

Pursuant to article IV/4 a) of the Constitution of Bosnia Herzegovina, Parliamentary Assembly of Bosnia and Herzegovina at the 29th session of House of Representatives held on 14th May and 4th June 2008 and at the 18th session of House of Peoples held on 17th June 2008, passed the

## **MEDICINAL PRODUCTS AND MEDICAL DEVICES ACT**

### **Chapter I – GENERAL PROVISIONS**

#### **Article 1**

##### **Scope of the Act**

- (1) Medicinal Products and Medical Devices Act of Bosnia and Herzegovina (hereinafter referred to as: the Act) regulates: definition of medicinal products and medical devices for use in human medicine; production, testing and marketing of medicinal products and medical devices; conditions and measures for ensuring quality, safety and efficacy of use of medicinal products and medical devices; supervision over medicinal products, and medical devices as well as over legal entities engaged in production, testing or wholesale marketing of medicinal products and medical devices; and any other issues of importance in the area of medicinal products and medical devices.
- (2) This Act applies also to medicinal products containing narcotic drugs and psychotropic substances as well as raw materials used for their production, unless it has been regulated by a separate Act, in compliance with international conventions regulating this type of medicinal products.
- (3) This Act shall establish an Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (hereinafter referred to as: the Agency) as an authority in the area of medicinal products and medical devices used in medical practices in Bosnia and Herzegovina (hereinafter referred to as: B-H).

#### **Article 2**

##### **Definitions**

The terms used in this Act bear the following meanings:

- a) **MEDICINAL PRODUCT** is any substance or a combination of substances intended for treating or preventing diseases in humans. Medicinal products include any substance or a combination of substances which can be administered to humans for the purpose of making a diagnosis, restoring or modifying physiological functions and for any other medically justifiable purpose.
- b) **SUBSTANCE** is any matter which can be of:
  - 1) Human origin, eg. human blood, human blood products etc;
  - 2) Animal origin, eg. microorganisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, etc;
  - 3) Plant origin, eg. microorganisms, plants, parts of plants, plant secretions, extracts, etc.
  - 4) Chemical origin, eg. elements of chemical substances in natural form and chemical products obtained by chemical change or synthesis, and others.
- c) **NAME OF MEDICINAL PRODUCT** is a name which can be invented but which shall not cause confusion with a usual name or a common name or a scientific name followed by a registered trademark or a marketing authorisation holder's name.
- d) **COMMON NAME** is an international non-proprietary name (INN) as recommended by World Health Organisation, or if one does not exist, a generally accepted common name.



- e) **MAGISTRAL MEDICINAL PRODUCT** is a prescribed medicine prepared in a pharmacy as specified by the physician's prescription for an individual patient.
- f) **GALENIC PREPARATION** is a medicinal product prepared in a galenic laboratory of a pharmacy in accordance with pharmacopoeic and other principles, with the purpose of being dispensed in that pharmacy.
- g) **HOMEOPATHIC MEDICINAL PRODUCT** is a medicinal product prepared from products, substances or mixtures of homeopathic origin, in accordance with procedures for preparation of homeopathic medicine with a degree of dilution as proscribed by the European pharmacopoeia, Pharmacopoeia of Bosnia and Herzegovina or the pharmacopoeia officially accepted by any country which is a member of EU;
- h) **HERBAL MEDICINAL PRODUCT** is any medicinal product which consists exclusively of one or more herbal substances, or one or more herbal preparations, or one or more herbal substances in combination with one or more herbal preparations contained as its active ingredient.
- i) **HERBAL SUBSTANCES** are whole, fragmented or cut plants or parts of plants, algae, fungi or lichen in unprocessed, dry or fresh state. Certain exudates which have not been processed are also considered as herbal substances. Herbal substances are precisely defined by the part of the plant being used and by its botanical name in accordance with binomial nomenclature (genus, species, variations and author).
- j) **HERBAL SUPPLEMENTS** are supplements obtained by processing herbal substances by scientifically proven methods.
- k) **TRADITIONAL MEDICINE MEDICINAL PRODUCTS** are medicinal products intended for self-healing use in a way as described in an instruction for use leaflet; intended for internal or external use; and for which there are records for having been in use for at least 30 years, or for at least 15 years in Bosnia and Herzegovina, or in countries members of the EU; and whose assumed pharmacological properties, safety and efficiency are based on a long term experience.
- l) **PHARMACOPOIEA** is a set of procedures for preparation of medicinal products, for testing and confirmation of their identification, testing and determination of purity and other parameters of the quality of medicinal products as well as of other substances used for preparation of medicinal products.
- m) **ACTIVE SUBSTANCE** is a pharmacologically active component in a given pharmaceutically controlled form.
- n) **MEDICINAL PRODUCT QUALITY** is a set of characteristics of a medicinal product which ensures that the declared or expected pharmaceutical-chemical-biological and microbiological results of the medicinal product testing have been satisfactorily met; or a set of characteristics determined by the qualitative analysis of all ingredients of a medicinal product, by the qualitative analysis of all active substances of a medicinal product, and by all other testing required to ensure that the quality of the medicinal product is in accordance with the requirements for obtaining the marketing authorisation.
- o) **BIOAVAILABILITY** of a medicinal product is the rate and degree by which the active substance or its active component has been absorbed from the pharmaceutical form and become available at the place of activity. Should the medicinal products be intended for systematic treatment, then the bioavailability is defined as the rate and degree by which the active substance or its active component has been released from the pharmaceutical form into the bloodstream.



- p) **BIOEQUIVALENCE** is a degree of similarity to the medicinal products which is achieved if:
- 1) The medicinal product is pharmaceutically equivalent to a referential medical product (if they have the same quantity of the same active substance in the same pharmaceutical form),
  - 2) The medicinal product is a pharmaceutical alternative of a referential medical product (if they have the same therapeutic molecular part with a different chemical form of the active substance, strength or pharmaceutical form), or
  - 3) The bioavailability, in terms of rate and degree after administering of the same dosage of the medicinal product, is similar to a referential medical product in such a degree that the achieved effects of safety and efficacy of the medicinal product may be considered essentially similar.
- q) **ESSENTIALLY SIMILAR MEDICINAL PRODUCTS** are medicinal products which have the same qualitative and quantitative composition of the active substance in the same pharmaceutical form as a referential medical product (or in different peroral pharmaceutical forms of the same medicinal product of the same composition /capsules, tablets, etc/ with an instantaneous release of the active substance), with a proven bioavailability, or bioequivalence.
- r) **GENERIC MEDICINAL PRODUCT** is a medicinal product which has the same qualitative and quantitative composition of the active substance in the same pharmaceutical form (or different peroral forms with an instantaneous release of the active substance) as a referential medicinal product, and the bioequivalence with the referential medicinal product has been proven by appropriate testing of bioavailability or bioequivalence, unless the testing is not deemed necessary based on scientifically accepted recommendations. Various mineral salts, esters, isomers, mixtures of isomers, ethers, complexes or derivatives of the active substance shall be considered the same as the active substance until it has been proven that they significantly differ from it in regards to safety and efficacy of the medicinal products.
- s) **PHARMACEUTICAL FORM** is any form of the medicinal product suitable for its administration (tablets, capsules, ointments, injection solutions, etc.)
- t) **MEDICINAL PRODUCTS WHICH MAY CAUSE RISKS** are immunological medicinal products (serums, vaccines, toxins, allergens), radiopharmaceuticals, medicinal products derived from human blood and plasma.
- u) **MEDICINAL PRODUCTS DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA** are medicinal products based on blood components, specifically including albumin, coagulating factors and immunoglobulins.
- v) **HUMAN BLOOD AND BLOOD PRODUCTS** are preparations derived from human blood. They are not considered medicinal products in view of this Act and are used as raw components for manufacturing medicinal products for which, in accordance with this Act, a marketing authorisation is required.
- w) **RADIOPHARMACEUTICAL** is any medicinal product containing one or more radionuclides.
- x) **RADIONUCLIDE GENERATOR** is a system with a main radionuclide for generating radionuclides required for preparation of fresh radiopharmaceuticals.
- y) **RADIONUCLIDE IN A CLOSED RADIOACTIVE SOURCE** is a radioactive substance, firmly closed in a container, which is used for external radioactive treatment of patients.
- z) **RADIONUCLIDE KIT** is a preparation which is to be made or combined with a radionuclide in a prepared radiopharmaceutical, most frequently immediately before its administration.



- aa) **RADIOPHARMACEUTICAL PRECURSOR** is a radionuclide required for X-ray marking of other components before their administration.
- bb) **RISKS ASSOCIATED WITH MEDICINAL PRODUCT USE** mean any risks regarding quality, safety or efficacy of the medicinal product in respect to the patient's or public health, as well as any risks associated with their unwanted effects on the environment.
- cc) **RATIO BETWEEN THE RISKS AND BENEFITS** is an assessment of positive therapeutic effects of a medicinal product in respect to the risks associated with its use.
- dd) **GOOD MANUFACTURING PRACTICE (GMP)** is a system of rules to ensure quality in respect to organisation, supervision and control over any aspects regarding manufacturing of medicinal products.
- ee) **GOOD CONTROL LABORATORY PRACTICE (GcLP)** is a component of Good Manufacturing Practice governing the quality assurance of medicinal products.
- ff) **GOOD LABORATORY PRACTICE (GLP)** is a system of guidelines for ensuring quality in organisational processes and conditions necessary for planning, implementing, supervising, recording (in form of a protocol) and reporting about preclinical laboratory studies.
- gg) **CONTROL LABORATORY OF THE AGENCY**, being an organisational unit within the Agency for Medicinal Products and Medicinal Devices of Bosnia and Herzegovina, is a laboratory responsible for testing and quality control of medicinal products and assessment of documentation on the quality of medicinal product (pharmaceutical-chemical-biological-microbiological).
- hh) **AUTHORISED LABORATORY** is a laboratory engaged by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, in accordance with this Act, to execute specific analyses, and which is a member of the Official Medicine Control Laboratories (OMCL) network; or a laboratory authorised by the Agency for Medicinal Product and Medical Devices of Bosnia and Herzegovina to perform testing of medicinal products during the process of their development and/or manufacturing, but prior to submitting an application for manufacturing or marketing of such medicinal products; or a laboratory authorised or recognised by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina to execute quality control of each batch of manufactured or imported medicinal product.
- ii) **GOOD TRANSPORTATION PRACTICE (GTP)** is a system of guidelines ensuring quality regarding organisation, implementation and supervision of transportation of medicinal products and medical devices from the manufacturer to end users.
- jj) **GOOD PHARMACEUTICAL PRACTICE (GPP)** is a system of guidelines ensuring quality of pharmacy services.
- kk) **GOOD STORAGE PRACTICE (GSP)** is a system of guidelines ensuring quality regarding organisation, implementation and supervision of storage of medicinal products and medical devices according to an established order.
- ll) **GOOD CLINICAL PRACTICE (GCP)** is an internationally recognised ethical and scientific system of guidelines ensuring quality in planning and implementation, recording, supervising and reporting about



clinical trials on humans, which ensures accuracy of data obtained during the trials, as well as protection of rights, safety and wellbeing of participants in the trials.

