



PROVISIONAL INSTITUTIONS OF SELF GOVERNMENT

KUVENDI I KOSOVËS
СКУПШТИНА КОСОВА
ASSEMBLY OF KOSOVO

Law No.2003/26

On Medicinal Products and Medical Devices

The Assembly of Kosovo,

Pursuant to the Regulation No. 2001/9 of 15 May 2001, "On a Constitutional Framework for Provisional Self-Government in Kosovo," in particular Chapters 5.1(h), Chapters 9.1.1, 9.1.26 (a),

For the purpose of providing a legislative basis for the regulation of medicinal products for human and veterinary use, including Narcotic Drugs , Psychotropic Substances and medical devices in Kosovo with a view to the protection of the public health of the Kosovo,

Hereby adopts the following :

Law On Medicinal Products and Medical Devices

CHAPTER 1
GENERAL PROVISIONS

Section 1
Scope and Application of the Law

1.1. This law defines medical products and medical devices for use in human and veterinary medicine, conditions for their production and placing on the market and into services assuring conditions for their quality , safety and efficacy.

1.2.This law defines measures to assure the quality , safety and efficacy of medical products and medical devices placed in Kosovo with reference to the following legislation applicable in the European Union.

1.3. This Law applies to all public authorities, public and private enterprises, as well as legal entities and natural persons engaged in the manufacturing, import/export, wholesale, dispensing/retailing and other activities that involve medicinal products and medical devices placed in Kosovo notwithstanding the provisions of paragraph 1.4 below.

1.4 With respect to the co-ordination of this Law with applicable and future Kosovo legislation that may concern medicinal products and medical devices placed in Kosovo, this Law does not address the following areas that shall be under the jurisdiction of separate Laws and their pursuant normative acts:

- (i).public procurement, pricing, financing, reimbursement and cost control of medicinal products and medical devices;
- (ii).usage of medicinal products and medical devices by consumers, including professional standards and procedures for the prescription and dispensation of medicinal products and medical devices;
- (iii).sourcing, trade, quality assurance and usage of whole blood, plasma, blood cells or transplants of organ, tissues and cells of either human or animal origin or their byproducts, unless defined as an advanced therapy medicinal product, or unless used like or together with medical devices;
- (iv).legislation, which covers the prevention of the use of illegitimate drugs and psycho trope substances and their precursors in compliance with, and numbering the demands of relevant Conventions of United Nations, relatively the only Convention of UN for narcotic medicaments of the year 1961 (as amended from Minutes of the year 1972) of UN Convention for psycho trope substances of the year 1971 and United Nation Convention of year 1988 against illegitimate trade of narcotic medicaments and psycho trope substances;
- (v).supervision of medicinal products and medical devices containing radioactive substances or relating to the safe use of radiation;
- (vi). cosmetic products, hygiene products and dietary supplements unless either a medicinal effect is claimed for or an active substance is included in the product or supplement;
- (vii).products whose principal intended purpose is as personal protective equipment; and
- (viii).intellectual property rights concerning medicinal products and medical devices, including but not limited to product and process patents, supplementary protection certificates, data protection and trade marks.

Section 2 Definitions and Rules of Interpretation

2.1.The definition “*Medicinal Product*” replaces the definition “*Pharmaceutical Product*” as stated in UNMIK Regulation 2000/52 ‘On the Import, Manufacture, Sale and Distribution of Pharmaceutical Products, including Narcotic Drugs and Psychotropic Substances’ (hereinafter “*UNMIK Regulation 2000/52*”).

2.2. Wherever used in this Law, each of the following definitions shall have the indicated meaning, in the singular or plural, unless the context clearly indicates otherwise.

2.2.1.“*Medicinal Product*” means and includes any of the following:

- (i). any substance or combination of substances presented as having properties for treating or preventing disease in human beings and animals;

- (ii). any substance or combination of substances which may be used in human beings and animals with a view to making a medical diagnosis or restoring, improving or modifying physiological functions.

2.2.2.“*Substance*” means matter irrespective of origin which shall include any of the following:

- (i). human, e.g. human blood and human blood products;
- (ii). animal, e.g. microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
- (iii). vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;
- (iv). mineral, e.g. elements, naturally occurring chemical substances and chemical products obtained by chemical change or synthesis; or
- (v). developed by means of biotechnological processes.

2.2.3.“*Medicinal Product for Human Use*” means a medicinal product intended exclusively for use in humans.

2.2.4.“*Veterinary Medicinal Product*” means a medicinal product intended exclusively for use in animals. Veterinary medicinal product shall also mean a device used for disinfection and extermination of arthropods and rodents, and used in direct or indirect contact with animals.

2.2.5.“*Active Substance*” means a substance producing the effects of medicinal products.

2.2.6.“*Excipients*” means the substances used to formulate active substances to medicinal products.

2.2.7.“*Pharmaceutical Form*” means the form incorporating the active substance producing effects of medicinal products through technological processes, taking into account the physical and chemical characteristics of excipients.

2.2.8.“*Pre-Mixes for Medicated Feeding Stuffs*” means any medicinal product prepared in advance for use in veterinary medicine, intended for the subsequent manufacture of medicated feeding stuffs.

2.2.9.“*Medicated Feeding Stuffs*” means any mixture of a veterinary medicinal product or products and feed(s) which is ready prepared for marketing and intended to be fed to animals without further processing.

2.2.10.“*Galenic Product*” means any medicinal product prepared by a licensed galenic laboratory pursuant to a recognized pharmacopoeia, neither prepared industrially nor manufactured by a method involving an industrial process and not requiring either a Manufacturing or Marketing Authorization.

2.2.11.“*Magistral Preparation*” means any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient and not requiring either a Manufacturing or Marketing Authorization.

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

2.2.13. “*Good Clinical Practice*” means an international ethical and scientific system of quality control, planning, implementation, recording, controlling and reporting on clinical trials:

- (i). on humans, providing for the credibility of data acquired through trials and the protection of rights and the safety of trial subjects pursuant to the Declaration of Helsinki and other relevant regulations;
- (ii). on target animals, providing for the credibility of data acquired through trials and the safety of trial subjects pursuant to regulations on animal protection and other.

2.2.14. “*Good Control Laboratory Practice*” means the component of Good Manufacturing Practice governing the quality assurance of medicinal products.

2.2.15. “*Good Laboratory Practice*” means the qualitative system governing organizational processes and conditions of planning, implementing, controlling, recording and reporting on non-clinical medical and environmental studies.

2.2.16. “*Good Manufacturing Practice*” means the system for ensuring quality, providing for the consistent manufacture and control of products by qualitative criteria and conformity assessing criteria with intended purpose as required by the marketing authorization and specification of the product.

2.2.17. “*Good Distribution Practice*” means the qualitative system governing the organization, implementation and control of transport of medicinal products from the producer to the final user.

2.2.18. “*Galenic Laboratory*” means a small medicinal product production unit that produces galenic Products.

2.2.19. “*Pharmacovigilance*” means both a process used for identifying and reacting to findings, either known in terms of reports in the international literature or unknown, regarding risks related to the use of medicinal products or to their interactions with other products or substances and the obligation to report to the competent authority all suspected adverse effects as defined in normative act pursuant to this Law.

2.2.20. “*Adverse Effect*” means an unwanted and unintended effect of a:

- (i). medicinal product which occurs when the product is used in approved doses and indications and is related to either the quality, safety or efficacy features of the medicinal product or an interaction with another medicinal product, either known or suspected;
- (ii). medical device which occurs when the device is used or applied in accordance with the approved indications and usage instructions of the device, either known or suspected.

2.2.21. “*Serious Adverse Effect*” means an Adverse Effect 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 directly attributable to an Adverse Effect of a medicinal product or medical device.

2.2.22. “*Medicinal Product Quality*” means the characteristic of the medicinal product which comes 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 of the marketing authorization.

2.2.23. “*Manufacturer of Medicinal Products*” means 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 were manufactured by themselves or on their behalf by a third party.

2.2.24. “*Official Medicines Quality Control Laboratory*” (hereinafter “OMQCL”) means a laboratory for analytical testing of medicinal products appointed by the competent authority for verifying whether the qualitative and quantitative composition of medicinal products present in Kosovo meet accepted international standards of medicinal product quality.

2.2.25. “*Labelling*” means all texts and symbols on the immediate and outer packaging of a medicinal product or medical device.

2.2.26. “*Traceability of a Medicinal Product*” means the documented distribution path from the the manufacturer, the legal entity or natural person marketing the medicinal product or medical device either through wholesale or retail to the final user.

