision and pharmacovigilence manner of veterinary medicinal products.

Article 12
Import of Medicinal Products

1. Importing medicinal products into the Republic of Kosovo requires, as follows

1.1. a Business Licence issued by the Competent Authority;

1.2. a Marketing authorisation for medicinal product issued by KMA;

1.3. an Importing Authorisation held by the importer granted by the KMA or an Import License issued by KMA and should meet the GMP standards;

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

1.5. medicinal product must have at least one (1) year validity prior to its expiry. It the medicinal product has defined deadline for use of one year or less after its manufacture, then the import should be allowed if the medicinal product has 2/3 of such deadline at the time of its import to the Republic of Kosovo.

2. License Holder of Pharmaceutical Wholesalers should provide evidence of meeting internationally recognized Good Distribution Practices (referred in this Law as GDP standards) until the issuance of a sub-legal act for GDP standards, pursuant to this Law, in order to obtain the national GDP certificate by KMA.

3. License Holder of Pharmaceutical Wholesalers shall have permanently and continuously at his disposal at least one Qualified Person responsible for quality assurance of the medicinal products imported, and qualified staff, facilities and equipment to import medicinal products according to the terms of GDP standards.

4. Detailed conditions for applying for and granting a license or an Importing Authorisation shall be determined in sub-legal act pursuant to this Law.

5. An import license, unless suspended or withdrawn, is valid for a period of three (3) months with a possibility of extension to a maximum time period of six (6) months.

6. An importer shall keep detailed records of all relevant activities as specified in the Importing Authorisation; such records shall include full information on all medicinal products and batches put on the market, their source and immediate destination.

7. Importing Authorisation holder shall inform the KMA and the Marketing Authorisation holder immediately if he obtains information that medicinal products which come under the scope of his Importing Authorisation are falsified, or are suspected of being falsified, irrespective of whether those medicinal products were distributed within the legal supply chain or by illegal means, including illegal sell by means of information society services.

8. Sponsors of clinical trials having obtained an authorization for the clinical trial, may through pharmaceutical wholesalers holding an Importing Authorisation, import reasonable quantities of medicinal products which are required for clinical trials, provided that the prior written approval for any specific importation is obtained from the KMA in accordance with this Law and sub-legal act pursuant to this Law. Medicinal Products imported for this purpose must not be sold and shall be clearly labeled: “For Clinical Trial”.

9. Natural persons entering or exiting the Republic of Kosovo may carry with them reasonable quantities of medicinal products for their personal use, proved by a medical report or a prescription.

10 Natural persons have the right to import reasonable quantities for one treatment, of medicinal products necessary for their personal use certified by a medical report or a prescription of a physician and the diagnosis determined by a medical centre in cases when such medicinal products have no Marketing Authorization granted by KMA, or have a Marketing Authorization granted by KMA but no import license issued by KMA within one (1) year.

11. The import for Natural Persons can also be made by licensed pharmaceutical wholesalers whereas the import license is given on the name of the Natural Person who before obtaining the medicinal product shall take also professional advices for its use.

12. Applicants applying for a Marketing Authorization at the KMA may import such samples of medicinal products as are required in the Marketing Authorization application procedure as defined in sub-legal act pursuant to this Law.

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

14. The KMA may directly export medicinal products, active substances, excipients and pharmacopoeia reference standards for the purpose of quality control of medicinal products placed on a market outside of the Republic of Kosovo in accordance with special export license conditions defined in sub-legal act pursuant to this Law.

15. KMA may allow the import of Orphan Medicinal Products defined according to the concerning EU Regulation or of Products that are included in the National List of Orphan Medicinal Products without Marketing Authorization, provided that such products are not registered in the Republic of Kosovo. The National List of Orphan Medicinal Products is determined by a sub-commission and reviewed on monthly basis. This list is published by KMA.

16. The import of Orphan Medicinal Products can be performed by a licensed pharmaceutical wholesaler whereas the Import license is given only for a limited amount of up to ten (10) boxes for one product or more, if KMA considers and justifies such a thing.

17. KMA issues banderoles for the amount of medicinal products licensed for import as well as authorised medicinal products manufactured in the Republic of Kosovo. Procedures related to the issuing of banderoles shall be determined by sub-legal act pursuant to this Law.

Article 13
Wholesale Trade of Medicinal Products

1. Wholesale trade of medicinal products in the Republic of Kosovo requires:

1.1. a Business License issued by the Competent Authority;

1.2. a Pharmaceutical wholesale license issued by KMA.

2. Pharmaceutical wholesalers shall provide evidence of meeting internationally recognized Good Distribution Practice (GDP) standards or GDP standards defined in sub-legal act pursuant to this Law, notwithstanding transitional arrangements provided for by this Law.