- mm) **MEDICINAL PRODUCTS OR MEDICAL DEVICES MANUFACTURER** is a legal entity authorised and responsible for manufacturing, development, quality assurance, packaging and labelling of medicinal products and medical devices, irrespective of whether the medicinal products or devices have been produced by themselves or by a third party on their behalf.
- nn) **MARKETING AUTHORISATION** is a certificate issued by an authority confirming quality, efficacy and safety of a medicinal product, i.e. certifying that the requirements for marketing of the medicinal products have been met and that the medicinal product may be marketed.
- oo) **MARKETING AUTHORISATION HOLDER** is a legal entity which can be a manufacturer residing in B-H, or a representative of a foreign manufacturer holding an office in B-H.
- pp) **WHOLESALE MARKETING AUTHORISATION HOLDER** is a legal entity with an authorisation for wholesale trade in accordance with this Act.
- qq) **ADVERSE REACTIONS** are any undesirable effects of a medicinal product, regardless of its dosage, which may occur during treatment with the proscribed use of the medicinal product.
- rr) **SERIOUS ADVERSE EVENTS** are any adverse effects resulting in patient's death or life-threatening condition, hospitalisation (which did not occur previously), or prolongation of existing hospitalisation, permanent damage (disability) or congenital abnormalities in their offspring.
- ss) **UNEXPECTED ADVERSE EVENTS** are any unexpected and adverse effects of a medicinal product which have not been stated in the summary of the main characteristics of the medicinal product.
- tt) **THE SUBSTANCE QUALITY ASSURANCE CERTIFICATE** is a certificate confirming that the substance conforms with the proscribed quality and validity.
- uu) **CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP)** is a document issued for a particular medicinal product upon request of a marketing authorisation holder by an authority of the country where the medicinal product is being manufactured. CPP contains particulars about the medicinal product (its name, composition of its active substance and excipients), place of manufacturing and packaging and particulars of the marketing authorisation holder. CPP is issued on the World Health Organisation form and is issued irrespectively of whether the medicinal product has been approved for marketing, or not, by the country where it is manufactured.
- vv) **MEDICINAL PRODUCT SERIAL NUMBER** is a controlled quantity of a medicinal product manufactured during one manufacturing process ensuring complete homogeneity of the product.
- ww) **BATCH NUMBER** is a combination of numbers or letters by which a medicinal product serial number and certificate of analysis of the series are identified in the manufacturer's documentation.
- xx) **ANALYSIS OF THE MANUFACTURED SERIES** is a quality analysis of all components of a medicinal product of one manufactured series, the quantity analysis of at least all active substances, and any other testing required for ensuring the quality of the medicinal product is in accordance with the medicinal product marketing authorisation.
- yy) **PHARMACOVIGILANCE** is a procedure used for identifying, collecting, monitoring, analysing and responding to the new findings regarding safety of a medicinal product and assessment of risks and benefits associated with the use of the medicinal product or its interaction with other medicinal products.



- zz) **ESSENTIAL MEDICINAL PRODUCTS** are basic medicines for most common diseases used to satisfy health care needs of majority of population where the assessment of such needs is done by a competent authority.
- aaa) **MEDICAL DEVICES** in view of this Act are: instruments, devices, materials and other products including any software necessary for their proper application; which are used on people, and which do not perform their main function, set by the manufacturer, on the basis of any pharmacological, immunological or metabolic activities, but are used alone or in combination.
- bbb) **MANUFACTURER/SUPPLIER OF MEDICAL DEVICES** is a legal entity responsible for the product and obliged to provide a quality assurance system. It can be a manufacturer residing in B-H, their representative with an office in B-H, importer or other legal entities who have marketed the medicinal device and made it available for use.
- ccc) **DECLARATION ON CONFORMITY OF A MEDICINAL DEVICE** is a declaration made by a manufacturer/supplier providing a guarantee that the medicinal device conforms with the basic requirements stipulated by this Act.
- ddd) **RETAILERS SPECIALISING IN MEDICAL DEVICES** are sales outlets for retail of medical devices.
- eee) **CONFORMITY ASSESSMENT AUTHORITY** is an independent legal entity, not associated with either a manufacturer or a supplier, authorised by a competent authority (i.e. a laboratory, a certification authority, or a control authority) to assess conformity of the medicinal device with the basic, or general and specific requirements, stipulated by this Act.

## **Chapter II – AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES**

### **Article 3**

#### **Institutional structure**

- (1) The Agency for Medicinal Products and Medical devices of Bosnia and Herzegovina (hereinafter referred to as: the Agency) is established by this Act to be an authority responsible in the area of medicinal products and medical devices which are manufactured and used in medical practices in Bosnia and Herzegovina.
- (2) The Agency is an independently managed organisation with properties of a legal entity.
- (3) Administration Act regulations shall apply on the organisation and activities of the Agency unless stipulated otherwise by this Act.

### **Article 4**

#### **The Agency Head Office**

- (1) The Agency Head Office shall be in Banja Luka. The Control Laboratory of the Agency shall be in Sarajevo. The Pharmacovigilance Head Office shall be in Mostar.
- (2) The Agency may have offices in places outside of its head office.

### **Article 5**

#### **The Agency Seal**

The Agency shall have a seal in accordance with the Seals of Institutions of Bosnia and Herzegovina Act.



## **Article 6 Objectives**

The Agency is established for the purpose of:

- a) Protecting and promoting public health care by ensuring a supply of quality, safe and efficient medicinal products and medical devices for use in human medicine, and for the purpose of establishing a functional, coordinate and uniform system for regulation of medicinal products and medical devices;
- b) Establishing and supervising a unified market for medicinal products and medical devices and ensuring their availability on the whole territory of B-H;
- c) Implementing cooperation and providing professional assistance to the relevant State and Entities Ministerial Authorities responsible for public health care through outlining policies, preparing proposals and implementing national policies for use of medicinal products and medical devices in human medicine;
- d) Making proposals and amendments of legislation in the area of medicinal products and medical devices, and harmonising the regulations with the international standards;
- e) Executing any other activities stipulated by this Act and regulations derived therefrom.

## **Article 7 The Role of the Agency in the area of medicinal products**

The role of the Agency in the area of medicinal products includes:

- a) Issuing, renewing or cancelling and amending of marketing of medicinal products authorisation;
- b) Activities regarding laboratory testing of medicinal products and providing professional expert evaluation of the quality of medicinal products;
- c) Issuing of good practice certificates (manufacturer, wholesale pharmacies, clinical, laboratory, transportation, etc.);
- d) Registering or approving of clinical trials of medicinal products and monitoring adverse effects occurring during clinical trials;
- e) Issuing of manufacturer of medicinal products authorisation based on a certificate on complying with good manufacturer practice;
- f) Issuing of wholesale marketing of medicinal products authorisation based on a certificate on complying with good distribution practice (good wholesale pharmacies practice);
- g) Establishing and maintaining an updated record of imported medicinal products for which a marketing authorisation has not been issued in B-H;
- h) Publishing an annual Register of medicinal products containing the list of medicinal products permitted for marketing in B-H;
- i) Making recommendations for an essential medicinal products list in Bosnia and Herzegovina necessary for protecting public health safety (hereinafter referred to as: the list of essential medicinal products in B-H);
- j) Collecting information, analysing and responding to adverse effects of medicinal products, or performing pharmacovigilance activities;
- k) Carrying out the assurance control of medicinal products activities;
- l) Carrying out pharmaceutical inspection of medicinal products of legal entities engaged in manufacturing and wholesale marketing of medicinal products, in view of issued authorisations;
- m) Organising information systems of medicinal products, including establishing a database covering medicinal products authorised for marketing in B-H, collecting data about sales and usage of medicinal products and establishing a cooperation with international informational medicinal products networks, as well as informing professionals and general public in the country about the medicinal products in view of the current legislation, and participating in the international exchange of information regarding adverse effects of medicinal products;



- n) Reviewing European pharmacopoeia and reviewing development of pharmacopoeia in Bosnia and Herzegovina;
- o) With the approval of relevant authorities from the state or entities, assisting in the international exchange of information and keeping records of marketing of narcotic drugs and psychotropic substances;
- p) Making recommendations for harmonising the legislation from the area of medicinal products with legislation from the European Union and with the guidelines provided by international institutions;
- q) Performing any other activities in the area of medicinal products in accordance with this Act and regulations derived therefrom.

### **Article 8**

#### **The Role of the Agency in the area of medical devices**

The role of the Agency in the area of medical devices includes:

- a) Keeping a register of medical devices for the territory of B-H;
- b) Keeping a register of manufacturers of medical devices for the territory of B-H;
- c) Keeping a register of legal entities engaged in wholesale of medical devices for the territory of B-H;
- d) Issuing of certificates of registering manufacturers of medical devices;
- e) Issuing of certificates of registering legal entities engaged in wholesale of medical devices;
- f) Issuing of certificates of registering medical devices in the Registry of medical devices;
- g) Collecting information, analysing and responding to undesirable occurrences in application of medical devices, or materiovigilance of medical devices;
- h) Assessing conformity and labelling of medical devices in B-H with harmonised European standards and technical regulations in accordance with the Technical Requirements and Conformity Assessment of Products Act;
- i) Carrying out professional inspection and supervision of manufacturing and wholesale marketing of medical devices, as well as of legal entities engaged in manufacturing or importing and wholesale marketing of medical devices in view of issued authorisations;
- j) Organising an information system of medical devices, including establishing a database covering medical devices registered in the Registry of medical devices, collecting data about legal entities engaged in manufacturing of medical devices or importing and wholesale marketing of medical devices, collecting data about sale and usage of medical devices, as well as data to enable rational usage of medical devices, and establishing cooperation with international informational medical devices networks;
- k) Performing any other activities in the area of medical devices in accordance with this Act and regulations derived therefrom.

### **Article 9**

#### **The Control Laboratory of the Agency**

- (1) The Control Laboratory of the Agency carries out activities regarding medicinal products testing and quality assurance of medicinal products and substances.
- (2) The Agency is entitled to engage other authorised laboratories to perform specific analyses which cannot be carried out within the Agency for Medicinal Products and Medical Devices.
- (3) Authorised laboratories from paragraph 2 of this Article must be within OMCL network (Official Medicine Control Laboratories).





**Article 10**  
**Organisation, method and place of realisation of individual tasks**

- (1) The organisation, method and place of realisation of individual tasks of the Agency shall be stipulated by Regulations on internal organisation and job classification of the Agency.
- (2) There are at least three departments within the Agency, namely: Department for Medicinal Products, Department for Medical Devices, and Department for Inspection and Supervision. Within the Agency, other departments and offices within the departments may be organised, according to the needs and tasks emerging from their line of business. Departments and offices of the Agency, being its internal functional units, prepare materials and otherwise assist the Agency committees in their work so that they may be located outside of the Agency head office, which shall be regulated by the Regulations referred to in paragraph 1 of this Article.

**Article 11**  
**A unified information system**

In order to ensure a unified system of manufacturing, distribution, testing and pharmacovigilance of medicinal products and materiovigilance of medical devices on the territory of Bosnia and Herzegovina, the Agency shall ensure that the head office and organisational units of the Agency are connected into a unified information system enabling access to all the necessary data for an efficient operating of the unified system.

**Article 12**  
**The Agency funding**

The Agency shall be funded from the Budget of institutions of Bosnia and Herzegovina and from the international obligations funds of Bosnia and Herzegovina.

**Article 13**  
**The Agency employees**

- (1) Employment in Government Institutions of Bosnia and Herzegovina Act applies to government employees of the Agency.
- (2) When commencing employment with the Agency, government employees referred to in paragraph 1 of this article are required to sign a declaration stating that there is no conflict of interest, or declare that there is an occurrence of conflict of interest between them and the Agency; sign a statement of confidentiality and an obligation to keep all the data learned about the Agency's line of business confidential after the termination of their employment with the Agency.
- (3) Conflict of interest referred to in paragraph 2 of this article is defined as carrying out business which causes or might cause material or other damages to the interest of the Agency.
- (4) Non declaring conflict of interest, or breaching the confidentiality of the data, represents the violation of official duties, which shall result in initiating a disciplinary procedure, in accordance with the Employment in Government Institutions of Bosnia and Herzegovina Act.
- (5) For other employees of the Agency, Employment in Institutions of Bosnia and Herzegovina Act shall apply.

**Article 14**  
**Corporate Bodies of the Agency**



Corporate Bodies of the Agency are: Professional Board, Director and the Agency Committees.