2.2.27. “*Withdrawal Period*” means the period of time which must elapse after administration of a veterinary medicinal product under normal conditions of use until the moment the treated animal may be slaughtered for the production of foodstuffs which are in no way deficient; i.e. period of time during which the animal tissues, milk, and eggs from the treated animals must not be used as food for human consumption due to possible residues of medicinal products exceeding the maximum level prescribed for these foodstuffs.

2.2.28. “*Maximum Level of Residues*” means the maximum level of residues of a veterinary medicinal product in foodstuffs resulting from its administration expressed in mg/kg or g/kg of foodstuffs weight which is still acceptable and allowed as prescribed.

2.2.29. “*Medicinal Prescription*” means the legal obligation for issuance of medicinal products or medical devices to humans or animals by either a licensed physician, dentist or veterinarian in the case that the usage of a medicinal product or medical device requires the supervision of a licensed physician, dentist or veterinarian as determined by this Law and its pursuant normative acts.

2.2.30. “*Medical Device*” means an instrument, device, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application which:

- (i). is intended by the manufacturer to be used for human beings for the purpose of:
 - (a). diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (b). diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - (c). investigation, replacement or modification of the anatomy or of a physiological process; or
 - (d). control of conception; and

- (ii).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; and
- (iii).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.

2.2.31. “*Active Implantable Medical Device*” means a medical device which:

- (i). relies for its functioning on the other source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and
- (ii).is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced; and
- (iii). even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product.

2.2.32. “*In Vitro Diagnostic Medical Device*” means a medical device which:

- (i).is a reagent, reagent product, calibrator, control material, test kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
- (ii).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) a physiological or pathological state;
 - (b) a congenital abnormality;
 - (c) the determination of the safety and compatibility of donors, including blood and tissue donations; or
 - (d) to monitor therapeutic measures; and
 - (e) includes 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.

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

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

2.2.35. “*Single-use combination product*” means 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.

2.2.36. “*Systems or Procedure Packs*” has the same meaning as in article 12 of EU Directive 93/42.

2.2.37. “*Harmonised Standard*” means:

- (i). a technical specification adopted by the European Committee for Standardization or the European Committee for Electro technical Standardization, or by both of those bodies, or an equivalent accepted international specification; or
- (ii). a monograph of the European Pharmacopoeia (in particular any monograph on surgical sutures and the interaction between medicinal products and materials used in medical devices containing medicinal products) or monograph from another recognized pharmacopoeia.

2.2.38. “*Conformity Assessment Body*” is synonymous with notified body and means either a laboratory independent of a supplier, or a certification body, or a control body or any other body involved in the conformity assessment procedure for medical devices.

2.2.39. “*Technical Specification*” means a regulation defining the characteristics of a medical device or the procedure and method of its manufacture. It may only cover and regulate technical terms, symbols, packaging, and declaration and labeling.

2.2.40. “*Manufacturer of Medical Devices*’ means a legal entity or natural person responsible for the design, manufacture, packaging and labeling of medical devices before placing them on the market under their own name, irrespective of whether they carried out the entire manufacture themselves or whether this was carried out on their behalf by a third party.

2.2.41. “*Authorised Supplier of Medical Devices*” means a legal entity or a natural person who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies instead of the manufacturer with respect to the latter’s obligations under this Law and its pursuant normative acts, including the requirement to provide a quality assurance system for the medical device concerned.

2.2.42. “*Professional User*” means:

- (i). either a health or social welfare institution licensed by the Kosovo Ministry of Health or Ministry of Labor and Social Welfare that provides for the position and rights of patients including mentally retarded patients;
- (ii). an authorized health professional using a medical device in the course of his duties;
- (iii). another legal entity or natural person supplying and/or providing for the usage of medical devices without being a retailer or wholesaler.

2.2.43. “*Intended Purpose*” means 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.

2.2.44. “*Placing on the Market*” means the first making available in return for payment or free of charge of a medical device with a view to distribution or use in 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.

2.2.45. “*Putting into Service*” means the stage at which a medical device has been made available to the final user as being ready for use for the first time for its intended purpose in Kosovo.

2.3 Authorizations and Licenses provided for by this Law shall be defined as:

2.3.1. “*Batch Certificate of Analysis*” is synonymous with batch release certificate and means either the manufacturer’s or OMQCL valid analysis of the qualitative and quantitative conformance of all constituents of the medicinal product batch concerning the provisions of both the Manufacturing and Marketing Authorization of the medicinal product and that shall only be issued by either the designated qualified person of the holder of a Manufacturing Authorization or the OMQCL of the state of origin of the manufacturer concerned.

2.3.2. “*Batch Import License*” means the official written permission to import a batch of medicinal products contingent on prior issuance of a Marketing Authorization, Import / Export License and Batch Certificate of Analysis.

2.3.3. “*Licence for Business*” means written official permission issued from Ministry of Trade and Industry.

2.3.4. “*Clinical Trial Authorization*” means the official written permission issued by the Kosovo Medicines Agency (hereinafter “KMA”) in the case of medicinal products and medical devices for human use and by the Kosovo Veterinary Service (hereinafter “KVS”) in the case of medicinal products and medical devices for veterinary use authorizing the sponsor and principle investigator of a proposed clinical trial to conduct the clinical trial in accordance with the provisions of Section 11 of this Law and pursuant normative acts issued pursuant to this Law.

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

2.3.6. “*Galenic Laboratory License*” means the official written permission issued by the KMA for both the manufacture and placing on the market of Galenic Products, pursuant to Section 8 of this law and its pursuant normative acts.

2.3.7. “*Licence for Import/Export of Products and Medical Equipments*” means written official permission from Ministry of Health for importing in or exporting from Kosovo products and medical equipments.

2.3.8. “*Licensed pharmacist*” means pharmacist who has a licence issued by Registration Board and Licensing Sanitary Professionals at Ministry of Health.

2.3.9. “*Manufacturing Authorization*” means the official written permission issued either by the KMA or KVS for manufacturers located in Kosovo, or by an equivalent competent authority for manufacturers located in other states or entities, authorizing the holder to manufacture medicinal products, in accordance with this law and normative acts issued pursuant to this law.

2.3.10. “*Marketing Authorization*” is synonymous with both medicinal product license and authorized medicinal product and means the requirement to provide both documentary and physical evidence that the quality, safety and efficacy of a medicinal product placed in Kosovo meets required standards stated in normative act pursuant to this Law notwithstanding transitional arrangements.

2.3.11. “*Professional Pharmacy License*” means the official written permission issued by the Ministry of Health for the dispensation and/or retail of medicinal products and/or medical devices as specified in Section 7 and Section 23 of this Law and its pursuant normative acts.

2.3.12. “*Wholesale License*” means the official written permission issued by the KMA for the wholesale trade of medicinal products and/or medical devices in Kosovo pursuant to this Law and its pursuant normative acts.

Section 3

Competent Authorities for Implementation and Supervision of this Law

3.1. The competent authorities for implementation of this Law are:

- (i). The competent authority for medicinal products for human use and medical devices shall be the Kosovo Medicines Agency (hereinafter “*KMA*”) who replaces the Kosovo Authority for Regulation of Medicaments (KARM) established according to the Regulation of UNMIK No.2001/19 ‘On Executive Branch of Provisional Institutions of Self government in Kosovo;
- (ii). The competent authority for veterinary medicinal products shall be the Kosovo Veterinary Service, (hereinafter “*KVS*”).

3.2. Advisory bodies and technical support services to be established for the further implementation of this Law shall be:

- (i). Kosovo Committee for Evaluation of Medicinal Products and Medical Devices, (hereinafter “*KCME*”) responsible for technical advice to the KMA and KVS concerning the issuance and maintenance of medicinal product and medical device authorizations and licenses as follows:
 - (a). Marketing Authorization applications, variations, renewals/maintenance of issued Marketing Authorizations;
 - (b). clinical trial applications;
 - (c). classification and technical evaluation of medicinal products and medical devices;
 - (d). classification of dispensation status of medicinal products and medical devices;
 - (e). evaluation of the safety of medicinal products and medical devices placed in Kosovo;
- (ii). sub committees to the KCME shall be created where necessary to allow it to fully perform its tasks with respect to the technical evaluation of different categories of medicinal product and medical device.