3. Conditions for issuing the pharmaceutical wholesale License shall be defined in sub-legal act pursuant to this Law.

4. Pharmaceutical wholesaler shall employ a licensed pharmacist responsible for monitoring of all medicinal products and overseeing the necessary qualified staffing, storage facilities and security systems for this purpose.

5. Pharmaceutical wholesaler shall:

5.1. keep detailed records of Standard Operation Procedures according to GDP standards, and such details to be inspected by the Inspectorate at any time;

5.2. purchase of medicinal products and medical devices exclusively from an entrepreneur holding Marketing Authorization, Manufacturing Authorisation or pharmaceutical wholesale License.

6. Pharmaceutical wholesaler must immediately inform the KMA and, where applicable, the Manufacturing Authorization Holder, of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified.

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

8. Each medicinal product imported into the Republic of Kosovo or manufactured in the Republic of Kosovo can be freely exported, but the exporters are obliged to give a notification to the KMA prior to the export related to the medicinal products as well as the quantity traded.

9. Under no circumstance shall a wholesaler distribute:

9.1. medicinal products to unlicensed pharmacies or unlicensed health institutions;

9.2. unauthorized medicinal products unless the medicinal product has received a specific exemption granted by KMA;

9.3. medicinal products that are defective as a result of a violation of GDP conditions as ascertained by quality assurance procedures applied by the KMA;

9.4. medicinal product that are falsified or suspect to be falsified.

10. KMA on monthly basis shall publish the list of licensed institutions.

Article 14
Dispensing and Retailing of medicinal products

1. Dispensing and retailing of medicinal products requires:

1.1. a Business Licence issued by the Competent Authority, and

1.2. a Professional Pharmacy Licence issued by KMA.

2. The Pharmacy should have a licensed pharmacist during its working hours.

3. Conditions to carry on a either a public pharmacy or a hospital pharmacy shall be determined by sub-legal act pursuant to this Law.

4. Sale of medicinal products, supplements/vitamins can be carried out through internet too. For prescribed medicinal products there must exist the online prescription.

5. Terms and criteria for sale of medicinal products through internet shall be regulates with sub-legal act, after fictionalization of Information Health System.

6. A pharmacy shall purchase medicinal products and medical devices only from entities holding the pharmaceutical wholesale Licence.

7. A pharmacy must immediately inform the KMA and, where applicable, the wholesaler, of medicinal products and medical devices they receive or are offered which they identify as falsified or suspect to be falsified.

8. A pharmacy shall keep detailed records of all activities as specified in the Professional Pharmacy Licence and shall be subject to inspection by the Pharmaceutical Inspectorate at any time.

9. The licensed pharmacy has the right to prepare and dispense magistral preparations for individual patients based on prescriptions issued.

Article 15
Galenic Laboratories

1. Operating a galenic laboratory in the Republic of Kosovo requires a Galenic Laboratory Licence issued by KMA.

2. A galenic product is a product prepared in the galenic laboratory according to current official pharmacopeia of the EU, based on this Law and sub-legal acts pursuant to this Law.

3. The magistral preparations are prepared and dispensed only by pharmacies and not by galenic laboratories, for the individual patient, based on the prescription of the licensed physician.

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

5. The certification for placement on the market of each batch prepared by the galenic laboratory shall be made by The Quality Control Laboratory at the cost of the galenic laboratory.

6. The galenic laboratory shall provide evidence of meeting internationally recognized GMP standards or GMP standards defined in sub-legal act pursuant to this Law, transitional arrangements provided for by this Law, in order to obtain the national GMP certificate by KMA.

7. The KMA, through sub-commissions, drafts the list of galenic products, and differentiates them from medicinal products.

8. Galenic laboratory shall keep detailed records of all activities as specified in the Galenic Laboratory Licence and that shall be subject to inspection by the Pharmaceutical Inspectorate at any time.

9. A galenic laboratory License shall, unless suspended or withdrawn, be valid for a period of five (5) years and subject to payment of annual tax.

Article 16
Marketing Authorisation of Medicinal Products

1. A medicinal product can only be placed in the Republic of Kosovo after having received an Marketing Authorisation granted by the KMA. The Marketing authorisation as referred to in this Law is synonymous with:

1.1. a Marketing authorisation for relevant medicinal products;

1.2. a Certificate of Registration for homoeopathic medicinal product;

1.3. a Certificate of Registration for traditional herbal medicinal product;

1.4. other products classified for registration by KMA.

2. The application for a marketing authorization for a medicinal product referred to in paragraph 1. of this Article shall be made at the KMA.