### **Article 15 Professional Board**

- (1) The Professional Board is a professional, regulatory, advisory and control body of the Agency, consisting of seven members.
- (2) Members of the Professional Board referred to in Paragraph 1 of this article shall be appointed by the Council of Ministers of Bosnia and Herzegovina and the members shall be chosen from distinguished experts in fields of pharmacy, medicine, chemistry and law from both Entities and from Brcko District of Bosnia and Herzegovina (hereinafter referred to as: Brcko District). Recommendations for their appointment shall be made by Ministry of Civil Affairs from the list of candidates prepared by Department of Health of each Entity and Department of Health of Brcko District.
- (3) Recommendations referred to in paragraph 2 shall contain names of three candidates from each Entity, and one candidate from Brcko District.
- (4) Chair of the Professional Board shall be elected by consensus of the Board members for one year term of office. The same member of the Board cannot be elected the chair for two consecutive years. The Professional Board may, depending on the discussion or voting matters, engage experts from other fields outside of the Board as well as committee members within the Agency.
- (5) The Professional Board members shall be appointed for a term of four years, with the option of re-election for one more term.
- (6) The Professional Board may make decisions under condition that at least five members shall be present at the session. Decisions shall be made by majority of votes (four members). In making decisions, voting must represent votes by one representative from each Entity and from each constitutive nation.
- (7) Matters relating to responsibilities, activities, voting and decision-making procedures of the Professional Board shall be defined in the Rules of procedure. The Professional Board shall adopt the Rules of procedure approved by the Minister of Civil Affairs of B-H.
- (8) Members of the Professional Board shall be required to sign a declaration of non-existing conflict of interest.

### **Article 16 Responsibilities of the Professional Board**

- (1) The Professional Board is responsible for:
  - a) Proposing the Policy on medicinal products and medical devices on the territory of B-H, which shall be approved by the Council of Ministers;
  - b) Considering and managing realisation of guidelines provided by responsible ministers regarding policy on medicinal products and medical devices;
  - c) Defining strategic goals of the Agency and making an assessment of the Agency's achievements in view of realisation of such goals;
  - d) Commenting on the Regulations on internal organisation and job classification of the Agency endorsed by the Agency Director with the approval by the Council of Ministers;
  - e) Making subordinate legislation in accordance with this Act and upon the recommendation by the Agency Director;
  - f) Formulating and coordinating good practices upon the recommendation by the Agency Director;



- g) Formulating proposals of general and other procedures by the Agency in accordance with the Act;
  - h) Endorsing annual plan of activities of the Agency and financial plan of the Agency upon the recommendation by the Agency Director;
  - i) Reviewing and adopting the annual report on activities, business operations and the balance sheet of the Agency;
  - j) Carrying out supervision over whole activities and business of the Agency, including the content, range and quality of realisation of the annual plan, and harmonisation of the annual report with the business plan;
  - k) Carrying out supervision over implementation of the Act and other subordinate legislation made in accordance with the Act;
  - l) Carrying out any other activities stipulated by the Act and regulations derived therefrom.
- (2) The Professional Board may propose making new or amendments to the existing legislation in respect to medicinal products and medical devices should it deem necessary for implementation of this Act and any other procedures derived therefrom.
- (3) The Professional Board, upon the recommendation by the Agency Director, shall adopt instructions regulating the confidentiality of the data or documents used in business activities of the Professional Board or the Agency in accordance with legislation on free access to information in B-H and the Entities.

**Article 17**  
**Agency Director – the appointment and term of office**

- (1) The Agency Director shall be responsible for managing the Agency.
- (2) The Director shall have a deputy who shall act in capacity of the Director in his/her absence.
- (3) Director and the Deputy Director shall be appointed for a term of four years, with the option of re-election for one more term.
- (4) The Director and the Deputy Director shall be appointed by the Council of Ministers upon recommendation by the Professional Board, in accordance with the Appointments of Ministers, the Council of Ministers, and Other Officials of Bosnia and Herzegovina Act. Employment in Government Institutions of Bosnia and Herzegovina Act shall apply to the Director and the Deputy Director.
- (5) Criteria for appointment of the Director include: tertiary education in pharmacy or medicine, at least five years of relevant professional experience and an active command of the English language.
- (6) Conflict of Interest in the Government Institutions of Bosnia and Herzegovina Act shall apply to the Agency Director and the Deputy Director.

**Article 18**  
**The Agency Director Dismissal**

- (1) The Director and the Deputy Director are dismissed by the Council of Ministers upon recommendation by the Professional Board.
- (2) The Agency Director and the Deputy Director shall be dismissed before the end of their term of office in the following circumstances:
  - a) If the Director or the Deputy Director does not perform his/her function in accordance with the Act or any other procedures derived therefrom;



- b) If there is a legally valid court ruling in the criminal procedure against the Director or the Deputy Director, except for traffic offences, which leaves them unsuitable for the role of the Director or Deputy Director;
- c) If there is evidence of conflict of interest;
- d) If the Director or the Deputy Director makes serious acts of negligence in the management;
- e) If there is a confirmed charge against the Director or the Deputy Director for a criminal offence of corruption or other forms of gaining personal interest, or illegal transactions, abuse of power or authority, embezzlement, unconscientious work in the office and/or illegal collections or payments;
- f) If the conditions for termination of employment are defined and enforced by law;
- g) If the Director or the Deputy Director offers resignation from the position.

### **Article 19**

#### **Authorities and responsibilities of the Agency Director**

- (1) The Agency Director represents and acts on behalf of the Agency and shall be responsible for legal, professional and ethical operations of the Agency as well as for an efficient management of the Agency.
- (2) The Director shall be accountable to the Council of Ministers.
- (3) The Director shall be responsible for the following duties and tasks:
  - a) Implementing the policy on medicinal products and medical devices in B-H, implementing the Act and regulations derived therefrom;
  - b) Executing decisions and recommendations made by the Professional Board;
  - c) Making proposals for the programme and plan of activities and development of the Agency;
  - d) Making proposals for the Regulations on internal organisation and job classification of the Agency to be adopted by the Council of Ministers;
  - e) Making proposals for the annual budget of the Agency;
  - f) Preparing annual report on financial operations of the Agency as well as the annual balance sheet;
  - g) Informing the Professional Board about all the issues pertaining to implementation of the policy on medicinal products and medical devices or relevant legislation;
  - h) Providing statistical data to the authorities in Bosnia and Herzegovina or abroad;
  - i) Setting up and ensuring functioning of the internal audit of the Agency;
  - j) Setting up and ensuring functioning of the information system of the Agency;
  - k) Appointing and dismissing operational managers of the Agency;
  - l) Performing any other duties and activities in accordance with the Act and procedures derived therefrom.

### **Article 20**

#### **Committees of the Agency**

- (1) Committees of the Agency are as follows:
  - a) Committee for medicinal products,
  - b) Committee for medical devices,
  - c) Committee for clinical trials,
  - d) Committee for pharmacopoeia,
  - e) Other committees for dealing with particular issues.
- (2) The Agency Director, with a prior consent provided by the Professional Board, shall appoint committee members.



- (3) Committee members from Paragraph 1 of this article shall be distinguished experts from the area of medical sciences or natural sciences (chemistry, biology, biochemistry, physics, electrical engineering, technology, etc) with relevant professional experience in activities run by the relevant committee.
- (4) Committee members from Paragraph 1, Clauses a) to d) shall be appointed for a term of four years, with the option of re-election for one more term.
- (5) Committees from Paragraph 1 of this article, with a prior consent provided by the Professional Board, shall prepare Rules of procedure, detailing issues of relevance for their field and method of work, voting and making decisions.
- (6) The Agency Director, with a prior consent provided by the Professional Board, shall endorse a list of B-H experts who, should the need arise, may be involved in activities of the committee from Paragraph 1 of this article.
- (7) Committees from Paragraph 1 of this article and the Agency Director may, for the purpose of professional assessment of documentation from Articles 23, 24, 25 and 26 of this Act, seek experts' opinion from Paragraph 6 of this article.
- (8) Committees from Paragraph 1 of this article are required to provide, on the Director's request, all findings, explanations and instructions if they are from the committee's field of work.
- (9) The Director shall approve Rules of procedure detailing competencies, field of work and responsibilities of each particular committee. The committees shall meet as necessary. In order to prepare findings, explanation or assessment of documentation on specific requests, the committee shall operate with at least two thirds of the total number of committee members. Findings, explanation, or assessment upon the specific request shall be provided by the simple majority of the committee members present at the session. Findings, explanation or assessments which are different from the majority must be presented in writing to the Agency Director.

#### **Article 21 Confidentiality**

Committee members and experts from article 20 of this Act shall sign a declaration to keep the confidentiality and that there is no conflict of interest in view of the paragraph 3 of article 13 of this Act.

#### **Article 22 Remuneration**

Committees and experts from article 20 of this Act shall be entitled to remuneration in the amount decided by the Agency Director and in accordance with the legislation governing these issues.

#### **Article 23 Committee for medicinal products**

- (1) Committee for medicinal products shall assess documentation regarding quality, safety and efficacy of each medicinal product enclosed to the application for obtaining a marketing authorisation, or for its renewal or amendment.
- (2) Committee for medicinal products shall recommend to the Professional Board a list of essential medicinal products in B-H.



- (3) Committee for medicinal products consists of 15 members. Departments of Health from each Entity shall recommend seven members, and the Department of Health of Brcko District shall recommend one member.

**Article 24**  
**Committee for clinical trials**

- (1) Committee for clinical trials shall assess documentation enclosed to the application for obtaining permission for clinical trials of medicinal products and to the application for registering the clinical trial, or an amendment or annex to an already registered and approved protocol of the clinical trial.
- (2) Committee for clinical trials consists of seven members. Departments of Health from each Entity shall recommend three members, and the Department of Health of Brcko District shall recommend one member.

**Article 25**  
**Committee for medical devices**

- (1) Committee for medical devices shall assess documentation enclosed to the application for registering medical devices without a required CE mark in accordance with the Technical Requirements and Conformity Assessment of Products Act, unless an authority ascertained by the Technical Requirements and Conformity Assessment of Products Act has already done the assessment.
- (2) Committee for medical devices shall assess documentation enclosed to the application for obtaining permission to perform clinical trials of the medical device, or the application for amendment or annex to an already registered and approved protocol of the clinical trial.
- (3) Committee for medical devices consists of nine members. Departments of Health from each Entity shall recommend four members, and the Department of Health of Brcko District shall recommend one member.

**Article 26**  
**Committee for pharmacopoeia**

- (1) Committee for pharmacopoeia shall review development of the European pharmacopoeia, provide recommendations for a national contribution to the European pharmacopoeia and shall provide recommendations for pharmacopoeia of Bosnia and Herzegovina.
- (2) Committee for pharmacopoeia consists of seven members. Departments of Health from each Entity shall recommend one member, Department of Health Brcko District shall recommend one member, Faculty of Pharmacy from each Entity shall recommend one member, and the Control Laboratory of the Agency shall recommend two members.

**Article 27**  
**Other permanent and occasional committees**

For the purpose of dealing with particular issues regarding medicinal products and medical devices, the Agency Director may establish permanent or occasional committees with representatives from Federation of Bosnia and Herzegovina (hereinafter referred to as: Federation of B-H), Republika Srpska (hereinafter referred to as: RS) and Brcko District of Bosnia and Herzegovina.

**III – MEDICINAL PRODUCTS**

**A. Conditions for marketing of medicinal products**

**Article 28**  
**Classification of medicinal products**



- (1) With respect to the method and place of dispensation of medicinal products and in accordance with marketing authorisations, the medicinal products are classified as:
  - a) Medicinal products dispensed only in pharmacies and only on medical prescription;
  - b) Medicinal products dispensed only in pharmacies, but without medical prescription;
  - c) Medicinal products administered only in health care facilities during provision of medical services.
- (2) The method and procedure for classification of medicinal products referred to in paragraph 1 of this article shall be stipulated by sub-legislation adopted by the Professional Board, upon the recommendation by the Agency Director.