- (iii). Kosovo Conformity Assessment Body for Medical Devices responsible for the issuance of a Declaration of Conformity in the case of medical devices manufactured in Kosovo or validation of a Declaration of Conformity from an external Conformity Assessment Body in the case that a medical device is manufactured outside of and intended for import into Kosovo;
- (iv). Appeals Board has the responsibility for dealing with any appeal issued by a legal entity or natural person concerning any decision made by the KMA or KVS with respect to the provisions of this Law and its pursuant normative acts;
- (v). Ethics Committee responsible for the ethical approval of clinical trials of experimental medicinal products and medical devices;
- (vi). an Official Medicines Quality Control Laboratory (OMQCL) shall be established within the KMA in order to provide a technical support service for the quality control of medicinal products and medical devices in order to protect the public health of the Kosovo population. The OMQCL shall be responsible for the tasks as stated in Sections 13 and 14 of this Law.

3.3. The composition, function and working of the advisory bodies and technical support services specified in paragraph 3.2 above shall be set out in normative act pursuant to this Law.

CHAPTER 2 MEDICINAL PRODUCTS

Section 4 Manufacturing of Medicinal Products

4.1. The requirement to obtain a manufacturing authorization for medicinal products intended to be placed in Kosovo concerns medicinal products either prepared industrially or manufactured by a method involving an industrial process.

4.2. The industrial manufacture of medicinal products placed in Kosovo shall be undertaken exclusively by a legal person holding a Manufacturing Authorization in the case of medicinal products:

- (i). manufactured in Kosovo, from the KMA;
- (ii). manufactured for import into Kosovo, the competent authority of the country responsible for issuing a Manufacturing Authorization.

4.3. It shall be an absolute condition for the Manufacturing Authorization of medicinal products placed in Kosovo that the applicant or holder provides evidence of meeting internationally recognized Good Manufacturing Practice (hereinafter “GMP”) standards and/or standards defined in normative act pursuant to this Law notwithstanding transitional arrangements provided for by this Law.

4.4. The granting of a Manufacturing Authorization by the KMA in the case of manufacture in Kosovo and recognition by KMA of a Manufacturing Authorization issued by competent authorities outside of Kosovo, in the case medicinal products imported into Kosovo, may be made conditional on the carrying out of certain obligations

imposed either when Manufacturing Authorization is granted or at a later date taking into consideration transitional requirements necessary for the Manufacturing Authorization holder to fully comply with GMP standards.

4.5. A Manufacturing Authorization holder in Kosovo may engage only in the manufacture of specific medicinal products, designated pharmaceutical forms or parts of the manufacturing process, or service production to other manufacturers, in accordance with provisions laid down by the Manufacturing Authorization according to normative act pursuant to this Law.

4.6. A Manufacturing Authorization applicant or holder in Kosovo shall name one qualified person responsible for manufacturing quality assurance and a qualified pharmacist for quality control, and maintain the necessary qualified staff, facilities and equipment to produce medicinal products according to the terms of the manufacturing license and to exercise proper quality assurance and final control of all medicinal products manufactured and released to the market.

4.7. A Manufacturing Authorization holder in Kosovo shall keep detailed records of all manufacturing activities as specified in the terms of the authorization and that shall be subject to inspection by the KMA inspectorate at any time with a view to ensuring that the manufacturer respects and maintains the terms of its Manufacturing Authorization.

4.8. A Manufacturing Authorization issued in Kosovo is valid indefinitely subject to annual renewal unless suspended or withdrawn.

4.9. A Manufacturing Authorization issued in Kosovo can be amended at the request of either the holder or the KMA subject to compliance with GMP standards and to the extent that such amendments do not exceed the provisions of this Law or normative act pursuant to this Law.

4.10. Any proposed change made by a Manufacturing Authorization holder to the terms of the authorization shall be notified to the KMA, and the Manufacturing Authorization amended on the basis that changes proposed by the authorization holder do not contravene the provisions of this Law and its normative acts.

Section 5 Import and Export of Medicinal Products

5.1. Medicinal products may be imported into Kosovo only when a Batch Import License has been granted by the KMA or KVS, the granting of which shall be contingent on the presentation and validation of:

- (i). License for import, issued from Ministry of Health ;
- (ii). a Marketing Authorization for the medicinal product concerned, issued by the KMA or KVS;
- (iii). a Wholesale License, issued by the KMA or KVS; and
- (iv). a Batch Certificate of Analysis for each batch of medicinal product imported.

5.2. Medicinal products may only be exported from Kosovo in the case of:

- (i) medicinal products manufactured in Kosovo where a Manufacturing Authorization has been issued by the KMA or KVS, taking into consideration transitional provisions stated in Section 4 above and where the Manufacturing Authorization is recognized by importing states or entities; or
- (ii) medicinal products for personal use.

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

5.4. An importer/exporter of medicinal products and his records shall be subject to inspection by the KMA and KVS at any time deemed appropriate.

5.5. A license to import or export medicinal products, unless suspended or withdrawn, shall have a one year validity with the requirement for renewal.

5.6. A health professional or a health institution having a need of an unauthorized medicinal product to treat an individual patient or group of patients in the specified health institution may be authorized to import such veterinary medicinal products from a foreign manufacturer or supplier subject to complying with defined procedures in this Law and its pursuant normative acts and that shall require written approval of the KMA or by the KVS.

5.7. Health professionals, health institutions or veterinary practitioners having obtained a Clinical Trial Authorization, may through licensed wholesalers, import reasonable quantities of medicinal products which are required for such trials, provided that the prior written approval for any specific importation is obtained from the KMA or KVS in accordance with this Law and its pursuant normative acts.

5.8. Natural persons entering or exiting Kosovo may carry with them reasonable quantities of medicinal products required for their personal use, or for the use in animals accompanying them.

5.9. Applicants for a Marketing Authorization may import such samples of medicinal products as are required in the Marketing Authorization application procedure as defined in normative act pursuant to this Law.

5.10. 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 in Kosovo and in accordance with special import license conditions defined in normative act pursuant to this Law.

5.11. The KMA may directly export medicinal products, active substances, excipients and pharmacopoeia reference standards for the purpose of quality control of medicinal products placed outside of Kosovo in accordance with special export license conditions defined in normative act pursuant to this Law.

5.12. In derogation of paragraph 5.1, this Law makes the provision for the waiving of a Batch Import License for authorized medicinal products according to provisions that shall take into consideration Batch Import License conditions employed by both EU Member and EU Accessing States and defined by the KMA and KVS in normative act pursuant to this Law.

5.13. Notwithstanding any future provision for the waiving of a Batch Import License for authorized medicinal products it shall be an absolute requirement for medicinal products belonging to the following categories to have a Batch Import License before they can be placed in Kosovo:

- (i). immunological products including vaccines;
- (ii). medicinal products derived from either narcotic or psychotropic substances;
- (iii). medicinal products derived from either human blood or human plasma;
- (iv). advanced therapy medicinal products;
- (v). radiopharmaceuticals;
- (vi). medicinal products authorized for use in clinical trials;
- (vii). unauthorized medicinal products in receipt of a Marketing Authorization exemption based on the grounds of compassionate feeling.

5.14. A provision is made for the allowance of parallel importation of medicinal products into Kosovo in accordance with and only when a normative act on parallel importation of medicinal products pursuant to this Law may come into force.

Section 6 Wholesale Trade in Medicinal Products

6.1. Wholesale trade of medicinal products in Kosovo may only be undertaken by a legal entity holding both a Business License and a Wholesale License and an Import/Export License in the case that wholesale trade concerns import or export of medicinal products.

6.2. The terms of a Wholesale License shall include conditions or restrictions needed to comply with recognized Good Distribution Practice (hereinafter “GDP”) and the trade of specified medicinal products.

6.3. The holder of a Wholesale License shall employ a licensed pharmacist responsible for monitoring of all medicinal products and maintain the necessary qualified staffing, storage facilities and security systems for this purpose and shall keep trade in medicinal products entirely separate from any other trading operations in which he may engage involving non-medicinal products.

6.4. The holder of a Manufacturing Authorization in Kosovo shall be entitled to operate as a wholesaler for medicinal products manufactured under the terms of the Manufacturing Authorization without the obligation to obtain a Wholesale License.

6.5. A wholesaler of medicinal products shall keep detailed records of all trading activities as specified in the Wholesale License issued pursuant to this Law and its pursuant normative acts and that shall be subject to inspection by the KMA or KVS both at the time of evaluation of a license application and at anytime thereafter.

6.6. A medicinal product Wholesale License shall, unless suspended or withdrawn, be valid for a five year period with annual renewal subject to meeting the terms specified in the license, this Law and normative acts pursuant to this Law.

6.7. Medicinal products belonging to one of the following categories shall only be supplied to licensed pharmacies and health institutions that have an explicit condition of their license in the case of pharmacies to dispense and in the case of health institutions to dispense and/or utilize medicinal products these categories of medicinal product:

- (i). medicinal products derived from human blood or human plasma;
- (ii). medicinal products containing narcotic or psychotropic substances;
- (iii). radiopharmaceuticals;
- (iv). immunological medicinal products; and
- (v). advanced therapy medicinal products.