3. The content and the procedures of the application for a Marketing Authorization of medicinal products referred to in paragraph 1. of this Article, their variation and renewal shall be defined in sub-legal act pursuant to this Law.

4. Minimal needed documentation for registration of Biosimilar and Biorenuncim products shall be determined in accordance with international standards, regulations and directives of the EU relevant for these categories.

5. A Marketing Authorization shall not be required for, as follows:

5.1. a magistral preparation and a galenic product;

5.2. an orphan medicinal product;

5.3. a radiopharmaceutical product prepared at the time of use by a person or by an establishment legally authorized to use such medicinal products in an approved health institution exclusively from authorized radionuclide generators, radionuclide kits or radionuclide precursors in accordance with the manufacturer's instructions;

5.4. a medicinal product used in an authorised clinical trial;

5.5. a medicinal product intended for treatment as a continuation of a treatment started abroad;

5.6. an additional product of nutrition, multivitamin, mineral and oligo-mineral, herbal substance, herbal preparation shall be defined by KMA;

5.7. a semi product that shall be further processed in a Manufacturing Authorisation Holder;

5.8. a medicinal product to be used in research and development;

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

5.10. a sample submitted for a marketing authorisation application.

6. A Marketing Authorization can be subject to particular conditions, in particular concerning the safety of the medicinal product or granted for a limited period of time.

7. A Marketing Authorization, unless suspended or withdrawn, shall be valid for a five (5) year period and subject to renewal. Once renewed, the Marketing Authorization shall be valid for an unlimited period, unless the KMA decides, on justified grounds related to pharmacovigilance, to proceed with one additional five (5) year renewal.

8. A Marketing Authorization holder shall:

8.1. inform the KMA of any new and/or significant findings for quality, safety and efficacy of the authorized medicinal product in accordance with the provisions of this Law;

8.2. deliver the medicinal products exclusively: to entities holding Pharmaceutical Wholesale Licence, and for healthcare establishments to hospital pharmacies.

9. A Marketing Authorization and the determined conditions thereto may be modified at the request of the Marketing Authorization holder, based on sub-legal act pursuant to this Law.

10. The Ministry of Health may conclude agreements with different countries for bilateral or unilateral recognition of Marketing Authorization by the Republic of Kosovo. The procedures for the Marketing Authorization of unilateral recognized medicinal product may be regulated by sub-legal act pursuant to this Law.

11. The Ministry of Health shall regulate the simplification of procedures for registration and import of medicinal products and medical devices which have no parallels authorised in the Republic of Kosovo by sub-legal act, pursuant to this Law.

12. The Ministry of Health with sub-legal act pursuant to this law shall regulate the simplification of procedures for marketing authorisation for medicinal products.

13. KMA undertakes necessary measures to ensure that the procedure for issuance of the marketing authorization for a medicinal product ends at latest in term of two hundred and ten (210) days from the day of submission of the valid application.

14. The Applicant or the marketing authorization holder is responsible for the accuracy of submitted documentation and data.

15. The Marketing authorization can be rejected only if after verification of the data and documents submitted it is clear that:

15.1. the medicinal product has not been sufficiently tested in accordance with the confirmed state of scientific knowledge; or

15.2. if the risk/benefit balance is not considered to be favourable; or

15.3. its therapeutic efficacy is insufficiently substantiated by the applicant; or

15.4. in the case of a medicinal product containing more than one active substance, insufficient grounds are provided to demonstrate that each active substance contributes towards a positive assessment of the medicinal product, whereby the special features of the particular medicinal product should be considered an evaluation of the risk; or

15.5. the medicinal product does not show the appropriate quality in accordance with recognized pharmaceutical rules; or

15.6. its qualitative and quantitative composition is not as declared.

16. The marketing authorisation shall be refused for a medicinal product which differs, in the nature or the quantity of its active substances, from a medicinal product bearing the same name which has been authorised for marketing or is already on the market.

17. Marketing authorisation shall likewise be refused if any particulars or documents submitted in support of the application do not comply with the provisions laid down in the sub-legal acts referred to in paragraph 3. of this Article.

18. The KMA provides confidentiality of the documentation submitted by the applicants.

19. Ministry of Health shall define with sub-legal acts pursuant to this Law the registration of multivitamins, minerals, oligo-minerals, herbal substances, herbal preparations and other products for which a marketing authorisation is not required.

20. Medicinal products which obtained a marketing authorisation by KMA for the first time shall be referred by the Pharmaceutical Inspectorate to quality tests conducted by the Quality Control Laboratory. This quality testing shall be performed at least once, prior to the placement in circulation of the medicinal product in the Republic of Kosovo. Marketing authorisation holder shall carry the quality test cost including the cost of samples collected for testing.