**Article 29**  
**Conditions for marketing of medicinal products**

Medicinal products may be marketed under the following conditions:

- a) That the Agency has issued a marketing authorisation for marketing of medicinal products in Bosnia and Herzegovina.
- b) That each series of the medicinal product has been manufactured in accordance with the documentation presented, which was the basis for issuing a valid manufacturing authorisation, and under condition that each batch of medicinal product has been tested for quality, in accordance with this Act and regulations derived therefrom, and with a valid marketing authorisation;
- c) That each batch has been marked by the Agency for medicinal products and medical devices trademark, in accordance with this Act and the relevant sublegislation.

**Article 30**  
**The principles of establishing conditions for obtaining a marketing of medicinal products authorisation**

- (1) Medicinal products marketed in B-H shall be manufactured and controlled in accordance with the methods and requirements of the European pharmacopoeia and Pharmacopoeia of Bosnia and Herzegovina, which shall be established by the Professional Board of the Agency upon the recommendation by the Committee for pharmacopoeia.
- (2) An exemption to the condition referred to in paragraph 1 of this article is in circumstances where the European pharmacopoeia or Pharmacopoeia of B-H do not specify details regarding manufacturing or the quality of a medicinal product, therefore the medicinal product may be manufactured and controlled by adhering to the methods of other recognized pharmacopoeias.
- (3) For the purpose of testing quality of a medicinal product, the procedures stated in the approved documentation accompanying the medicinal product shall be adhered to; and the medicinal product documentation shall be enclosed to the application for issuing a marketing of medicinal products authorisation; or any other procedures adopted by the Agency and in accordance with the condition referred to in paragraph 1 of this article shall be adhered to.
- (4) An exemption from the conditions referred to in paragraphs 1 – 3 of this article is when medicinal products, which are marketed in Bosnia and Herzegovina, may be manufactured and controlled in accordance with the methods recommended and explained in detail by the manufacturer, under condition that such methods have not been otherwise explained by other recognized pharmacopoeias.

**B. A marketing of medicinal products authorisation**



**Article 31**  
**A marketing of medicinal products authorisation**

- (1) Medicinal products shall be marketed in B-H only after a marketing of medicinal products authorisation has been issued in accordance with this Act and legislation derived therefrom.
- (2) The authorisation referred to in paragraph 1 of this article shall not be required for:
  - a) Magistral medicinal products;
  - b) Galenic preparations;
  - c) Medicinal products intended for clinical trials for which a permission or certificate of registering the clinical trial has already been issued by the Agency;
  - d) Products intended for further processing;
  - e) Medicinal products intended for pre-clinical trials and scientific research;
  - f) Medicinal products received as humanitarian aid;
  - g) Radionuclides in a closed radioactive source;
  - h) Whole blood, blood plasma or blood cells of human origin, except for plasma prepared in the manner which has included industrial processing.
- (3) Except for the medicinal products listed in paragraph 2 of this article, the authorisation shall not also be required for the medicinal products which shall be imported for the purpose of emergency treatment of individual patients, based on the assessment of their medical needs, as well as for the medicinal products necessary for protection of public health where the import of medicinal products has been requested by a public health care facility.

**Article 32**  
**An applicant for a marketing of medicinal products authorisation**

- (1) An application for the marketing of medicinal products authorisation can be lodged by a manufacturer residing in B-H or by a legal entity representing a foreign manufacturer holding an office in B-H.
- (2) A manufacturer's representative is required to obtain a Contract on Representation, registered with the Department of Foreign Trade and Economic Relations of B-H. The representative shall inform the Agency about the Contract registered with the relevant Ministerial office, and provide complete information about the manufacturer's liability insurance, applicable on the territory of B-H, for any damages which might be caused to the user of medicinal products.
- (3) The applicant referred to in paragraph 1 of this article (hereinafter referred to as: the Proposer) shall appoint an officer responsible for marketing of medicinal products and an officer responsible for pharmacovigilance activities.
- (4) The officer responsible for marketing of medicinal products shall be a graduate from Faculty of Pharmacy, and the officer responsible for pharmacovigilance shall be a graduate from either Faculty of Pharmacy, Medicine or Dental Surgery.

**Article 33**  
**An application for issuing a marketing of medicinal products authorisation**

- (1) The application for issuing the marketing of medicinal products authorisation shall contain at least the following information:





- a) Administrative part of the documentation, namely particulars about: manufacturer of the medicinal product; place of manufacturing; the proposer or a future marketing of medicinal products authorisation holder; summary of main characteristics of the medicinal product; information for patients; proposal for packaging of the medicinal product; a list of countries where the medicinal product has been approved to be marketed; experts' recommendations as the integral part of the medicinal product documentation and which have been presented in writing by the Proposer's experts for the assessment of documentation regarding quality, safety and efficacy of the medicinal product;
  - b) Analytical part of the documentation, namely pharmaceutical-chemical-biological parts of the documentation containing particulars about: the quality of medicinal product; qualitative and quantitative composition of the medicinal product; description of method of manufacturing of the medicinal product; description of quality control in the process of manufacturing the medicinal product; description of the quality of the finished product; studies on the medicinal product stability; and any other necessary information for protection of public health and the environment;
  - c) Pharmacological-toxicological part of the documentation containing particulars about: pharmacodynamic and pharmacokinetic characteristics of the medicinal product; toxicity of the medicinal product; effects of the medicinal product on reproductive function; effects of the medicinal product on embryo-foetal toxicity; mutagenic and cancerogenic potentials of the medicinal product; information about the local tolerance; about excretion of the medicinal product; and any other necessary information for protection of public health and the environment;
  - d) Clinical part of the documentation, namely general information about: clinical trials; methods of carrying out clinical trials; results of clinical trials; clinical-pharmacological particulars; particulars about the bioavailability and bioequivalence (if necessary); particulars about clinical safety and efficacy; particulars about special conditions for carrying out clinical trials (if necessary); and information about post-marketing authorisation experiences in other countries.
- (2) The Proposer is responsible for the accuracy of the data in the documentation.
  - (3) The documents supporting the application for the marketing of the medicinal products authorisation and the application itself, as well as the summary of the main characteristics of the medicinal product and the information for patients, shall be written in one of the official languages in use in Bosnia and Herzegovina.

#### **Article 34** **Exemptions**

- (1) Regarding conditions referred to in Article 33 of this Act, the Proposer shall not be required to enclose results of their pharmacological-toxicological or clinical trials if they can demonstrate that:
  - a) The medicinal product for which an application for marketing authorisation is being made is essentially similar to the medicinal product for which a marketing authorisation has already been issued in Bosnia and Herzegovina; and that the marketing authorisation holder gives their consent in writing that the results of their pharmacological-toxicological and clinical trials provided in the supporting medicinal product documentation may be referred to; or
  - b) That instead of providing their own results of pharmacological-toxicological and clinical trials of the medicinal product, the information from already published and publically available literature containing all necessary particulars from the requested supporting documentation referred to in paragraph 1, clauses c) and d) of article 34 may be presented by the Proposer, under condition that the ingredients and safety of the medicinal product have been well known, and that their efficacy has been demonstrated, and/or that the active substance has been in use for at least 10 years as a medicinal product in B-H, EU or in other countries having the same requirements regarding the standard of quality, safety and efficiency of the medicinal product; or
  - c) That the medicinal product for which an application for a marketing authorisation has been made is essentially similar to the medicinal product for which the marketing authorisation has already been issued and is valid for at least eight years, and that the medicinal product meets the same standards regarding the quality, safety and efficacy in B-H, EU or in other countries which have the same



standards, under provision that the Agency shall be entitled to issue a marketing authorisation at least 10 years after the issuing of a marketing authorisation for the medicinal product essentially similar to the medicinal product to which the Proposer is referring in their supporting documentation. Any additional marketing authorisations for medicinal products of different strength, pharmaceutical form, posology, as well as any variations and extensions of the same medicinal product in EU, B-H or in other countries with the same standards regarding the quality, safety and efficacy of the medicinal product shall be regarded as the integral part of the initial marketing authorisation for the purpose of implementation of this paragraph.

- (2) If an application is made for approving a new indication, dosage, strength or posology of the medicinal product in relation to the essentially similar medicinal product on the market, the Proposer shall be required to provide the supporting documentation in form of results of relevant pharmacological-toxicological and clinical trials.
- (3) If the medicinal product in question contains the same fixed composition of known ingredients which have already been approved individually as a medicinal product, then it shall not be deemed necessary to provide the supporting documentation relating to each particular ingredient.

### **Article 35**

#### **Subject of the authorisation**

- (1) For any form, dosage or packaging size of a medicinal product, an application for a marketing of the medicinal product authorisation, supported by the documentation referred to in Article 33 of this Act, shall be submitted to the Agency.
- (2) Filed documentation shall be considered confidential, except for particulars regarding the summary of the main characteristics of the medicinal product, the information for patients and particulars from the packaging of the medicinal product.
- (3) The summary of the main characteristics of the medicinal product shall contain at least the following particulars: basic information about the medicinal product (name, generic name, qualitative and quantitative composition, pharmaceutical form, strength and method of packaging); the manufacturer; marketing of the medicinal product authorisation holder; posology and methods of administration; indications; contraindications; safety measures; dispensing; adverse effects; expiry date; storage; and any other necessary information.

### **Article 36**

#### **Content of the application, procedure and conditions for obtaining the authorisation**

- (1) Content of the application, procedure and conditions for obtaining the marketing of medicinal documentation authorisation, and the form and the content of the supporting documentation shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.
- (2) Besides conditions referred to in paragraph 1 of this article, the Minister of Civil Affairs, upon recommendation by the Professional Board of the Agency, shall proscribe additional or different requirements for obtaining the authorisation for marketing of medicinal products that may cause risks, for medicinal products of herbal origin, or for homeopathic medicinal products.

### **Article 37**

#### **Processing the application**



- (1) The Agency shall approve or reject a marketing authorisation within 210 days from the receipt of a valid application, upon the recommendation provided by the Committee for Medicinal Products regarding the appropriateness of the supporting documentation and the assessment of the quality, safety and efficacy of the medicinal product.
- (2) The timeframe from paragraph 1 of this article is deferred from the date when the Agency makes a request for any additional documentation, information or explanation from the Proposer until the new requirements of the Agency shall be met.
- (3) The marketing of the medicinal product authorisation shall be issued for a period of five years.
- (4) The marketing of the medicinal product authorisation, or its rejection, shall be issued in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (5) The integral part of the authorisation from paragraph 3 of this article is the approved summary of the main characteristics of the medicinal product, the information for patients and the outline, or already produced, form of packaging of the medicinal product.
- (6) The content of the marketing of the medicinal product authorisation shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

#### **Article 38**

##### **Marketing authorisation prior to proscribing conditions**

- (1) In exceptional circumstances (epidemics, natural disasters of greater range, state of war and any other special circumstances) the Agency Director may approve marketing of the medicinal product prior to proscribing conditions stipulated by this Act or legislation derived therefrom.
- (2) Approval referred to in paragraph 1 of this Act shall be valid until special circumstances which prompted its application cease to exist.

#### **Article 39**

##### **Reasons to reject an application**

The Agency shall reject an application for a marketing of a medicinal product authorisation if, based on the assessment of the supporting documentation, the following has been established:

- a) That the ratio between the benefits and the risks is unfavourable;
- b) That the efficacy of the medicinal product is unsatisfactory, unsubstantiated or insufficiently substantiated;
- c) That the qualitative and quantitative composition of the medicinal product is not in accordance with the supporting documentation;
- d) That the supporting documentation is not in accordance with this Act and legislation derived therefrom.