6.8. Under no circumstance shall a wholesaler distribute:

- (i). medicinal products to unlicensed pharmacies or unlicensed health institutions;
- (ii). unauthorized medicinal products unless the medicinal product has received a specific exemption granted by either the KMA or KVS;
- (iii). medicinal products with a shelf life expiry date of less than 6 months, except in the case of medicinal products which by their nature, and in accordance with their marketing authorization, have a shelf life less than 6 months;
- (iv). medicinal products that are defective as a result of a breach of GDP conditions as ascertained by quality assurance procedures applied by the KMA and KVS.

Section 7 Dispensing and Retail of Medicinal Products

7.1. Medicinal products for human use may only be dispensed and retailed through a licensed pharmacy, whereas in the case of veterinary medicinal products through a licensed veterinary practitioner.

7.2. A licensed pharmacy is one that has both a Business License and a Professional Pharmacy License.

7.3. All pharmacies, public and private including those belonging to health institutions, shall be required to obtain a Professional Pharmacy License.

7.4. A precondition for the obtaining of a Professional Pharmacy License shall be the requirement to nominate a Licensed Pharmacist who shall be responsible for:

- (i). the operations of only one designated pharmacy;
- (ii). the dispensation of magisterial preparations to individual patients in accordance with the terms of the license, this Law and its pursuant normative acts.

7.5. Veterinary medicinal products shall be labeled with a notice “for use in animals only” and shall only be dispensed either by a pharmacist in receipt of a license from the KVS or by persons qualified in veterinary medicine.

7.6. A pharmacy shall keep detailed records of all trading activities as specified in the Professional Pharmacy License and that shall be subject to inspection by the KMA both at the time of evaluation of a license application and at anytime thereafter.

7.7. A pharmacy shall stock and supply medicinal products for dispensation/retail only in accordance with requirements set by the KMA pursuant to the terms of the License, this Law or any normative act pursuant to this Law.

7.8. A pharmacy shall keep in stock at all times all those authorized medicinal products listed by the Ministry of Health as being vital or essential to the health care system.

7.9. A Professional Pharmacy License shall, unless suspended or withdrawn, be valid for a five year period with annual renewal and meeting the terms specified in the terms of the License and in normative act pursuant to this Law.

7.10. A licensed pharmacy has the right to dispense magistral preparations to individual patients in accordance with the terms of the license, this Law and normative acts issued pursuant to this Law.

7.11. Health institutions, are obliged to acquire and maintain stocks of authorized medicinal products appropriate to the needs of their patients, provided these products are obtained from licensed pharmacy wholesalers or pharmacy manufacturers.

7.12. A licensed pharmacy or licensed veterinary practitioner can not dispense:

- (i). unauthorized medicinal products unless the medicinal product has received a specific exemption granted by either the KMA or KVS;
- (ii). authorized medicinal products that have a shelf life expiry date less than 3 months from the date of dispensing, except in the case of medicinal products which by their nature, and in accordance with their marketing authorization, have a shelf life less than 3 months;
- (iii). dispense medicinal products contrary to their classification and dispensing status as defined and provided for under Section 10 of this Law.

Section 8

Pharmacy Production and Galenic Laboratories

8.1. Magistral preparations, by definition, shall only be produced and dispensed by pharmacies for individual patients based on prescriptions issued by licensed medical practitioners and according to guidelines as defined by the Ministry of Health.

8.2. A galenic product is differentiated from a magistral preparation and a medicinal product by the criteria that:

- (i). a galenic product is not produced to meet the needs of an individual patient with reference to the definition of a magistral preparation;
- (ii). the manufacturing quality of the galenic product attains acceptable quality standards so as to ensure that the product does not require a Manufacturing Authorization taking into consideration its pharmaceutical form, route of administration and traditional usage in Kosovo.

8.3. In order to operate a galenic laboratory in Kosovo it is necessary to obtain a Galenic Laboratory License from the KMA in accordance with the conditions set out in normative act pursuant to this Law.

8.4. A Galenic Laboratory License shall state:

- (i). the products that can be produced by a galenic laboratory according to quality, safety and efficacy standards as set out in normative act pursuant to this Law;
- (ii). the restrictions and requirements on the placing on the market of products produced by a galenic laboratory in accordance with requirements defined in normative act pursuant to this Law.

8.5. The KMA, based on technical advice from the KCME, reserves the right to classify a magistral preparation or galenic product as a medicinal product requiring both a Manufacturing Authorization and a Marketing Authorization.

Section 9 Marketing Authorization of Medicinal Products

9.1. A medicinal product can only be placed in Kosovo if it has received a Marketing Authorization either from the KMA or KVS, taking into consideration technical advice received from its advisory committees, notwithstanding the provisions of paragraph 9.6 and transitional arrangements as provided for by this Law and its pursuant normative acts.

9.2. A Marketing Authorization holder shall be a legal or natural person meeting the conditions for obtaining a Marketing Authorization as determined by this Law and its pursuant normative acts.

9.3. The requirement to obtain a Marketing Authorization concerns medicinal products either prepared industrially or manufactured by a method involving an industrial process.

9.4. The granting of a Marketing Authorization shall require both validation and accurate presentation of medicinal product quality, safety and efficacy that requires:

- (i). the application being presented in an acceptable dossier format as specified in normative act pursuant to this Law;
- (ii). submission of required, accurate and validated documentation and necessary authorizations, licenses and certificates as specified in normative act pursuant to this Law;
- (iii). accurate and validated presentation of labeling, Summary of Product Characteristics (SmPC) and Package Leaflet (Patient Information Leaflet) of the medicinal product for usage in Kosovo.

9.5. Pursuant to Paragraph 9.4 above, the procedures and documentation required for the granting of a marketing authorization make provision for:

- (i). a complete and independent (stand alone) application in the case that the medicinal product has not received an authorization outside of Kosovo;
- (ii). simplified applications according to both administrative and technical categories of the medicinal product as specified in normative act pursuant to this Law.

9.6. Notwithstanding the provisions of paragraph 9.1 a Marketing Authorization for medicinal products shall not be required for:

- (i). magistral preparations;
- (ii). galenic products;
- (iii). a radiopharmaceutical 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;
- (iv). medicinal products for which an appropriate authorization for use in clinical trials has been granted;
- (v). medicinal products intended for treatment as a continuation of a process for medical treatment started abroad;
- (vi). medicinal products either authorized in another state or not yet authorized in any state on an individual patient case basis according to criteria and procedures determined by the KMA (compassionate feeling);
- (vii). intermediate products which will be processed further;
- (viii). medicinal products to be used in research and development; and
- (ix). whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a manufacturing method.

9.7. Concerning veterinary medicinal products, a Marketing Authorization cannot be issued under any circumstance where:

- (i). the product is a magistral veterinary medicinal product which leaves prohibited residues in meat, organs or products which are used as food for human consumption;
- (ii). the product is based on hormones, steroid and non-steroid anabolics, bronchodilators, thyrostatics, animal somatotrophins, beta agonists for mass consumption, except for the treatment of an individual animal under conditions set by the KVS; and
- (iii). a withdrawal period ("karens" period) has not been established for the product.

9.8. Any product placed in Kosovo ostensibly for nutritional, hygienic, cosmetic, household or veterinary use that for which is either claimed a medicinal effect or which contains a known active substance shall require a Marketing Authorization subject to the decision of the KMA based on advice of the KCME taking into consideration applicable EU Law and guidelines.

9.9. In the event of epidemics, epizooties, major natural disasters or states of emergency, the Minister of Health and/or the Head of the Kosovo Directorate for Rural Affairs (hereinafter "DRA") can, based on the opinion of the KMA and/or the KVS, exceptionally issue a Marketing Authorization for a certain amount and type of medicinal product before the conditions for granting the Marketing Authorization have been established.

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

9.11. A Marketing Authorization, unless suspended or withdrawn, shall initially be valid for a five year period and subject to ongoing review and/or renewal, the procedures and conditions for which shall be determined in normative act pursuant to this Law.

9.12. A Marketing Authorization holder shall be obliged to inform the KMA or KVS 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, its pursuant normative acts and the conditions stated in the Marketing Authorization.

9.13. A Marketing Authorization and the determinate conditions thereto may be modified at the request of the Marketing Authorization holder by application to the KMA or KVS for a variation to the Marketing Authorization subject to approval by the KMA or KVS in accordance with normative act pursuant to this Law.