21. A Marketing authorisation shall not affect the civil and liability of the manufacturer and, where applicable, of the marketing authorisation holder.

22. Every month, the KMA shall publish the list of product with Marketing Authorization.

Article 17
Prescription of Medicinal Products

1. When a Marketing Authorization is granted, the KMA, taking into consideration the advice of the commission, shall classify the prescription status of a medicinal product into either:

1.1. a medicinal product subject to medical prescription (Prescription Only Medicine – “POM”); or

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 medical prescription according to the following classification:

2.1. medicinal products subject to renewable or non-renewable medical prescription;

2.2. medicinal products subject to special medical prescription and prescription for narcotics.

3. Medicinal products shall be subject to medical prescription when they:

3.1. are likely to present a risk to public health either directly or indirectly, even when used correctly, if used 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 investigation;

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

4. Where medicinal products are subject to 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 specific medicinal products is 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.

6. Conditions for prescription of medicinal products shall be determined by sub-legal act pursuant to this Law.

Article 18
Clinical Trials of Medicinal Products

1. Conducting clinical trials in human subjects, whether patients or healthy persons, of either unauthorized or of authorized medicinal products within approved indications, for new indications and new dosage strengths in the Republic of Kosovo requires:

1.1. a favourable opinion of the Ethics Committee, and

1.2. an authorisation for the clinical trial granted by KMA.

2. All clinical trials, shall be designed, conducted and reported in accordance with the principles of Good Clinical Practice.

3. The sponsor shall apply for an opinion on the clinical trial at the Ethics Committee. The content and the procedure of the application shall be determined by sub-legal act pursuant to this Law. The Ethics Committee shall have a maximum of sixty (60) days from the date of receipt of a valid application to give its reasoned opinion to the applicant and the KMA.

4. The sponsor shall apply for the authorisation of the clinical trial at the KMA. The content and the procedure of the application shall be determined by sub-legal act pursuant to this Law. Prior to decide on the application the KMA shall obtain an opinion of the Ethics Committee.

5. The KMA and the Ethics Committee provide confidentiality of the documentation submitted by the applicants.

6. Participating trial subjects shall be offered a reasonable reimbursement for their expenses, but shall not be induced to participate by any payment or reward in excess of this compensation.

7. All participating subjects in a trial shall be fully informed, in a manner appropriate to their understanding, of the purpose, nature and possible risks of the trial and their participation shall be dependent on their consent, given freely and without duress in the light of 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.

8. 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.

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

10. KMA is authorized for inspecting clinical trials for compliance with good clinical practice. Conditions are determined in a sub-legal act pursuant to this Law.

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

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

Article 19
Advertising and Promotion of Medicinal Products

1. Medicinal product advertising and promotion is an activity of informing on or encouraging to the use of the medicinal product with an aim to increase the number of prescriptions, delivery, sale or consumption of medicinal products. Conditions are determined in this Law and sub-legal act pursuant to this Law.

2. Advertising shall include in particular:

2.1. the advertising of medicinal products addressed to public;

2.2. the advertising of medicinal products addressed to persons qualified to prescribe them or to persons trading in them;

2.3. visits by medical and sales representatives to persons qualified to prescribe medicinal products or to persons trading in medicinal products;

2.4. the supply of samples of medicinal products should be carried out pursuant to prior approval by donor and recipient of sample. Number of received samples must not exceed number ten (10) of samples within a year. The sample should clearly note in the external packing “Free sample – not for sale”;

2.5. sponsorship of promotional meetings for persons qualified to prescribe medicinal products or for persons trading in medicinal products;

2.6. sponsorship of conferences, meetings and scientific congresses for persons qualified to prescribe medicinal products or for persons trading in medicinal products.

3. The following activities shall not be considered as advertising of medicinal products:

3.1. information placed on packaging or enclosed to packaging of medicinal products provided that it is in accordance with the marketing authorization;

3.2. correspondence, accompanied by information materials of non-promotional nature, needed to answer questions about a particular medicinal product;

3.3. announcements of informative nature not addressed to the public, relating, for example, to pack changes, adverse reaction warnings, provided that such announcements do not include any medicinal product claims;

3.4. trade catalogues and price lists, containing exclusively the trade name, the usual common name, the dose, the dosage form and the price of the medicinal product, and in the case of a reimbursable medicinal product, the official retail price, provided that the contents do not include any medicinal product claims, including therapeutic indications;

3.5. information relating to human or animal health or diseases, provided that there is no reference, even indirect, to medicinal products.