#### **Article 40**

##### **Expiry of the authorisation or revoking the authorisation**

- (1) The marketing of the medicinal product authorisation shall expire on the date of expiry or upon the marketing authorisation holder's request.
- (2) The Agency shall be entitled to revoke the issued marketing of the medicinal product authorisation by official duty or upon the marketing authorisation holder's request.



- (3) The Agency shall revoke the issued marketing of the medicinal product authorisation by official duty in the following circumstances:
- a) If the medicinal product has been marketed contrary to the marketing authorisation, provisions of this Act and legislation derived therefrom;
  - b) If the medicinal product is harmful when used in the proscribed manner;
  - c) If the medicinal product does not meet the standards of contemporary medical science and health care needs, and does not comply with the expected ratio between the benefits and risks;
  - d) If the qualitative and/or quantitative composition of the medicinal product is not in accordance with the composition declared in the documentation supporting the application for the marketing authorisation;
  - e) If particulars in the supporting documentation do not reflect the real situation;
  - f) If the medicinal product has not been marketed within three years from the date of issue of the marketing authorisation, unless the Agency gives its consent to it, based on the explanation provided in the application made by the marketing authorisation holder.

#### **Article 41**

##### **Renewal of the marketing of the medicinal product authorisation**

- (1) The marketing of the medicinal product holder is required to apply for a renewal of the authorisation at least six months prior to the expiry of the authorisation.
- (2) The Agency is required to make a decision upon the application referred to in paragraph 1 of this article within 90 days after the receipt of a complete application for the renewal of the marketing of the medicinal product authorisation; the decision shall be made in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (3) The timeframe from paragraph 2 of this article shall be deferred from the date when the Agency makes a request for any additional information or explanation from the Proposer until the new requirements of the Agency shall be met.
- (4) The request referred to in paragraph 1 of this article shall contain at least: the updated administrative information, the information on a periodic report about safety of the medicinal product, the additional particulars regarding the quality, safety and efficacy of the medicinal product, if necessary, and the additional information needed for the assessment of the ratio between benefits and risks.
- (5) Detailed content of the application, procedure and conditions for the renewal of the marketing of the medicinal product authorisation, as well as the form and content of the requested supporting documentation shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

#### **Article 42**

##### **Marketing of the medicinal products after expiry of the marketing authorisation**

- (1) The medicinal product with an expired marketing authorisation which has not been renewed within the timeframe and in the manner stipulated in article 41 of this Act may be marketed within 12 months after the marketing authorisation expiry, except in circumstances referring to the safety and efficacy of the medicinal product.
- (2) The application for the renewal of the marketing authorisation cannot be submitted for the medicinal product where this application has not been lodged within the timeframe and in the manner stipulated by



article 41 of this Act; however, the application shall be submitted in accordance with the procedure proscribed as if the original marketing authorisation had not been issued in the first place.

#### **Article 43**

#### **Discontinuation of manufacturing or marketing of the medicinal product prior to the expiry of the authorisation**

Should the manufacturer decide to discontinue manufacturing or marketing of a medicinal product prior to the expiry of the marketing authorisation, they shall be deemed to notify the Agency about their decision within six months prior to the discontinuation of manufacturing or marketing of the medicinal product at latest, stating the reasons for their decision.

#### **Article 44**

#### **Amendments to the authorisation**

- (1) The marketing authorisation holder shall be required to continually stay abreast with: scientific and technological development in regards to the medicinal product; new findings regarding the assessment of the quality, safety and efficacy of the medicinal product; amendments to any documentation which had been supplied during the procedure of obtaining the marketing authorisation; and new research relating to the medicinal product.
- (2) The marketing authorisation holder shall be deemed to regularly notify the Agency about the minor amendments (amendments of the I.A and I.B types) in the documentation, or in the marketing authorisation, and shall implement them only under condition that the Agency had not responded negatively about the amendment within 30 days after receipt of the report which contained all required documentation in this respect.
- (3) The marketing authorisation holder shall be required to submit to the Agency, without delay, an application for implementation of major amendments (amendments of the II type) to the marketing authorisation.
- (4) The Agency shall make a decision upon the application referred to in paragraph 3 of this article within 60 days after the receipt of a complete application; it shall be made in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (5) The timeframe from paragraph 4 of this article shall be deferred from the date when the Agency makes a request for any additional information or explanation from the Proposer until the new requirements of the Agency shall be met.
- (6) Detailed content of the application or request, procedure and conditions for the amendment of the marketing of the medicinal product authorisation, as well as the form and content of the requested supporting documentation shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency. Classification of amendments shall be proscribed by the Professional Board upon the recommendation by the Agency Director.

#### **Article 45**

#### **Cost of processing the application**

Fees and payment terms regarding processing of the application for the marketing authorisation shall be decided by the Council of Ministers upon the recommendation by the Agency Director and all incurring costs shall be borne by the applicant.



## **C. Testing of medicinal products**

### **Article 46 Testing of medicinal products**

- (1) Prior to its marketing, a medicinal product shall be analytically (pharmaceutically-chemically-biologically-microbiologically), pharmacologically-toxicologically and clinically tested, and its quality, safety and efficacy confirmed.
- (2) For the purpose of obtaining any additional information about the medicinal product or about the control of the medicinal product, the medical product may be additionally analytically (pharmaceutically-chemically-biologically-microbiologically), pharmacologically-toxicologically and clinically tested even after the marketing authorisation had been issued.

### **Article 47 Authorisation for testing of medicinal products**

- (1) Analytical testing of medicinal products (pharmaceutical-chemical-biological-microbiological testing), pharmacological-toxicological and clinical testing of medicinal products can be performed by legal entities meeting the criteria of adequate premises, equipment and human resources, as well as any other requirements and good practice principles.
- (2) Criteria to be met by legal entities responsible for the analytical, pharmacological-toxicological and clinical testing of medicinal products, as well as the procedure of their verification, shall be proscribed by the Professional Board upon the recommendation by the Agency Director.
- (3) Good practice regulations (on good laboratory/control laboratory/clinical/distributing/storage practice) as well as regulations regarding testing of bioequivalence and bioavailability shall be adopted by the Professional Board upon the recommendation by the Agency Director.
- (4) The Agency shall issue a testing authorisation in relation to paragraph 1 of this Act to the applicant in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (5) Authorisations referred to in paragraph 4 of this article shall be published, on the applicant's expense, in the «Official Gazette of B-H».

### **Article 48 Analytical testing of medicinal products**

- (1) Analytical testing of medicinal products, or pharmaceutical-chemical-biological-microbiological testing shall be performed in accordance with the application for a marketing of medicinal products authorisation.
- (2) Procedure for the analytical testing of the medical product, described in the documentation supporting the application for the marketing authorisation, must comply with the current scientific and technological advancements and principles of good laboratory practice.
- (3) The documentation for performing the analytical testing of the medicinal product shall refer to the European pharmacopoeia, Pharmacopoeia of B-H, or pharmacopoeia which is valid in a country – member of EU; or it shall contain detailed description of methods, equipment and any other necessary information regarding the testing which must be sufficiently detailed and clearly written to enable repeat analysis and comparison of results obtained.



- (4) Further detail regarding methods of analytical (pharmaceutical-chemical-biological-microbiological) testing of medicinal products shall be adopted by the Professional Board upon the recommendation by the Agency Director.

#### **Article 49**

##### **Pre-clinical testing of medicinal products**

- (1) Pharmacological-toxicological or pre-clinical testing of medicinal products shall be performed by determining safety of medicinal products, performed in accordance with principles of good laboratory practice.
- (2) Procedure of the pharmacological-toxicological testing of the medicinal product, described in the documentation supporting the application for a marketing authorisation, must comply with the current scientific and technical advancements and principles of good laboratory practice.
- (3) The documentation for performing the pharmacological-toxicological testing of the medicinal product must contain detailed descriptions of methods, equipment and any other necessary information regarding the testing, which must be sufficiently detailed and clearly written to enable repeat procedure of pharmacological-toxicological testing and comparison of results obtained.
- (4) The pharmacological-toxicological testing must determine pharmacodynamic, pharmacokinetic and toxic characteristics of the medicinal product which have been detected on animals in controlled laboratory environment and predict any possible effects of such products on humans.
- (5) Any additional regulations regarding methods of the pharmacological-toxicological testing shall be adopted by the Professional Board upon the recommendation by the Agency Director.

#### **Article 50**

##### **Clinical testing of medicinal products**

- (1) Clinical testing shall be performed by testing a medicinal product on both healthy and sick individuals with the aim to find or confirm clinical, pharmacological, pharmacodynamic or pharmacokinetic effects of the medicinal product which is being tested; detect adverse effects of the medicinal product, or research its absorption, distribution, metabolic reactions and excretion for the purpose of confirming safety and efficacy of the medicinal product. The clinical testing of the medicinal product shall include its bioequivalence as well as bioavailability.
- (2) Procedure for the analytical testing of the medical product, described in the documentation supporting the application for a marketing authorisation, must comply with the current scientific and technological advancements and principles of good clinical practice in clinical trials and medical ethics. Results of the clinical testing must include results obtained from any available clinical testing of the medicinal product, be it positive or negative.
- (3) The documentation referring to the clinical testing of the medicinal product must contain detailed testing results, sufficiently detailed and objectively described, to enable making an objective evaluation of the ratio between the benefits and risks for the patient, an assessment of safety and efficacy of the medicinal product, and a recommendation whether the medicinal product fulfills the requirements for issuing the marketing authorisation.

#### **Article 51**



## **Conditions for clinical testing of a medicinal product**

Clinical testing of a medicinal product shall be performed only under condition that positive results have been obtained during the pharmacological-toxicological testing.

### **Article 52**

#### **Reporting of clinical testing**

- (1) Prior to commencement of clinical testing of the medicinal product, the Proposer of the clinical testing of the medicinal product who has not yet obtained a marketing authorisation shall be deemed to lodge an application with the Agency for permission to perform the clinical testing.
- (2) The applicant for the clinical testing of the medicinal product who has already obtained the marketing authorisation for B-H shall be required to report the clinical testing to the Agency.
- (3) The Proposer and the applicant for the clinical testing may be the sponsor of the clinical testing or may be the principal researcher on their behalf.
- (4) Prior to commencement of the clinical testing, a legal entity performing the clinical testing of the medicinal product and the sponsor of the clinical testing shall be deemed to insure their liability for potential damages to the participant in the testing which might be caused by the clinical testing.
- (5) The clinical testing of the medicinal products cannot be financed from the compulsory health insurance funds.

### **Article 53**

#### **Processing an application for the clinical testing procedure**

- (1) Within 60 days at latest after receipt of a complete application for permission for testing the medicinal product for which a marketing authorisation has not yet been issued, the Agency shall be required to make a decision on granting the permission, or rejecting the application for permission for clinical testing; the decision shall be based upon the recommendations provided by the Committee for the clinical testing relating to: purposefulness of the clinical testing, validity of the supporting documentation, ethical evaluation, protection of rights of participants in the clinical testing and adhering to the good clinical practice principles.
- (2) The timeframe from paragraph 1 of this article shall be deferred from the date when the Agency makes a request to the Proposer for any additional information or explanation until the new requirements of the Agency shall be met.
- (3) The Agency shall decide whether to issue a permission or reject the application for the clinical testing in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.

### **Article 54**

#### **Procedure following the application for the clinical testing with an existing marketing authorisation**

- (1) Within 30 days of the receipt of a complete application for the clinical testing with an existing marketing authorisation for B-H, the Agency shall be required to advise the Proposer about the reasons for rejecting the proposed clinical testing.





- (2) The rejection of the application for performing of the clinical testing referred to in paragraph 1 of this article shall be issued in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (3) The timeframe from paragraph 1 of this article shall be deferred from the date when the Agency makes a request for any additional information or explanation until the new requirements of the Agency shall be met.
- (4) In case that the applicant does not receive a negative response from the Agency within 30 days, they may commence with the clinical testing of the medicinal product.