9.14. The time frames for the granting of a Marketing Authorization and a variation to a Marketing Authorization by the KMA or KVS shall be set out in normative act pursuant to this Law.

Section 10

Classification of Dispensation Status of Medicinal Products

10.1. When a Marketing Authorization is granted, the KMA, taking into consideration the technical advice of the KCME, shall classify the dispensation status of a medicinal product into either:

- (i). a medicinal product subject to medical prescription (Prescription Only Medicine - "POM"); or
- (ii). a medicinal product not subject to medical prescription (Over The Counter – "OTC").

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

- (i). medicinal products on renewable or non-renewable medicinal prescription;
- (ii). medicinal products subject to *special* medicinal prescription and that shall be recorded and controlled by the KMA;
- (iii). medicinal products on *restricted* medicinal prescription, reserved for use in certain medical special cases and/or clinical indications.

10.3. Medicinal products shall be subject to medical prescription where they:

- (i). are likely to present a risk to public health either directly or indirectly, even when used correctly, if utilized without medical supervision; or
- (ii). 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; or
- (iii). contain Active Substances, the activity and/or adverse effects of which require further investigation; or
- (iv). are normally prescribed by a physician to be administered parenterally.

10.4. Where medicinal products are subject to *special* medical prescription, the following factors shall apply:

- (i). 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
- (ii). the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or
- (iii). the medicinal product contains an Active Substance which, by reason of its novelty or properties, could be considered as belonging as a precautionary measure to the category of medicinal product described paragraph 10.4 (ii).

10.5. Where medicinal products are subject to restricted prescription, the following factors shall be taken account of:

- (i). the medicinal product, because of its product characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment;
- (ii). the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in health institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere; or
- (iii). the medicinal product is intended for outpatients but its use may produce serious adverse effects requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment course.

10.6. The KMA, taking into consideration the technical advice of the KCME, may waive application of paragraphs 10.3, 10.4 and 10.5 having regard to:

- (i). the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging and labeling; and/or
- (ii). other circumstances of use it has specified.

10.7. Medicinal products subject to medical prescription can be dispensed or sold only according to a valid prescription from a physician, dentist, or veterinarian, or as requested by a health institution.

10.8. Medicinal products not subject to prescription shall be those that do not meet the criteria specified in paragraphs 10.3, 10.4 and 10.5.

10.9. The KMA and KVS, taking into consideration the advice of the KCME, shall draw up the list of medicinal products subject to medical prescription for human and veterinary use respectively, specifying the category of classification and the list shall be updated annually.

10.10. On the occasion of a Marketing Authorization renewal, updating or a variation application for a reclassification, or when new facts are brought to its notice, the KMA, taking into consideration the advice of the KCME shall examine, and, as needed, amend the classification of a medicinal product by applying the criteria specified in paragraphs 10.3, 10.4 and 10.5.

10.11. For specified types of medicinal products, their usage **is** strictly confined to authorized health institutions licensed by the Ministry of Health according to requirements stated in the terms of the license and based on recommendation made by KMA considering technical advice received from KCME.

10.12. It shall be prohibited to administer human medicinal products to animals, except in exceptional cases and if so prescribed by the KVS.

Section 11 Clinical Trials of Medicinal Products

11.1. Clinical trials in human subjects, whether patients or healthy persons, of either unauthorized medicinal products or of authorized medicinal products within approved indications, for new indications and new dosage strengths, may only be conducted in accordance with the requirements of this Law, its pursuant normative acts, requirements of Good Clinical Practice (hereinafter “GCP”) in clinical testing, principles of medical ethics as well as the mandatory and guaranteed protection of personal data.

11.2. Clinical trials of veterinary medicinal products shall take place in accordance with foreseen conditions of this Law, its pursuant normative acts and requirements of GCP in clinical testing and the principles of veterinary medical ethics.

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

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

11.5. Prior to receiving a Clinical Trial Authorization from the KMA or KVS, the health institution and the investigator should:

- (i). hold a GCP license that shall be issued in accordance with normative act pursuant to this Law;
- (ii). obtain the approval of the Ethics Committee and provide the Committee with a full account of trial documentation and a declaration that the informed consent of all trial subjects has been or will be obtained.

11.6. A clinical trial is conducted only after a Clinical Trial Authorization has been granted by the KMA or KVS following advice received from the KCME, having regard to the trial’s purpose, usefulness, possible risks and benefits to the trial subjects, the competence of the institutions and the investigators and shall be subject to assessment and monitoring by the KMA or KVS in accordance with this Law, its pursuant normative acts, GCP requirements and the terms of the Clinical Trial Authorization.

11.7. The sponsor shall provide each individual investigator and health institution with documentation consistent with that submitted to the KMA or KVS and with evidences of approval of the trial by the KMA or KVS.

11.8. 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.

11.9. 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.

11.10. 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.

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

11.12. Medicinal products supplied by the sponsor for the purpose of the clinical trials shall be clearly labeled 'For clinical trial'.

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

Section 12 Advertising and Promotion of Medicinal Products

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

12.2. Advertising and promotion of an unauthorized medicinal product is prohibited and fined according to applicable legislation in Kosovo.

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

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

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

12.6. Medical sales representatives shall carry with them and present on request, the full SmPC of any medicinal product that they intend to promote.

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

12.8. Notwithstanding the provisions of paragraph 12.7, a manufacturer or a holder of a Marketing Authorization or their representatives may enable persons qualified for prescribing and dispensing of medicinal products to acquire additional knowledge of new medicinal products. Training through which such additional knowledge is acquired must stay within professional and scientific objectives, its sole purpose must be the acquisition of knowledge and it may be made available only to persons qualified for prescribing and dispensing medicinal products.

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

12.10. Health professionals shall have access to neutral and objective source of information about authorized medicinal products that are provided by the KMA or KVS in conjunction with the Ministry of Health or the Ministry of Agriculture Forestry and Rural Development, MAFRD and relevant professional bodies, the type and format of which shall be defined in normative act pursuant to this Law.

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

- (i). vaccination campaigns carried out by the industry and approved by the KMA and / or KVS;
- (ii). in the interest of the public health with a view to preventing an epidemic, an epizootic, or in case of a natural disaster or in other similar emergencies, the KMA and/or KVS can allow advertising and promotion of certain medicinal products via the mass media.

12.12. Advertising or promotional material for authorized medicinal products shall be granted by the KMA and/or KVS prior to publication and in accordance with procedures and conditions stated in normative act pursuant to this Law.

Section 13 Quality Assurance of Medicinal Products

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

13.2. The KMA, via its Official Medicines Quality Control Laboratory (hereinafter "OMQCL"), shall through assessment of documentation, inspections and laboratory quality control assure that all medicinal products either placed in or exported from Kosovo conform to internationally standards.

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

- (i). reference standards set by the European Pharmacopoeia, other Pharmacopoeias recognized by the KMA or other validated methods of analysis;
- (ii). Good Control Laboratory Practice (hereinafter “GCLP”).

13.4. In order to assure the quality of medicinal products placed in or exported from Kosovo the OMQCL shall be obliged to perform the following tasks:

- (i). quality assessment of an application for a medicinal product Marketing Authorization;
- (ii). batch release control that shall be obligatory for vaccines, sera and blood products manufactured or produced in Kosovo;
- (iii). control measures applied to medicinal products placed in Kosovo such as random sampling, testing of sensitive medicinal products (i.e. products where quality is critical to safety and efficacy of usage), solving of suspected and identified product quality problems, control of the first imported batch of authorized medicinal product, identification of counterfeit medicines and other related measures;
- (iv). re-analysis of medicinal products that already have a Batch Certificate of Analysis in the case where internationally recognized GMP standards are suspected to be not in place;
- (v). methodology validation for quality control in accordance with accepted international standards;
- (vi). international co-operation in development of medicinal product quality assurance procedures and standards including pharmacopoeial standards;
- (vii). other quality assurance tasks that may be deemed necessary in accordance with normative act pursuant to this Law.

13.5. The OMQCL shall be entitled to perform any quality assurance procedure it decides is appropriate for any given medicinal product in order to protect public health.

13.6. In the case that a medicinal product does not meet the defined and applied quality standards, remedial action shall be taken as defined in normative act pursuant to this Law including the provision for a complete withdrawal of the concerned product from the Kosovo market.