4. Advertising of a medicinal product without Marketing Authorization granted by KMA is forbidden.

5. Advertising of a medicinal product subject to medical prescription (POM), which is addressed to public, is forbidden.

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

7. Advertising of a medicinal product has to comply with all information provided on it to health conditions of its Marketing Authorization, in particular its approved SmPC.

8. Advertising 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.

9. Medicinal product advertising shall not be misleading, should present the medicinal product objectively.

10. Medicinal product advertising shall not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased.

11. Medicinal product advertising shall not be addressed to children or contain any element addressed to children.

12. Advertising or promotion for medicinal products shall be approved by the KMA taking into consideration the advice of the Commission.

Article 20
Quality Assurance of Medicinal Products

1. Quality assurance of medicinal products concerns the establishment by the Marketing authorisation holder 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 the Republic of Kosovo in order to protect public health.

2. The KMA based on the recommendation of The Quality Control Laboratory shall be entitled to perform any quality assurance procedure that is appropriate for any given medicinal product in order to protect public health. Procedures shall be determined by sub-legal act pursuant to this Law.

3. In the case that a medicinal product does not meet the defined and applied quality standards, or in case that medicinal product is falsified or is suspected to be falsified, remedial action shall be taken as defined by a sub-legal act pursuant to this Law, including the provision for a complete removal of the concerned medicinal product from the Republic of Kosovo market for a fixed term up to one (1) year or permanent removal.

Article 21
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 paragraph 1.1. of this Article to act in compliance with specified procedures and submit relevant items as stated in paragraph 1.2. of this Article, 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 new or altered types of technology (advanced therapy medicinal products) or new 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 market of the Republic of Kosovo 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 pursuant to this Law.

2. With respect to the use of human blood or human plasma as a starting 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 covered by the application of the monographs of the European Pharmacopoeia regarding blood and plasma and measures recommended by the World Health Organization and the Council of Europe, 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 the Republic of Kosovo of medicinal products derived from human blood and human plasma shall be subject to control in terms of quality, safety and efficacy by the KMA, or any other referring laboratory authorized by KMA.

6. Usage of authorized medicinal products derived from human blood and human plasma shall be strictly confined to health institutions licensed by the Ministry of Health.

7. The marketing authorization holder 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, the absence of specific viral contaminations.

8. With respect to the provisions of paragraph 7. of this Article, 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 Quality Control Laboratory, either during the examination of the Marketing Authorization or at any time after the Marketing Authorization has been granted**.**

Article 22
Pharmacovigilance

1. The KMA shall operate a pharmacovigilance system which shall be used to collect information on the risks of medicinal products as regards patients or public health. Details of this pharmacovigilance system shall be determined in sub-legal act pursuant to this Law.

2. Taking into account such information, KMA may impose an obligation to the marketing authorisation holder either to change the conditions of the Marketing Authorization for the concerned medicinal products, or to withdraw/to suspend the Marketing Authorization or to order recall the concerned medicinal products from the market.

3. In its assessment of the information on adverse reactions of medicinal products, leading to an administrative decision related to the Marketing Authorization, the KMA may consult The Commission or its relevant sub-committee.

4. The KMA shall oblige Marketing authorisation holder and Health Care Professionals to submit reports on all suspected serious adverse reactions of medicinal products. Reporting procedures shall be determined by sub-legal act pursuant to this Law.

5. A marketing authorisation holder shall operate pharmacovigilance system for the fulfilment of his pharmacovigilance tasks equivalent to the pharmacovigilance system of the KMA referred to in paragraph 1. of this Article. Details of this pharmacovigilance system shall be determined in sub-legal act pursuant to this Law.

6. A Marketing Authorization Holder shall have permanently and continuously at its disposal a local responsible person for pharmacovigilance in the Republic of Kosovo. Responsibilities of this person shall be described in sub-legal act pursuant to this Law.

Article 23
Medicinal Product Disposal

1. Medicinal products without either an Import License or Marketing Authorization including the provisions of Article 20 paragraph 3. of this Law, or of non-compliant quality, or falsified or with an expired shelf life, or stored or prepared under other than stipulated conditions according to the requirements of 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 the life and health of humans or animals or to the environment.

2. Unusable medicinal products exclude: unusable whole human blood, and plasma or blood cells of human origin; the disposal of which shall be determined by procedures set out under sub-legal act.

3. The procedures for disposal of unusable medicinal products shall be set out in a sub-legal act pursuant to this Law and in coordination with the Ministry of Health, Ministry of Environmental Protection and Spatial Planning, Ministry of Internal Affairs, Ministry of Agriculture, Forestry and Rural Development.

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

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

6. The list of authorized entities to dispose of unusable medicinal products shall be defined by the Ministry of Health and the Ministry of Environment and Spatial Planning.