#### **Article 55**

#### **Temporary or permanent discontinuation of the clinical testing of a medicinal product**

In order to protect public health, the Agency shall be entitled to impose a decision on temporary or permanent discontinuation of the clinical testing of a medicinal product.

#### **Article 56**

#### **Cost of the clinical testing and the cost of processing the application**

- (1) Expenses related to the clinical testing and processing the application for approval of the clinical testing shall be borne by the proposer, or the applicant for the clinical testing.
- (2) In case that the Agency, or Department of Health of either Entity, or Department of Health of Brcko District, or another state or entity ministerial or legal entity, requires the clinical testing for the purpose of protection of public health, any expenses related to such testing shall be borne by the proposer of the clinical testing only if it is proven that the safety or efficacy of the medicinal product is in accordance with the Act or legislation derived therefrom.
- (3) If it has been proven that the safety or efficacy of the medicinal product referred to in paragraph 2 of this article is contrary to this Act and legislation derived therefrom, then any expenses related to the clinical testing shall be borne by the marketing of the medicinal product authorisation holder or the medicinal product manufacturer.
- (4) Detailed regulations regarding the necessary documentation and the procedure for applying for or registering for the clinical testing of the medicinal product, the requirements to be met by legal entities legitimate to perform clinical testing, as well as the procedure related to their verification, supervision of the clinical testing, and conditions stipulated by the Agency imposing a temporary or permanent discontinuation of the clinical testing of the medicinal product, shall be proscribed by the Minister of Civil Affairs, upon the recommendation by the Professional Board of the Agency. The cost related to the approval to perform the clinical testing shall be proscribed by the Council of Ministers upon the recommendation by the Agency Director.

#### **D. Manufacturing of medicinal products**

#### **Article 57**

#### **Manufacturing of medicinal products**

- (1) Manufacturing of medicinal products includes a complete process or some parts of the process involving pharmaceutical-technological manufacturing of a finished medicinal product, including: manufacturing or purchasing the substance, technological processing, packaging, control of the quality, storage and distribution of the product.



- (2) Manufacturer of the medicinal product is a legal entity responsible for manufacturing, development, quality assurance, packaging and labelling of the medicinal product, irrespective of whether they have produced it or a third party has produced it on their behalf.
- (3) Manufacturer of the medicinal product shall be permitted to manufacture only the medicinal products for which an authorisation has been obtained covering either the manufacturing procedure as a whole, or the parts of it.
- (4) Legal entities referred to in paragraph 2 of this article may manufacture medicinal products only under condition that they have obtained the manufacturing of medicinal products authorisation.

#### **Article 58**

##### **Application for a manufacturing authorisation**

- (1) An application for a manufacturing authorisation on the territory of B-H shall be lodged with the Agency, separately for each pharmaceutical form and for each production plant.
- (2) Within 90 days of the receipt of a complete application, the Agency shall be required to issue the authorisation or reject the application for manufacturing of medicinal products on the territory of B-H.
- (3) The authorisation referred to in paragraph 2 of this article includes the right to sell such medicinal products to wholesale marketing of medicinal products authorisation holders. The authorisation shall be issued in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (4) The timeframe from paragraph 2 of this article shall be deferred from the date when the Agency makes a request for any additional information or explanation to the applicant for the manufacturing authorisation until the new requirements of the Agency shall be met.
- (5) The Agency shall issue the manufacturing authorisation on the territory of B-H based on the assessment of the manufacturer's compliance with the good manufacturer's practice and that the following conditions have been met:
  - a) That the applicant has adequate premises, equipment and qualified personnel for manufacturing, testing and quality control, suitable for the intended quantities and requirements of manufacturing as well as conditions for storage and distribution of medicinal products;
  - b) That a person in charge of manufacturing has been employed on a full time basis, holds a university degree in pharmaceutical or pharmaceutical-technical discipline (pharmaceutical engineering or pharmaceutical technology), with additional knowledge and skills necessary for supervision of preparation, manufacturing and storage of medicinal products during all production stages;
  - c) That a person in charge of release of medicinal product batches has been employed on a full time basis, holds a university degree in pharmacy and has additional knowledge and skills for testing medicinal products, and who shall be available at all times;
  - d) That a person in charge of pharmacovigilance has been employed on a full time basis, holds a university degree in either pharmacy or medicine and has additional knowledge and skills in the area of clinical pharmacy and clinical pharmacology;
  - e) That the quality system has been implemented in accordance with the good manufacturer's practice.
- (6) Compliance with requirements defined in paragraph 5, Clauses a) b) c) and d) of this article shall be established by the relevant Department of Health in either Entity, or Department of Health of Brcko District. Decision issued by the responsible Department of Health in either Entity shall certify that the



requirements have been fulfilled regarding: characteristics of the premises, equipment and personnel responsible for manufacturing, testing and quality control suitable for the intended quantities and requirements of intended manufacturing, storage and distribution of medicinal products; as well as the name of the person in charge of manufacturing and storage of medicinal products in all stages of production, and the name of the person in charge of release of medicinal product batches who shall be available for different types of control.

- (7) Decision defined in paragraph 6 of this article is the condition which applies for registration of the business entity with the relevant court, as well as the condition for the Agency to issue the manufacturing authorisation.
- (8) The responsible Agency employee (GMP inspector) shall establish whether the requirements have been fulfilled by carrying out the inspection on site; the requirements comprise of the system of quality assurance complying with good manufacturing practice as defined in paragraph 5, clause e) of this article.
- (9) All necessary documentation, the application for a manufacturing authorisation procedure, requirements to be fulfilled by legal entities engaged in manufacturing, and the process of their verification and supervision, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

#### **Article 59** **Expiry of manufacturing authorisation**

- (1) The manufacturing authorisation shall be issued for a period of five years.
- (2) The authorisation from paragraph 1 of this article shall be revoked in case where the manufacturer of the medicinal product, without prior authorisation by the Agency, has changed conditions set for issuing the manufacturing authorisation; or if they cease to comply with the requirements stipulated by this Act and legislation derived therefrom.
- (3) Regarding any changes in the manufacturing authorisation in view of conditions defined in article 58, the manufacturing authorisation holder shall be required to report them to the Agency in the relevant Department of Health of Federation of B-H, or RS, or Department of Health of Brcko District.

#### **Article 60** **Manufacturer's responsibility**

The manufacturer of the medicinal product shall be responsible for its quality, safety and efficacy under condition that the medicinal product has been used in a proscribed manner.

#### **Article 61** **Inspection control**

The manufacturer of medicinal products shall be required to make possible the inspection control be carried out on the request by the Agency.

#### **E. Distribution of medicinal products**

#### **Article 62** **Distribution of medicinal products**

- (1) Distribution of medicinal products shall be carried as wholesale and retail.



- (2) Retail of medicinal products shall be proscribed by legislation adopted by Entities, or Breko District, in accordance with this Act.

### **Article 63**

#### **Wholesale distribution and A wholesale distribution authorisation**

- (1) Wholesale distribution includes: supply, storage, transportation and marketing of medicinal products, including their import and export.
- (2) Wholesale distribution may be carried out only by legal entities authorised by the Agency and holding a distribution authorisation.
- (3) Legal entities carrying out the wholesale distribution of medicinal products shall market the medicinal products only to legal entities and private persons holding a wholesale or retail distribution authorisation.

### **Article 64**

#### **Application for issue of a wholesale distribution authorisation**

- (1) An application for issue of a wholesale distribution of medicinal products authorisation on the territory of B-H shall be submitted to the Agency.
- (2) The Agency shall be required to issue the wholesale distribution authorisation on the territory of B-H within 60 days after the receipt of a complete application; it shall be made in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (3) The timeframe from paragraph 2 of this article shall be deferred from the date when the Agency makes a request to the applicant for the wholesale distribution authorisation for any additional information or explanation until the new requirements of the Agency shall be met.
- (4) The wholesale distribution authorisation shall be issued for a period of five years.
- (5) The Agency shall issue the wholesale distribution authorisation on the territory of B-H based on the assessment of the compliance with the good distributor and good storage practices, and that the following conditions have been met:
- That the applicant has adequate premises, equipment and qualified personnel for transportation, storage and wholesale distribution, suitable for the quantities and types of the distributed medicinal products and in accordance with the harmonised legislation on the territory of B-H;
  - That a person in charge of receiving and dispensing of medicinal products and checking documentation has been employed on a full time basis, holds a university degree in pharmacy, with additional knowledge and skills necessary for testing of medicinal products and who shall be available at all times;
  - That appropriate documentation is kept so that any momentaneous revoking of the medicinal products from shelves shall be made possible; also, follow up of any complaints regarding the medicinal products;
  - That quality control has been implemented;
  - That the applicant provides guarantee for a continuous and satisfactory supply of the medicinal products and, if necessary, a supply of the urgently needed medicinal products in the shortest possible time.



- (6) Besides requirements defined in paragraph 5 of this article, the Minister of Civil Affairs, upon the recommendation by the Professional Board of the Agency, may proscribe additional conditions for certain types of medicinal products.
- (7) Compliance with requirements defined in paragraph 5, Clauses a) and b) of this article shall be established by the relevant Department of Health in either Entity, or Department of Health of Brcko District. Decision issued by the responsible Department of Health in either Entity shall certify that the requirements have been fulfilled regarding: characteristics of the premises, equipment and personnel responsible for transportation, storage and wholesale distribution suitable for the quantities and type of distributed medicinal products, and the name of person in charge of receiving and dispensing of the medicinal products who shall be available for different types of control.
- (8) Decision defined in paragraph 7 of this article is the condition which shall apply for registration of a person/entity who intends to engage in the wholesale distribution at the relevant court, as well as the condition for the Agency to issue the wholesale distribution of medicinal products authorisation on the territory of B-H.
- (9) The responsible Agency employee shall establish whether the requirements have been fulfilled by carrying out the inspection on site; the requirements comprise of the system of quality assurance complying with good distribution practice or other requirements as defined in paragraph 5, clauses c), d) and e) of this article which are the prerequisites for the issue of the wholesale distribution authorisation.

#### **Article 65**

##### **Additional conditions for the wholesale distribution of medicinal products**

- (1) Besides articles 63 and 64 of this Act, legal entities engaged in the wholesale distribution of medicinal products, including import of medicinal products, shall be required to fulfill the following criteria:
  - a) Employ a person in charge of distribution of medicinal products who shall be responsible for quality control of each imported batch of medicinal products in accordance with the wholesale distribution of medicinal products authorisation;
  - b) Sign a contract with the authorised control laboratory for medicinal products.
- (2) All necessary documentation, the application for the wholesale distribution of medicinal products authorisation procedure, requirements to be fulfilled by legal entities engaged in the wholesale distribution of medicinal products, and the process of their verification and supervision, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency. The cost of the procedure shall be determined by the Council of Ministers upon the recommendation by the Agency Director.

#### **Article 66**

##### **Import of medicinal products**

- (1) For import of medicinal products for which the Agency has already issued a marketing authorisation in B-H, a separate import authorisation by the Agency shall not be required. The Agency shall notify Department of Foreign Trade and Economic Relations of B-H about the current marketing authorisations for the purpose of further actions to be taken by the Department.
- (2) An exception to the definition described in paragraph 1 of this article is that the importer of medicinal products shall be required to obtain an authorisation by the Agency to import medicinal products which may cause risks. The authorisation shall be issued in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.