Section 14

Quality Assurance of Immunological Medicinal Products and Medicinal Products Derived from Human Blood or Plasma

14.1. In the interest of public health, the KMA requires a holder of a marketing authorization for immunological medicinal products meeting the criteria set out in paragraph 14.1 (i) below to comply by specified procedures and submit relevant items as stated in paragraph 14.1 (ii) below as follows:

- (i).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;
- (ii).submit samples from each batch of the bulk and/or the medicinal product for examination by the OMQCL before release on to the Kosovo market notwithstanding a mutual recognition procedure for batch release determined between the KMA and the competent authorities of EU Member and EU Accessing States. The time frame for batch analysis shall be defined in normative act pursuant to this Law.

14.2. 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.

14.3. Measures referred to in paragraphs 14.2 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.

14.4. The safety measures referred to in paragraph 14.2 must also be evidenced by importers and exporters of medicinal products derived from human blood or human plasma with reference to relevant international standards.

14.5. The production within and importation into 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.

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

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

14.8. With respect to the provisions of paragraph 14.7 above, manufacturers shall notify the KMA of the method used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma and the KMA may submit samples of the bulk and/or the medicinal product for testing by the OMQCL, either during the examination of the Marketing Authorization or at anytime after the Marketing Authorization has been granted.

Section 15 Pharmacovigilance

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

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

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

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

15.5. The KMA shall define specific requirements on health professionals with respect to the reporting of suspected adverse effects of medicinal products in normative act pursuant to this Law.

15.6. In case of suspected non-compliant quality of a medicinal product it causes adverse effects, the KMA shall take samples for testing by the Official Medicines Quality Control Laboratory (OMQCL).

15.7. The KVS shall establish a parallel pharmacovigilance system for collection of reports on adverse effects related to the use of veterinary medicinal products. Special attention shall be paid to the safety of animals, and also to the safety of those persons administering the medicinal products to animals and to the safety of consumers of products of animal origin.

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

15.9. A holder of a Marketing Authorization shall be required to maintain detailed records of all reported known or suspected adverse effects related to an authorized medicinal product placed in Kosovo occurring either within or outside of Kosovo and that shall be subject to inspection by the KMA and KVS.

Section 16 Medicinal Product Disposal

16.1. Medicinal products without either an Import License or Marketing Authorisation (notwithstanding the provisions of paragraph 9.6), or of non-compliant quality, or with an expired shelf life, or stored or prepared under other than stipulated conditions according to the requirements of Good Distribution Practice (GDP), or obviously damaged or not completely consumed (hereinafter “unusable medicinal products”) must be disposed of,

including their packaging, so as to prevent a threat to the life and health of humans or animals or to the environment.

16.2. The procedures for disposal of unusable medicinal products shall be set out in normative act pursuant to this Law and in coordination with the Ministry of Environmental Protection and Spatial Planning.

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

16.4. Information that consent has been granted for disposal shall be provided by the authority that granted the consent to the KMA for a medicinal product for human use or to the KVS in the case of a veterinary medicinal product.

16.5. The list of legal entities authorised to dispose of unusable medicinal products (which, by definition, excludes unusable whole human blood, plasma or blood cells of human origin, the disposal of which shall be determined by procedures set out under separate law), shall be determined by the Ministry of Environmental Protection and Spatial Planning.

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

16.7. Manufacturers, wholesalers and retailers of medicinal products and health institutions located in Kosovo are obliged to surrender unusable medicinal products to the legal entities specified in paragraph 16.3.

16.8. A pharmacy is obliged to accept unusable medicinal products surrendered by natural persons. 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 16.3 and with their disposal by such legal entities shall be covered by the relevant authority in Kosovo.

16.9. The cost of disposal of unusable medicinal products, with the exception of those specified under paragraph 16.8, shall be borne by the manufacture, wholesaler, pharmacy or health institution .

16.10.KMA shall define, that in respect to the aid and control system of medicinal products in term like much less than 3 months before the term expires shall carry out the distribution to the pointed or necessary location for use.

Section 17

Supervision of the Regulation of Medicinal Products

17.1. The KMA and KVS shall ensure by the supervisory measures stated in this Section that the legal requirements governing medicinal products that consist of this Law and its pursuant normative acts and guidelines are complied with.

17.2. Supervisory measures shall be performed by inspection of manufacturers, wholesalers and dispensers/retailers of medicinal products to determine that the requirements of this Law and its pursuant normative acts are being met.

17.3. Concerning manufacturing, galenic production, wholesale and dispensing/retailing of medicinal products in Kosovo, supervisory measures shall be carried out by inspectors of the KMA and KVS who shall be empowered to:

- (i). inspect establishments involved in the manufacturing, galenic production, wholesale and dispensing of medicinal products in Kosovo;
- (ii). take samples;
- (iii). examine any documents relating to the object of the inspection;
- (iv). temporarily confiscate and seal medicinal products until the precautionary measure of obligatory confiscation of medicinal products used in committing the offence is declared if and when the holder of any license referred to in this law or any normative act issued pursuant to this law, does not comply with the terms and conditions of the license.

17.4. Concerning a holder of or an applicant for a Marketing Authorization, the KMA and KVS shall perform supervisory measures by their designated inspectors who shall be empowered to:

- (i). inspect manufacturing sites and any laboratories entrusted by the holder of a Manufacturing Authorization stated in the Marketing Authorization or application irrespective of country of origin;
- (ii). take samples;
- (iii). examine any documents relating to the object of the inspection subject to confidentiality restrictions placed by relevant authorities with regard to the method of preparation of the active substance;
- (iv). examine manufacturing processes to ensure that these processes are correctly validated and attain batch-to-batch consistency;
- (v). report on whether the manufacturer complies with the principles and guidelines of GMP as defined by normative act pursuant to this Law and provide a corresponding report to the manufacturer that has undergone the inspection.

17.5. The KMA and KVS may derogate inspection of the manufacturing sites and laboratories of a holder of or an applicant for a Marketing Authorization to the competent authority of another state or entity in the case where a bilateral or other agreement governed by international convention may apply.

17.6. The KMA and KVS shall take all appropriate measures to ensure that a holder of a Marketing Authorization and, where appropriate, a holder of a Manufacturing Authorization furnish proof of the controls carried out on the medicinal product and/or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods set out in normative act pursuant to this Law.

17.7. The KMA and KVS shall prohibit the advertising and promotion of medicinal products that are against the provisions of this Law and its pursuant normative acts and order the removal or destruction of the material used for illegal advertising of medicinal products.

17.8. The KMA and KVS can order a legal entity or natural person to bring their operations concerning medicinal products in line with defined practices within a defined period of time since the receipt of the order calling for this measure as provided for in normative act pursuant to this Law.

17.9. The KMA and KVS shall have the right to:

- (i). ban the manufacture, testing and marketing of medicinal products on the grounds of non-conformity with prescribed conditions;
- (ii). withhold marketing of a medicinal product or a particular batch which does not satisfy the prescribed conditions;
- (iii). order the destruction of medicinal products in breach of the provisions of this Law and its pursuant normative acts;
- (iv). ban the import of a medicinal product which has not been granted a Marketing Authorization by the KMA or KVS or has been transported against the manufacturer's instructions;
- (v). suspend an authorization or license in the case of a material breach of the provisions of this Law, its pursuant normative acts and the terms of the authorization or license until the infringement is satisfactorily addressed within time limits set out by the KMA or KVS;
- (vi). revoke an authorization or license in the case of a material breach of the provisions of this Law, its pursuant normative acts and the conditions of the authorization or license in the case either where the conditions for suspending an authorization or license are not addressed within determined time limits or where it is deemed that the infringement resulted in death or serious injury due to failure of a legal entity or natural person to respect the provisions of this Law, its pursuant normative acts and the terms of the authorization or license.

17.10. Any appeals issued against the orders for the implementation of supervisory measures stated in this Section shall be submitted to the Appeals Board and shall not prevent the implementation of such orders.

17.11. The Kosovo Customs Service shall not permit the customs clearance for the release of medicinal product shipments to the Kosovo market without evidence of a Batch Import License issued by the KMA notwithstanding future provisions that may be made granting exceptions for certain authorized medicinal products.

17.12. The KMA and KVS reserve the right to order other supervisory measures concerning medicinal products necessary for the implementation of this Law and its pursuant normative acts.

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

CHAPTER 3 MEDICAL DEVICES

Section 18 Classification of Medical Devices

18.1. Medical devices shall be classified into:

- (i). general medical devices;
- (ii). active implantable medical devices; and
- (iii). *in vitro* diagnostic medical devices.

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

- (i). Class I - medical devices constituting a low risk potential for users;
- (ii). Class IIa - medical devices constituting higher risk potential for users;
- (iii). Class IIb - medical devices constituting a high risk potential for users; and
- (iv). Class III - medical devices constituting the highest risk potential for users.