7. Authorized authorities in the Republic of 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.

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

9. A pharmacy is obliged to accept unusable medicinal products surrendered by natural persons purchased in that pharmacy. The costs incurred by the pharmacy in connection with the surrender 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 the Republic of Kosovo.

10. The cost of disposal of unusable medicinal products, with the exception of those specified under paragraph 8. of this Article, shall be borne by the manufacturer, pharmaceutical wholesaler and retailer, or other healthcare institution.

CHAPTER IV
MEDICAL DEVICES

Article 24
Differentiation of Medical Devices

1. Medical devices shall be differentiated 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 are classified in accordance with the classification criteria set out in EC Directive into:

2.1. Class I – medical devices constituting a low risk potential for patients and users;

2.2. Class IIa – medical devices constituting higher risk potential for patients and users;

2.3. Class IIb – medical devices constituting a high risk potential for patients and users and

2.4. Class III – medical devices constituting the highest risk potential for patients and users.

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

3.1. used exclusively in human or health care;

3.2. dispensed on prescription or without in pharmacies;

3.3. dispensed on prescription or without prescription in specialized shops.

4. 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.

5. Should an article be a combination of a medicinal product and medical device, it will be classified according to its primary purpose as declared by the manufacturer in accordance with classification criteria laid down by the KMA. Combinations of medical devices are classified according to the strictest rule applying to one of the components.

6. 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 Committee.

Article 25
Placing on the Market and Putting into Service of Medical Devices

1. The KMA shall take all necessary measures to ensure that medical devices are 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 the Republic of Kosovo, the manufacturer or his authorized representative shall submit to the KMA the registration file. The registration procedure and the registration file, format and content of file shall be defined in sub-legal act pursuant to this Law, considering the class of the medical device.

3. Based on the satisfactory evaluation of the registration file submitted by the manufacturer of a medical device or his authorised representative, the KMA shall issue a registration certificate for the 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 the Republic of Kosovo, KMA, having processed the registration file, based on the technical advice of The Committee 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 26
Essential Requirements for Medical Devices

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

1.1. medical devices 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, where applicable, 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 the use of the medical device must be investigated during its designing and manufacturing and users must be informed about any residual risks that cannot be eliminated;

1.3. any special requirements concerning the type and purpose of the medical device must be fulfilled.

2. The essential requirements for active implantable medical devices, are the requirements contained in Annex 1 to Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (O.J. EC No. L 189, p.17), last amended by Directive 2007/47/EC (O.J. EC No. L 247, p.21), for in vitro diagnostic medical devices the requirements contained in Annex I (and Annex II for IVDs in List A and B) to Directive 98/79/EC, and for other medical devices, the requirements contained in Annex 1 to Council Directive 93/42/EEC of 14th June 1993 on medical devices (O.J. EC No. L 169, p.1), last amended by Article 2 of Directive 2007/74/EC (O.J. EC No. L 247, p. 21), in the valid version in each case.

3. A medical device will be deemed to meet essential requirements if it has been designed, manufactured and fitted with appropriate equipment in accordance with harmonized standards.

4. In the absence of harmonized standards KMA shall give detailed guidance 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.

5. The KMA shall determine in detail the essential requirements for medical devices in accordance with Directive 90/385/EEC, 93/42/EC and 98/79/EC in sub-legal act pursuant to this Law.

Article 27
Conformity Assessment Procedure and Labeling of Medical Devices

1. Conformity assessment procedure is a procedure by which compliance of medical devices with the requirements referred to in Article 29 of this Law is determined.

2. The procedure for assessing the conformity of medical devices with the essential requirements depends on the type and classification of medical devices.

3. Where the conformity assessment procedure requires the involvement of a conformity assessment body the manufacturer must choose a body accredited by respective competent authority. The conformity of medical devices with the respective requirements shall be certified by a Declaration of Conformity on the basis of the documentation issued by the manufacturer Based on the Declaration of Conformity, the manufacturer must label its products with the required conformity marking. It is prohibited to mark a medical device with a marking contrary to the provisions of this Law.

4. Ministry of Health shall, through sub-legal act pursuant to this Law, determine in details the conformity assessment procedures and their applicability to the different types and classes of medical devices in accordance with Directives 90/385/EEC, 93/42/EC and 98/79/EC, the designation and supervision of conformity assessment bodies as well as the contents of the Declaration of Conformity and conformity marking requirements.

5. The Declaration of Conformity and the conformity marking of medical devices, issued abroad, shall be valid in the Republic of Kosovo.

6. Notwithstanding this paragraph, 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 requirements, which are in agreement with the requirements regarding medical devices laid down by this Law and its pursuant sublegal 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 established for such bodies by this Law and its pursuant sublegal acts.