- (3) Relevant authorities, ie. Department of Health of either Entity or Department of Health of Brcko District may give their permission for the import of medicinal products for which a marketing authorisation has not been issued in the following circumstances:
- a) To meet urgent individual patient's needs, upon the recommendation by a health care institution;
  - b) To allow an emergency import of limited quantities of medicinal products for which a marketing authorisation has not been issued but which are required for necessary protection of public health, upon the recommendation by a health care institution;
  - c) To import medicinal products required for scientific research.
- (4) Authorisation referred to in paragraph 3 of this article shall relate only to one-off import and shall be valid for one-off import only, regardless of whether the quantities approved have been imported only partially.
- (5) In case where the permission has been obtained granting import of medicinal products for which a marketing authorisation has not been previously issued, the relevant authorities, ie. Department of Health of either Entity or Department of Health Brcko District, shall be required to notify the Agency about it within 24 hours from the moment the permission has been granted.
- (6) In case the permission referred to in paragraph 3 of this article has been granted, the importer shall be required to submit a report to the Agency every three months, specifying details regarding the import and distribution of such medicinal products.
- (7) An exception to the definition referred to in paragraph 3 of this article is in case that the Council of Ministers of B-H declares a state of emergency, then the Agency may, upon the joint recommendation by Department of Health of either Entity and Department of Health of Brcko District, grant an import of medicinal products for which a marketing authorisation has not been granted previously, should such medicinal products be essential for prevention or dealing with the consequences of such an emergency.
- (8) Import of medicinal products in quantities needed for testing in the process of obtaining a marketing authorisation shall be granted by the Agency.
- (9) Minister of Civil Affairs upon the recommendation of Professional Board of the Agency and in accordance with the recommendation by the relevant Department of Health of either Entity and Department of Health of Brcko District shall proscribe all necessary documentation and procedure for applying for an import of medicinal products authorisation for which a marketing authorisation has not been issued by the Agency, as well as the procedure for obtaining a permission for import of medicinal products which may cause risks.

#### **Article 67**

##### **Expiry of the wholesale distribution authorisation**

The wholesale distribution authorisation shall expire if the authorisation holder has changed conditions upon which the authorisation had been issued, or no longer fulfills the requirements determined by this Act and legislation derived therefrom.

#### **Article 68**

##### **Marketing authorisation ban**

- (1) It is illegal to market products described as having medicinal properties which, according to this Act and legislation derived therefrom, have not been classified as medicinal products.



- (2) It is illegal to market medicinal products which have expired, or which have been proven of being of inadequate quality, safety or which have not been harmonised with the marketing authorisation or permission for an emergency import.
- (3) In case where it has been established that the medicinal products have been proven of inadequate quality, safety or which have not been harmonised with the marketing authorisation, the Agency shall urgently inform the responsible institutions via Department of Health of either Entity and Department of Health of Brcko District about the particular medicinal product and recommend the necessary measures to be taken.

**Article 69**  
**Handling medicinal products**

Legal entities and private persons, professional institutions and bodies which, within their line of business, or in any other capacity come in contact with medicinal products (ie. transporters, post office workers, customs officers) shall handle the medicinal products in accordance with the instructions provided by the orderer to avoid any deterioration of the medicinal product or its possible misuse.

**Article 70**  
**Retail of medicinal products**

- (1) Retail of medicinal products outside of pharmacies is not permitted. Legal entities engaged in the manufacturing and wholesale distribution of medicinal products shall not be permitted to engage in retail of medicinal products.
- (2) Legal entity or private persons dealing with retail of medicinal products may procure medicinal products only from manufacturers or wholesale distributors holding a manufacturing or distribution authorisation issued in accordance with this Act, and shall market only the medicinal products for which the marketing authorisation has been issued.

**F. Labelling of medicinal products**

**Article 71**  
**Labelling of medicinal products**

- (1) Medicinal products marketed and distributed in B-H must be labelled on the outer and immediate packaging, indicating basic information about the medicinal product in one of the official languages used in Bosnia and Herzegovina.
- (2) Information from paragraph 1 of this article may be provided in one or more foreign languages under condition that the content of the text is identical in each language.
- (3) Each packaging of medicinal product marketed in B-H must contain a package leaflet – information for patients – written in one of the official languages used in B-H and which is in accordance with the summary of main characteristics of the medicinal product, unless the necessary information has already been provided on the outer packaging.
- (4) The information for patients must contain basic information about the medicinal product (name, generic name, qualitative and quantitative composition, pharmaceutical form, strength and packaging form), about the manufacturer, the marketing authorisation holder, method of use, indications, contraindications, safety measures, posology and administration, adverse effects, expiry, storage and any other necessary information.



- (5) The outer packaging of the medicinal product must contain at least basic information about its characteristics (name, generic name, quantitative and qualitative composition of active substance, pharmaceutical form, strength and packaging form), about the manufacturer, the marketing authorisation holder, posology and method of use, method of storing, expiry, batch number, the marketing authorisation number and other identification codes, special warnings and any other necessary information.
- (6) The immediate packaging must contain at least basic information about the medicinal product (name, generic name, quantitative and qualitative composition of active substance, pharmaceutical form and strength), about the marketing authorisation holder, expiry date, batch number and any other necessary information if it is allowed by the size of the immediate packaging.
- (7) The manner of labelling medicinal products, the structure and content of the information in the leaflet for patients, instructions for disposing of the medicinal product in case of its malfunctioning or incompliance, as well as any specific rules for packaging and labelling of medicinal products to be used exclusively in health care facilities shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

## **G. Pharmacovigilance**

### **Article 72 Pharmacovigilance**

- (1) The marketing authorisation holder, medical personnel, or any other legal entity or private persons who during performing their duties discover undesirable effects of a medicinal product, or become suspicious about the medicinal product, shall be required to inform the Agency about it; the Agency shall keep a register of undesirable effects of medicinal products, perform analyses and respond to their findings in order to protect public health, in accordance with this Act and legislation derived therefrom.
- (2) The marketing authorisation holders shall be required to submit periodical reports about safety of medicinal products to the Agency in set periods of time, or upon the Agency's request.
- (3) The method and procedure of reporting the undesirable effects of medicinal products, the method of dealing with the findings, responsibilities of medical personnel, responsibilities of the marketing authorisation holder, the method of submitting and the content of the periodical reports as well as methods of organising pharmacovigilance, shall be proscribed by the Professional Board upon the recommendation by the Agency Director.

## **H. Reporting about medicinal products and advertising medicinal products**

### **Article 73 Reporting about medicinal products and advertising medicinal products**

- (1) Advertising medicinal products is any form of providing information about the medicinal products to encourage general public or professionals to prescribe, procure, market or use medicinal products.
- (2) Conditions and methods of advertising medicinal products to professionals, degree and discipline of education and other criteria to be met by any persons dealing with informing professionals as well as conditions and methods of advertising medicinal products which are available over the counter without medical prescription to general public shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

### **Article 74**





### **Advertising medicinal products to professionals**

- (1) Medicinal products are advertised to professionals by manufacturers and marketing authorisation holders in professional books, professional magazines and other professional publications, as well as by direct informing professionals involved in prescribing or dispensing of medicinal products.
- (2) Advertising prescription-only medicinal products to professionals shall be permitted only in view of providing information from the summary of main characteristics of the medicinal product, or from the conditions for its marketing.
- (3) Advertising prescription-only medicinal products to professionals may be effected by providing the professionals with only the smallest packaging of the medicinal product labelled as «free sample / not for sale».
- (4) The marketing authorisation holder, manufacturers, legal entities or private persons engaged in marketing of medicinal products, or legal entities or private persons dealing in such matters on their behalf or on behalf of their associations, must not offer any direct or indirect material benefits to the persons prescribing or dispensing of medicinal products.
- (5) The marketing authorisation holder, manufacturers, legal entities or private persons engaged in marketing of medicinal products, or legal entities or private persons dealing in such matters on their behalf or on behalf of their associations, may provide the persons prescribing or dispensing of medicinal products with the additional information about new medicinal products or about products which have already been marketed.
- (6) Dissemination of information from paragraph 5 of this article must be effected in such manner so that it shall not go beyond scientific-professional aims of such education, and so that it shall be organised to provide new information about medicinal products exclusively to professionals prescribing or dispensing of medicinal products.

### **Article 75**

#### **Advertising medicinal products to general public**

Marketing authorisation holders and manufacturers of medicinal products which may be dispensed without prescription are allowed to advertise medicinal products and their characteristics to general public, unless the Agency decides otherwise.

### **Article 76**

#### **Advertising ban**

- (1) It is illegal to advertise in public media to general public medicinal products which are classified as prescription-only.
- (2) An exception to the definition referred to in paragraph 1 of this article, shall be the case when, in order to protect public health safety and in emergencies (epidemics, natural disasters of greater range, state of war or other states of emergency), the Agency Director, upon the recommendation by the Professional Board, may give permission to advertising in public media for the purpose of informing the public about the use of specific medicinal products.
- (3) It is illegal to advertise to general public medicinal products by attributing non existing characteristics to the medicinal product, by exaggerating positive effects of the medicinal product, or by describing effects of the medicinal product inappropriately or in a headline-grabbing manner, or in any other manner which may mislead users of the medicinal product.



- (4) It is illegal to address children directly when advertising medicinal products.
- (5) It is illegal to give out free samples of the medicinal product to general public.
- (6) It is illegal to advertise medicinal products for which a marketing authorisation has not been issued.

#### **Article 77**

##### **The method of informing professionals about marketed medicinal products**

- (1) The Agency shall inform professionals about medicinal products for which a marketing authorisation has been issued by:
  - a) Publishing the information in the official gazettes of B-H, Federation of B-H, RS and Brcko District at least once in three months;
  - b) Publishing the Register of Medicinal Products of B-H so that the register may become accessible to professionals;
  - c) Publishing the information in the medicinal products database.
- (2) The Agency and/or Departments of Health of Entities and Department of Health of Brcko District may inform the public in public media about medicinal products and activities taken in that respect should it be necessary to protect public health safety.

#### **I. Quality control of medicinal products**

#### **Article 78**

##### **Quality control of medicinal products**

- (1) Quality control of medicinal products is performed by establishing whether the quality of medicinal product complies with conditions upon which the marketing authorisation has been issued.
- (2) Quality control of medicinal products is performed in accordance with European pharmacopoeia, Pharmacopoeia of B-H, or any other recognised pharmacopoeia, by methods of analysis provided by manufacturer and described in detail, or by any other proven methods of analysis.

#### **Article 79**

##### **Types of quality control of medicinal products**

- (1) Quality control of medicinal products carried out by the Control Laboratory of the Agency shall be:
  - a) Regular quality control of all medicinal products marketed in B-H, which is performed at least once in five years;
  - b) Quality control of the first batch of medicinal product prior to its marketing and also during the renewal and variations which require the quality control;
  - c) Quality control of each batch of manufactured or imported medicinal product or substance;
  - d) Special quality control, or the quality control performed upon request by the Agency, either during the application for the marketing authorisation process, or after the marketing authorisation has been issued;
  - e) Specific quality control, or the quality control of each batch of medicinal products which may cause risks or any other specific categories of medicinal products.



- (2) An exception to the definition referred to in paragraph 1 of this article, is the quality control from clause c) of this article which may be carried out by a laboratory which has been authorised or recognised as competent for carrying out such tasks by the Agency.
- (3) In case where the quality control referred to in paragraph 1 clause c) of this article is carried by the Control Laboratory of the Agency, the manufacturer/importer shall be required to provide the Agency with a sample prior to placing the product on the market, and the timeframe for carrying out the quality control is within 30 days.
- (4) In case where the quality control referred to in paragraph 1 clause c) of this article is carried out by an authorised, or a recognised laboratory, the manufacturer/importer shall be required to provide the Agency with the sample and the findings of the completed quality control.
- (5) The method of quality control as defined in paragraph 1 which shall be carried out by the Control Laboratory of the Agency shall be proscribed in further detail by the Professional Board upon the recommendation by the Director.