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

- (i). non-invasive,
- (ii). invasive, and
- (iii). active.

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

- (i). used exclusively in human or veterinary health care;
- (ii). dispensed on prescription or over the counter in pharmacies;
- (iii). dispensed on prescription or over the counter in specialized shops; or
- (iv). freely marketed.

18.5. The KMA shall determine in greater detail the classification of medical devices and the manner of their dispensation in normative act pursuant to this Law.

18.6 Should an article be a combination of a medicinal product and medical device or a combination of a medical device and a freely marketed object, it will be classified according to its primary purpose as declared by the manufacturer in accordance with classification criteria laid down by the KMA.

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

Section 19 Placing on the Market and Putting into Service of Medical Devices

19.1. The KMA shall take all necessary steps 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.

19.2. Before a medical device can either be placed on the market or put into service in Kosovo, the manufacturer or his supplier shall submit to the KMA a notification. The format, content and procedure for the notification, taking into consideration the class of the medical device, shall be defined in normative act pursuant to this Law.

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

19.4. 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.

19.5. Upon application, the KMA 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 Section 21 of this Law and its pursuant normative acts, in the case that the device is determined by the KMA, based on the technical advice of the Kosovo Committee for Medical Devices, to be of importance for the protection of public health in Kosovo.

19.6. 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.

Section 20 Essential Requirements for Medical Devices

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

- (i). they must be designed, manufactured, installed, maintained and applied in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, 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;
- (ii). Any health risks associated with use of the device must be investigated during its design and manufacture and users must be informed about any risks that cannot be eliminated;
- (iii). they have been assigned a classification by the KMA in accordance with the provisions of Section 18 above;

- (iv).their manufacturer shall apply the quality system approved for the design and construction of the medical device in accordance with harmonized standards;
- (v).special prescribed requirements concerning the purpose of the device are met in accordance with the type of medical device;
- (vi).in demonstrating the conformity of a medical device in accordance with relevant essential requirements and in the related approval, the manufacturer must apply tests and inspections carried out by a conformity assessment body (notified body) approved by the KMA.

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

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

20.4. The KMA shall determine in greater detail the essential requirements for medical devices in normative act pursuant to this Law.

Section 21

Compliance, Conformity Assessment Procedure and Labeling of Medical Devices

21.1. Conformity assessment procedure is a procedure by which it is directly or indirectly established whether medical devices fulfill the requirements referred to in the previous Section.

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

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

- (i). for medical devices of class I the manufacturers themselves shall establish conformity with prescribed essential requirements and draw up a conformity declaration on their own responsibility, the exceptions being measuring mechanisms and sterile products of class I, treated as if belonging to class II or III;
- (ii). the conformity of medical devices of classes IIa, IIb and III with the prescribed essential requirements shall be established and the quality assurance system supervised by a conformity assessment body or bodies appointed for performing this activity by the KMA.

21.4. The KMA shall, through normative act pursuant to this Law, determine in greater detail the conditions to be fulfilled , the appointment procedure for conformity assessment bodies, conformity assessment procedures in accordance with the prescribed essential requirements, discharge and scope of reference.

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

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

21.7. On the basis of a Declaration of Conformity, the manufacturer must label their products with the prescribed conformity marking.

21.8. The KMA shall prescribe the contents of the Declaration of Conformity and conformity marking requirements in normative act pursuant to this Law.

21.9. Notwithstanding the provisions of the previous paragraphs of this Section, medical devices intended for investigation and custom-made devices for individual users shall not need to be marked in accordance with this Law.

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

Section 22 Manufacture of Medical Devices

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

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

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

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

22.5. Manufacturers of medical devices or their authorized supplier must provide a Declaration of Conformity for each of their products, pursuant to the procedures referred to in Section 21 above.

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

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

- (i). notify the KMA of their business;
- (ii). provide evidence that they perform their business in such a way as to ensure the protection of public health;

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

(iv).take up liability insurance for any possible damage caused to the user or third party.

22.8 The KMA shall prescribe the license conditions for manufacturing of medical devices in Kosovo in normative act pursuant to this Law.

Section 23

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

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

23.2. The import of medical devices into Kosovo shall require:

(i). an Import License issued by the Kosovo Ministry of Trade and Industry; and

(ii). a Batch Import License issued by the KMA that shall take into consideration the classification status of the medical device.

23.3. The requirement to obtain a Batch Import License for a medical device shall be waived according to the classification status of the medical device as defined in normative act pursuant to this Law.

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

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

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

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

Section 24

Professional Use of Medical Devices

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

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

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

(iii). the instructions and procedures concerning the use are appropriate.

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

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

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

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

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

Section 25 Clinical Trials of Medical Devices

25.1. 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.

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

25.3. 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.

25.4. 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.

25.5. The manufacturer of the medical device under investigation (or sponsor of the investigation) must insure the investigator against any possible damage caused by the investigated medical device.

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

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

Section 26 Monitoring of Adverse Effects to Medical Devices

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

26.2. 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.

26.3. Manufacturer, suppliers, dispensers and professional users of medical devices who discover or suspect any adverse effect to a medical device, must report such adverse effects to the KMA.

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

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

26.6. 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 normative act pursuant to this Law.

Section 27 Advertising and Promotion of Medical Devices

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

27.2. Notwithstanding the above, the KMA may, based on the technical advice of the Kosovo medical devices committee, allow public advertising and promotion of medical devices which do not constitute a high risk to users.

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

27.4. The detailed conditions for advertising and promotion of medical devices shall be determined by normative act pursuant to this Law.

Section 28 Supervision of the Regulation of Medical Devices

28.1. The KMA ensures by the supervisory measures stated in this Section that the legal requirements concerning medical devices and pursuant normative acts issued by the basis of this law should be fully completed.

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

28.3. The KMA inspectorate shall be authorized to carry out the following supervisory measures:

- (i). request all necessary information from the manufacturer and/or supplier including issued Declarations of Conformity and related technical documentation;
- (ii). 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;
- (iii). collect sample medical devices and submit them for conformity assessment;
- (iv). prohibit the issue of a Declaration of Conformity in the case that a medical device is considered to be non-conforming;
- (v). order the elimination of the established non-conformities;
- (vi). request that medical devices are marked with prescribed markings or order the elimination of non-prescribed markings;
- (vii). 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;
- (viii). 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;
- (ix). 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;
- (x). order the destruction of non-conforming medical devices, if necessary for the protection of public health and safety;
- (xi). temporarily confiscate and seal medical devices until the reasons for the precautionary measure of confiscation have been eliminated;
- (xii). suspension or revocation of licenses in the case of a material breach of license conditions;
- (xiii). monitoring of the functioning of Conformity Assessment Bodies in accordance with requirements defined in normative act pursuant to this Law.

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

28.5. Suspension of an authorization or license shall occur in the case of a material breach of the provisions of this Law, its pursuant normative acts and the terms of the authorization or license until the infringement is avoided within time limits set out by the KMA and KVS.

28.6. Revocation of an authorization or license shall occur in the case of a material breach of the provisions of this Law, its pursuant normative acts and the conditions of the authorization or license in the case either where the conditions for suspending an

authorization or license are not addressed within determined time limits or where it is deemed that the infringement resulted in death or serious injury due to failure of a legal entity or natural person to respect the provisions of this Law, its pursuant normative acts and the terms of the authorization or license.

28.7. Any appeals issued against the orders for the implementation of supervisory measures stated in this Section shall be submitted to the Appeals Board and shall not prevent the implementation of such orders.

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

28.9. 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 section 28.3 (iv) of this Law.

28.10. 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 normative acts.

28.11. 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 4 FUNCTIONS OF THE COMPETENT AUTHORITIES

Section 29 Functions of the Kosovo Medicines Agency

29.1. The functions of the KMA concerning medicinal products for human use shall be:

- (i). deciding whether or not a product is to be considered as a medicinal product and the classification of a medicinal product;
- (ii). issuing Marketing Authorizations for a medicinal product intended to be placed in Kosovo;
- (iii). maintenance and regular publication of a register of authorized medicinal products and their classification;
- (iv). approval of variations to a Marketing Authorization;
- (v). renewal/approval of maintenance of existing Marketing Authorizations;
- (vi). issuing of Manufacturing Authorizations for manufacturers located in Kosovo and validation of a Manufacturing Authorization concerning medicinal products imported into Kosovo;
- (vii). issuing of Wholesale Licenses;
- (viii). issuing of Batch Import Licenses subject to other license conditions and provisions stated in this Law;

- (ix). classification of dispensation status of medicinal products placed in Kosovo;
- (x). issuing of Clinical Trial Authorizations;
- (xi). Pharmacovigilance;
- (xii). definition and approval of medicinal product advertising and promotion standards as defined in normative act pursuant to this Law;
- (xiii). quality assurance and control of medicinal products placed in Kosovo;
- (xiv). monitoring of the trade and usage of medicinal products containing narcotic and psychotropic substances and their precursors in accordance with the requirements of relevant UN conventions;
- (xv). coordination with the Ministry of Health in determining and implementing Kosovo pharmaceutical policy particularly pertaining to dissemination of objective information on the quality, safety and efficacy of medicinal products to health professionals and the population and implementation of a pharmacovigilance system;
- (xvi). supervisory functions as stated in Section 17 of this Law; and
- (xvii). other functions that may be required in accordance with this Law and its pursuant normative acts to ensure the effective regulation of medicinal products for human use placed in Kosovo in order to protect public health.