7. This Article does not apply to medical devices intended for clinical investigation and custom-made devices.

Article 28
Manufacture of Medical Devices

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

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

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

4. Manufacturers or their authorized representative must report the respective conformity assessment body all relevant changes relating to a medical device.

5. Manufacturers of medical devices in the Republic of Kosovo or an authorized representative must also satisfy the following conditions:

5.1. notify the KMA of their business;

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

5.3. employ an appropriately qualified person as defined by the KMA;

5.4. take up liability insurance for any possible damage caused to the patient, user or third person during the adequate use of the medical device.

Article 29
Import, Export, Wholesale, Retail and Dispensing of Medical Devices

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

2. The import of medical devices into the Republic of Kosovo shall require:

2.1. an Import License issued by KMA;

2.2. pharmaceutical wholesaler license for medical devices.

3. The requirements to obtain a Import License for a medical device shall be waived according to the classification status of the medical device as defined in sub-legal act pursuant to this Law.

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 labelled in compliance with standards set out in the sublegal act pursuant to this Law.

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

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

7. The dispensation of certain medical devices may require a medicinal prescription as defined in the sublegal act pursuant to this Law.

Article 30
Professional Use of Medical Device

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 ensuring safe use; 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 labelling 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 or in the possession or introduced into a patient.

Article 31
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 a device the investigating institution or sponsor shall make a written notification to and receive authorization from the KMA before commencing a clinical trial.

2. The notification related to intend clinical trials shall be mandatory for all medicinal 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 by the investigated medical device.

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

7. The detailed conditions and procedures for clinical evaluations and – in case of IVDs – performance evaluations and for conducting clinical trials of medical devices in the Republic of Kosovo shall be set out in sublegal act pursuant to this Law.

Article 32
Monitoring of Adverse Effects to 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 labelling or instructions for use which have or are suspected to have led or could have lead to a serious adverse effect in a patient, user or other person in the Republic of Kosovo.

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. The suppliers, dispensers and professional users of medical devices in the Republic of Kosovo, who discover or suspect any serious adverse effect of a medical device, must report such adverse effects to the KMA.

4. The KMA shall determine the requirements to be fulfilled by entities 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 the Republic of 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 sublegal act pursuant to this Law.

Article 33
Advertising and Promotion of Medical Devices

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

2. Notwithstanding paragraph 1. of this Article the KMA, based on the technical advice of the Committee may allow public advertising and promotion of medical devices which do not constitute 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 performance of the device.

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

Article 34
Inspection and Supervision of Medical Devices

1. The Pharmaceutical Inspectorate, by the supervisory measures stated in this article, ensures that the legal requirements concerning medical devices and pursuant sublegal acts issued by the basis of this Law are fully met.

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

3. The Pharmaceutical Inspectorate is authorized to carry out the following supervisory measures:

3.1. request all necessary information from the manufacturer and/or authorised representative 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 for assessment of conformity;

3.4. prohibit the issue of a Declaration of Conformity in the case when a medical device is considered to be non-conforming;

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 with standards determined by the law, 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 violation of license conditions;

3.13. monitoring of the functioning of Conformity assessment bodies in accordance with requirements defined with this Law and sublegal act pursuant to this Law.

4. The Pharmaceutical Inspectorate can order a 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 Suspension of a license shall occur in the case of a relevant violation of the provisions of this Law, its pursuant sub-legal acts and the terms of the license until the infringement is avoided.

6. Revocation of a license shall occur in the case of a relevant violation of the provisions of this Law and sub-legal act pursuant to this Law.

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

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 sections 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 sublegal acts.

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

CHAPTER V
OTHER PROVISIONS

Article 35
Fees

1. A fee shall be paid by applicants to the KMA for obtaining and maintaining of the authorizations and licenses stated in this Law and sub-legal act pursuant to this Law.

2. In accordance with fee procedures applied by The Quality Control Laboratories in EU Member States and EU Accessing States, the costs of providing medicinal product quality assurance by the Quality Control Laboratory with respect to the provisions of Articles 15 and 16 of this Law shall be covered by:

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

2.2. 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 where a material breech is proven; or

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

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

3. The costs of testing and withdrawal from the market or the destruction of a medicinal product or medical device in breach of the provisions of this Law and its pursuant sublegal acts shall be paid by the legal entity or natural person which has manufactured or imported the medicinal product or medical device in question.

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

5. The fees and costs specified in this Section shall be approved by the Ministry of Health and shall be used by KMA in conformity with the laws and sub-legal acts determined by the Ministry of Health.

Article 36
Financing of KMA

KMA shall be financed in accordance with the legislation in force.

Article 37
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.