29.2. The functions of the KMA concerning medical devices shall be:

- (i). evaluated whether or not a device is to be considered a medical device;
- (ii). evaluated the product class to which a medical device belongs if there is a disagreement between a conformity assessment body and the manufacturer;
- (iii). authorization for either/or placing on the market or putting into service of medical devices in Kosovo based on a valid Declaration of Conformity notwithstanding exceptions provided by this Law;
- (iv). maintenance and regular publication of a register of authorized medical devices and their classification status;
- (v). licensing of legal entities or natural persons manufacturing, wholesaling, retailing/dispensing and putting into service medical devices;
- (vi). issuing of Batch Import Licenses for medical devices on the basis of the criteria for classification in compliance with the section 18.2 i-iv of this Law;
- (vii). classification in impartial way and dispensation status of medical devices placed in Kosovo taking into consideration the nature and purpose of a medical device;
- (viii). approval of clinical trials for medical devices;
- (ix). monitoring of adverse effects to medical devices;
- (x). insurance of advertising and promotional standards of medical devices;

- (xi). supervisory functions as stated in Section 28 of this Law; and
- (xii). other functions that may be required in accordance with this Law and its pursuant normative acts to ensure the effective regulation of medical devices placed in Kosovo in order to protect public health.

Section 30
Functions of the Kosovo Veterinary Service

30.1. The functions of the KVS concerning the regulation of veterinary medicinal products shall be:

- (i). issuing Marketing Authorizations for veterinary medicinal products;
- (ii). maintenance and regular publication of a register of authorized veterinary medicinal products and their classification;
- (iii). approval of variations to a Marketing Authorization;
- (iv). renewal/approval of maintenance of existing Marketing Authorizations;
- (v). issuing of licenses for the wholesale, dispensing / retail of veterinary medicinal products;
- (vi). issuing of Batch Import Licenses for veterinary medicinal products subject to other license conditions and provisions stated in this Law;
- (vii). classification of dispensation status of veterinary medicinal products placed in Kosovo;
- (viii). issuing of Clinical Trial Authorizations for veterinary medicinal products;
- (ix). Pharmacovigilance of veterinary medicinal products;
- (x). definition and approval of veterinary medicinal product advertising and promotion standards as defined in normative act pursuant to this Law;
- (xi). supervisory functions as stated in Section 17 of this Law; and
- (xii). other functions that may be required in accordance with this Law and its pursuant normative acts to ensure the effective regulation of veterinary medicinal products.

Section 31
Decision-making, Drafting and Implementation of
Normative Acts Pursuant to this Law

31.1. The KMA and KVS shall make their decisions, based on the advice from the appointed Committees, independently and in accordance with this Law and its pursuant normative acts with recourse to appeal procedures.

31.2. The KMA and KVS shall be responsible for the drafting and implementation of normative acts pursuant to this Law.

CHAPTER 5 FEES and PENALTIES

Section 32 Fees and Costs

32.1. A license fee shall be paid by applicants to the KMA and KVS for obtaining and maintaining of the authorizations and licenses stated in this Law, the fees for which shall be stated in normative act pursuant to this Law.

32.2. An inspection fee shall be applied by the KMA and KVS in order to ensure the correct implementation of this Law and its pursuant normative acts concerning:

- (i). applications for medicinal product and medical device authorizations and licenses as stated in this Law in the case where KMA or KVS considers that the issuance of such authorizations or licenses cannot be based on documentary evidence submitted by the applicant alone taking into consideration the provisions of this Law and its pursuant normative acts;
- (ii). inspection of activities of legal entities or natural persons in Kosovo pertaining to requirements for maintenance of authorization or license conditions;
- (iii). inspection of persons, legal entities or natural persons that infringe authorization and license conditions stated in this Law, and the inspection fee which shall be applied by the Kosovo judicial authorities against the infringing party subject to an appeals process.

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

32.4. In accordance with fee procedures applied by OMQCLs in EU Member and EU Accessing States, the costs of providing medicinal product quality assurance by OMQCL with respect to the provisions of Sections 13 and 14 of this Law shall be covered either by:

- (i). Marketing Authorization applicants and holders for quality assurance related to a new application or maintenance/updating of an existing authorization respectively; or
- (ii). in the case where testing relates to a suspected breach 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 breach is proven; or
- (iii). in the case of testing of unauthorized medicinal products placed in Kosovo, the cost shall be covered by the legal entity or natural person responsible for placing the unauthorized product in Kosovo; or
- (iv). by the KMA concerning medicinal product testing for reasons other than those stated above in this paragraph.

32.5. 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 normative acts shall be paid by the legal entity or natural person which has manufactured or imported the medicinal product or medical device in question.

32.6. Professional services provided by the KMA and KVS to other authorities in Kosovo with respect to the provisions of this Law and its pursuant normative acts shall incur a service fee.

32.7. The fees and costs specified in this Section shall be approved by the Ministry of Finance and Economics shall be published and shall be payable to the Kosovo Consolidated Budget.

Section 33

Penalties

33.1. Violation of the provisions of this Law, its pursuant normative acts and the terms of authorizations and licenses issued according to this Law shall be the subject of penalties as specified in normative act pursuant to this Law.

33.2. Penalties defined pursuant to this Law shall take into consideration the extent of infringement of the Law and its obligation to protect the public health of Kosovo and shall provide for the imposition of custodial sentences and fines and restrictions on the activities of legal entities and natural persons in accordance with the degree of infringement.

33.3. The imposition of penalties defined in normative act pursuant to this Law shall be the responsibility of the KMA, KVS and the Kosovo Courts.

CHAPTER 6 TRANSITIONAL ARRANGEMENTS, EMERGENCY SITUATIONS AND FINAL PROVISIONS

Section 34

Transitional Arrangements

34.1. Normative acts pursuant to this Law shall state transitional rules for a proper implementation of this Law.

34.2. The transitional period for the implementation of this Law is over when all Chapters and Sections of the Law are fully provided for by normative act pursuant to this Law, at the latest five years after this Law coming into force.

34.3. The Government in association with relevant professional associations shall establish an Ethics Committee responsible for the ethical approval of clinical trials of experimental medicinal products and medical devices within one year of this Law coming into force.

34.4. The KMA and KVS shall establish the advisory bodies as stated in Section 3 of this Law within one year of this Law coming into force.

34.5. The medicinal product quality assurance function for implementation of this Law as set out in Sections 13 and 14 of this Law shall be performed by a qualified laboratory external to Kosovo contracted by the KMA until such a time that the OMQCL function is established within Kosovo and that shall be done within two years of this Law coming into force.

34.6. The KVS shall fully establish its functions with respect to regulation of veterinary medicinal products and make legal provision for both coordination of specified functions with the KMA and derogation of specified functions to the KMA within one year of this Law coming into force.

34.7. The Government shall make provisions for establishing a conformity assessment body for medical devices in Kosovo responsible for issuing a Declaration of Conformity concerning medical devices manufactured in Kosovo and the validation of a Declaration of Conformity concerning medical devices imported into Kosovo and that shall be established using rules for conformity assessment based on harmonized standards. This provision shall be implemented within two years of this Law coming into force.

Section 35 Emergency Situations

35.1. In the case of acute emergency and major catastrophic situations, as defined by the Government, the provisions of this Law may be waived, based either on direct request made to the KMA and/or KVS by the Government or as a result of unilateral action taken by KMA and/or KVS, as required in order to protect public health until such time as normal conditions are re-established.

35.2. Any exceptional measures taken unilaterally according to this provision by KMA and/or KVS shall be reported immediately to the Government.

Section 36 Applicable Law

By this Law are abrogated all other Law acts which are in power.

Section 37 Entry into Force

The law enters into force on the date of promulgation .

Law No.2003/ 26
4 December 2003