2. The KMA shall initiate the civil procedure, economical or criminal misdemeanour for illegal actions of natural persons or legal entities.

3. The Pharmaceutical Inspectorate may impose fines in an amount up to one thousand (1.000) Euro.

4. For activities without authorization or license of the natural or legal person, except for the penal responsibility there shall apply also the absolute prohibition for operation in the field covered by this Law for period of three (3) to five (5) coming years.

5. Other actions, except for penal responsibility shall be fined from one thousand (1.000) up to fifty thousand (50.000) Euro, depending on the responsibility of the person and potential damages caused to the health of people.

6. Failure to comply with Article 13 paragraph 9. of this Law according to the conditions defined, results in the immediate punishment in the amount of five thousand (5000) euro and the immediate closure of the activity as a pharmaceutical trader until clarification of the case.

7. In case KMA certifies that an activity that is in contradiction with Article 19 paragraph 5. of this Law when KMA shall undertake punitive measures including punishment with fine in the amount of five thousand (5.000) Euro or suspension of up to six (6) months of the product from the market.

8. Activities of falsifying, marketing or storing for the purpose of marketing of falsified medicinal products or falsified active substance except the punishment for criminal offence shall results a fine from five thousand (5.000) up to thirty thousand (30.000) Euro.

Article 38
Regulation of price of medicinal products and medical devices

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

Article 39
Emergency Situations

1. In the case of acute emergency, lack of medicinal products in the market, catastrophic situations, such as epidemics, big natural disasters, KMA with the approval of the Minister of Health 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 – parallel, registered in the Republic of Kosovo. Regarding the amount, type, quality and the timeframe, the professional working group assigned by the KMA proposes to apply the special measures, as follows:

1.1. The Minister of Health notifies the government, respectively the Prime Minister about the measures that were undertaken and submits the reasons why such a measure was undertaken.

1.2. The Prime Minister, within seven (7) days from the date of notification can request the annulment of the decision and if such a thing does not happen the Ministry of Health and KMA continue with further procedures to overcome the situation.

2. The CEO of KMA, according to the working group proposal and the approval of Minister, undertakes the special measure for implementation of this decision.

Article 40
Donations of Medicinal Products and Medical Devices

1. Medicinal products subject of donations, shall be imported and used in the Republic of Kosovo through the KMA only at the prior approval of the Minister of Health.

2. Medicinal products referred to in paragraph 1. of this Article should have the clear and permanent label where it says that the medicinal product is a donation and is given for free.

3. The authorization for import of medicinal products that are a donation should be issued if:

3.1. for each medicinal product there are detailed information including the International Non-proprietary Name (INN), or the proprietary name, amount and expiry date.

3.2. the type and amount of medicinal products is necessary for the health protection system.

3.3. the medicinal product and medical device should have at least one (1) year of remaining expiry date.

3.4. if the medicinal product and medical device has determined a total use term of one (1) year or less from the date of production, the import should be allowed if the medicinal product has 2/3 of such term remaining when imported to the Republic of Kosovo.

3.5. there should be a marketing authorization in the place from there it comes and there should be verified its quality by the Quality Control Laboratory if the place of origin is a third country and in this case there should be an Analysis Certificate or the Product Quality Statement.

3.6. for all criteria not included in this Law, it is obligatory to take into consideration the criteria for donation of medicinal products defined by the World Health Organization.

3.7. paragraph 3.3 and paragraph 3.4 of this Article may be reconsidered by Donation Commission of the Ministry of Health in special circumstances when a donation is necessary and the demand for it is urgent.

4. Medicinal products that are a donation and that are imported to the Republic of Kosovo violating the provisions of this Law should be returned to the sender.

5. KMA shall also supervise the warehousing, labeling and distribution of donated medicinal products.

6. The same legal provisions described for medicinal products apply also for medicinal devices.

Article 41
Transitory Provisions

1. The responsible authority to issue sub-legal acts pursuant to this Law is the Ministry of Health.

2. Until promulgation of new sub-legal act pursuant to this Law, there shall apply the acts in power if they are not in contradiction with this Law.

3. Sub-legal acts pursuant to this Law shall be promulgated within the timeframe of six (6) months.

4. The member of the Ethics Committee, Board of Appeals and the Commission for evaluation of medicinal products and medical devices shall be appointed within six (6) months upon entry into force of this Law.

Article 42
Abrogation of Applicable Legal Provisions

This Law abrogates the Law on Medicinal Products and Medical Devices No.03/L-188 dated 18, October 2010.

Article 43
Entry into Force

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

Law No. 04/L-190
07 April 2014

Promulgated by Decree No. DL-016-2014, dated 18.04.2014, President of the Republic of Kosovo Atifete Jahjaga