### **Article 80**

#### **Implementation of the quality control of medicinal products**

- (1) The quality control of medicinal products shall be performed by the Control Laboratory of the Agency, or an authorised laboratory, upon the recommendation by:
  1. The Agency;
  2. Importer;
  3. Legal entity engaged in the wholesale distribution;
  4. Marketing authorisation holder.
- (2) The authorised laboratory shall notify the Agency, the orderer and the marketing authorisation holder, or issue a certificate about the findings of the quality control of medicinal products.
- (3) Based on the established quality control, the Agency may revoke already issued marketing authorisation of medicinal product, ban distribution of a specific batch of medicinal product, or request implementation of changes, should it be proven that:
  - a) The medicinal product, if used as instructed, is detrimental for health;
  - b) The medicinal product does not comply with the declared characteristics by its qualitative and quantitative composition, and
  - c) The quality analysis findings do not correspond to any other requirement or obligation in regards to issuing of the marketing of medicinal product authorisation.
- (4) Conditions, circumstances and procedure of engaging authorised laboratories for the purpose of quality control, as well as methods of keeping records of quality controls performed following the described method, shall be proscribed by the Professional Board upon the recommendation by the Agency Director.

### **Article 81**

#### **Exemption of medicinal products for the quality control purpose and the cost of the quality control**

- (1) Manufacturers of medicinal products, marketing authorisation holders, and legal entities engaged in marketing of medicinal products shall be required to allow the Agency exemption of necessary quantities of medicinal products for the purpose of quality control in accordance with article 79 of this Act.



- (2) The cost of the quality control of medicinal products referred to in article 79, paragraphs a), b), c), and e) of this Act shall be borne by the marketing of medicinal products authorisation holder.
- (3) The cost of quality control referred to in article 79, paragraph d)) of this Act shall be borne by the Agency.
- (4) Exempt from paragraph 3 of this article, in case where it has to be proven that the quality of medicinal product does not comply with conditions upon which the marketing authorisation has been issued, the cost of quality control of medicinal product shall be borne by the marketing authorisation holder.
- (5) Methodology of forming the cost of analytical testing of medicinal products for the purpose of quality control shall be proscribed by the Council of Ministers upon the recommendation by the Agency Director.

## **J. Availability of medicinal products**

### **Article 82**

#### **A list of essential medicinal products**

In order to enable protection of basic public health care in the area of medicinal products, manufacturers and legal entities engaged in the wholesale distribution of medicinal products shall be required to have a supply of a determined quantity of essential medicinal products available in order to enable better availability of medicinal products to citizens.

### **Article 83**

#### **Establishing the list of essential medicinal products**

- (1) Every two years, at least, the Council of Ministers, upon the recommendation by the Professional Board of the Agency, with prior consent obtained from responsible Departments of Health of Entities and Department of Health of Brcko District, shall establish a list of essential medicinal products in Bosnia and Herzegovina.
- (2) Medicinal products from the list of essential medicinal products in B-H represent the minimum of medicinal products which shall be prescribed and dispensed at the expense of compulsory health insurance funds, as well as the minimum of medicinal products which shall be used in hospital health care.
- (3) The list of medicinal products referred to in paragraph 1 of this article shall be published in the official gazettes of Bosnia and Herzegovina, Federation of Bosnia and Herzegovina, RS and Brcko District.

### **Article 84**

#### **Pricing of medicinal products**

- (1) In order to ensure better availability and supply with the medicinal products in B-H, the Council of Ministers, upon the recommendation by the Agency Director and with the prior recommendation provided by the Professional Board, shall control the prices of the medicinal products by one of the following methods:
  - a) By establishing minimum and maximum values of wholesale and retail margins on prices of medicinal products, and/or
  - b) By establishing a maximum price of medicinal products by comparative and/or referential cost of medicinal products based on pharmaco-economic studies or other parameters.
- (2) Method of price control, or method of forming prices of medicinal products, as well as the method of reporting about the cost of medicinal products as referred to in paragraph 1 of this article, shall be



proscribed in further detail by the Council of Ministers upon the recommendation by the Agency Director, with prior advice by the Professional Board.

**Article 85**  
**Medicinal products of humanitarian aid origin**

- (1) Medicinal products of humanitarian aid origin may be imported and used in Bosnia and Herzegovina only after consent by relevant Departments of Health of Entities and Department of Health of Brcko District has been provided.
- (2) Medicinal products referred to in paragraph 1 of this article shall not be subject to marketing.
- (3) Each individual packaging of the medicinal product described in paragraph 1 of this article must contain clear and permanent mark that the medicinal product is of humanitarian aid origin and that it is free of charge.

**Article 86**  
**Granting import of medicinal products of humanitarian aid origin**

While making decisions on granting import of medicinal products of humanitarian aid origin, relevant Departments of Health of Entities and Department of Health of Brcko District shall give priority to medicinal products from the list of essential medicinal products in B-H, or the list of essential medicinal products provided by World Health Organisation.

**Article 87**  
**Conditions for import of medicinal products of humanitarian aid origin**

- (1) In order to obtain an authorisation for import of medicinal products of humanitarian aid origin, the following conditions must be met:
  - a) Specification for each individual medicinal product with the information about its INN and trademark of the name/names of the medicinal product, quantities and expiry of the medicinal product must be provided;
  - b) Reason why the offered quantities and types of medicinal products are a necessity for the health care;
  - c) That the expiry date falls at least a year later;
  - d) Manufacturer's certificate on quality control of the medicinal product must be provided, unless in exceptional circumstances.
- (2) Regulatory provisions regarding the import of medicinal products of humanitarian aid origin shall apply in the same way as for the import of medical devices of humanitarian aid origin.

**Article 88**  
**Procedure of handling the medicinal products imported contrary to the regulations of this Act**

Medicinal products of humanitarian aid origin, transported to Bosnia and Herzegovina contrary to the regulations of this Act, shall be returned to the supplier, or destroyed at their expense.

**Article 89**  
**Supervision of medicinal products and medical devices of humanitarian aid origin**

Relevant Departments of Health of Entities and Department of Health of Brcko District shall be required to ensure supervision over equipment, storage and distribution of medicinal products and medical devices of humanitarian aid origin.



**Article 90**  
**Administration of medicinal products in health care facilities**

- (1) Medicinal products shall be administered to patients in ambulatory outpatients primary health care clinics and other health care facilities (hereinafter referred to as: outpatient clinics, hospitals and hospital departments).
- (2) Outpatient clinics, hospitals and hospital departments shall be supplied with medicinal products from pharmacies or hospital pharmacies.

**Article 91**  
**Medicinal products which may be kept in health care facilities**

- (1) In outpatient clinics, hospitals and hospital departments, only medicinal products required for treatment of patients in accordance with the services of health care facility may be kept.
- (2) Outpatient clinics, hospitals and hospital departments are not permitted to dispense medicinal products to patients.

**Article 92**  
**Conditions for storage and administration of medicinal products**

- (1) In the outpatient departments, hospitals and hospital departments, conditions regarding premises, equipment and personnel qualified for storage and administration of any medicinal products used in the facility must be met.
- (2) Further detail of conditions referred to in paragraph 1 of this article shall be proscribed by Department of Health of either Entity and Department of Health of Brcko District.

**Article 93**  
**Pharmaceutical waste**

- (1) It is illegal to market incompliant medicinal products.
- (2) The medicinal product shall be considered incompliant in the following circumstances:
  - a) Expiry date has passed;
  - b) Organoleptic characteristics of the medicinal product have been changed (appearance, colour, taste, smell);
  - c) Outer or immediate packaging has been damaged;
  - d) Laboratory quality control has established that the medicinal product does not comply with the proscribed quality;
  - e) The medicinal product has been revoked for any other reason.
- (3) Incompliant medicinal products referred to in paragraph 2 of this article shall be considered pharmaceutical waste.

**Article 94**  
**Disposing of the pharmaceutical waste**

- (1) The pharmaceutical waste shall be disposed of in the manner which shall not jeopardize lives and health of people and their environment.
- (2) Disposal of the pharmaceutical waste shall be effected in the manner, instructed by the manufacturer, which has been accepted during the process of issuing a marketing of medicinal products authorisation.



- (3) Further detail regarding acceptable methods of disposal of the pharmaceutical waste, as well as the content of instructions for disposing of the pharmaceutical waste, issued by the manufacturer, and categories of waste, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

**Article 95**  
**Cost of disposing of the pharmaceutical waste**

Cost of disposing of the pharmaceutical waste shall be borne by the owner of pharmaceutical waste, or a legal entity or private persons with whom the pharmaceutical waste has been found.

**IV – MEDICAL DEVICES**

**Article 96**  
**Medical devices**

- (1) Medical devices in view of this Act are: instruments, devices, materials and other products including any software necessary for their proper application, used on people, and which do not perform their main function, set by the manufacturer, on the basis of pharmacological, immunological or metabolic activities, but are used alone or in combination, for the purpose of:
1. Diagnosing, preventing, monitoring, treating or alleviating causes or results of diseases;
  2. Diagnosing, monitoring, treating or alleviating injuries; alleviating disabilities or providing replacements or alleviating consequences caused by disability;
  3. Testing, replacing or modification of anatomical or physiological functions;
  4. Birth control.
- (2) In order to enhance its function, it is permitted that the medical device be supported by other substances demonstrating their pharmacological, immunological or metabolical functions.

**Article 97**  
**Main type - *In vitro* medical devices**

*In vitro* diagnostic medical devices are such medical devices which include: reagents, reagent kits, reagent products, materials for control and calibration, instruments and apparatuses, equipment or system used on their own or in combination; they are intended for use in *in vitro* conditions for testing biological samples, including samples of human tissues, necessary for obtaining information about:

1. Physiological or pathological conditions;
2. Congenital abnormalities;
3. Compatibilities with potential acceptors;
4. The data required for monitoring of therapeutic procedures.

**Article 98**  
**Other types of medical devices**

Medical devices also include:

1. Products intended by the manufacturer for use in combination with other medical devices which enable its use;



2. Products intended for individual patients which have particular construction properties and have been made, in accordance with written instructions, by an expert skilled in that area;
3. Products intended for clinical testing.

#### **Article 99**

#### **Different classifications of medical devices**

- (1) According to the degree of risk to their users, medical devices are classified as follows:
  1. Class I – medical devices presenting a low degree of risk for their users;
  2. Class II-a – medical device presenting a higher degree of risk for their users;
  3. Class II-b – medical devices presenting a high degree of risk for their users;
  4. Class III – medical devices presenting the highest degree of risk for their users.
- (2) According to their nature, dependence on energy sources and other properties, medical devices are classified as:
  1. Non-invasive;
  2. Invasive;
  3. Active.
- (3) According to the length of time needed for their application on humans, medical devices are classified as:
  1. Transitory, which are constantly applied for the period of less than 60 minutes;
  2. Short-term, which are constantly applied for up to 30 days;
  3. Long-term, which are constantly applied for more than 30 days.
- (4) *In vitro* diagnostic medical devices are classified as:
  1. *In vitro* diagnostic medical devices used exclusively by professionals and which are, according to the type of medical devices, classified as: list A and list B;
  2. *In vitro* diagnostic devices for self-diagnosing;
  3. Any other *in vitro* diagnostic devices.
- (5) According to the place and method of dispensing, the medical devices are classified as:
  1. Medical devices dispensed only on prescription/by order and only in pharmacies or shops specialising in retail of medical devices;
  2. Medical devices dispensed over the counter without prescriptions and only in pharmacies or shops specialising in retail of medical devices;
  3. Medical devices dispensed on prescription/by order in hospital pharmacies;
  4. Medical devices dispensed over the counter to general public.
- (6) If the medical device has been presented in combination with a medicinal product, or in combination with a product available for purchase by general public, then the classification is done in respect to its primary intended use as declared by the manufacturer.
- (7) Conditions and methods of classification of certain types of medical devices in view of this Act shall be proscribed in more detail by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

#### **Article 100**

#### **Basic requirements for medical devices – General and special requirements for medical devices**





- (1) Medical devices must conform with requirements regarding general safety of the product and comply with basic requirements classified as general and special ones.
- (2) Medical devices must comply with the following general requirements:
  - a) They have to be designed, manufactured, installed, maintained and used so that if used under proscribed conditions they perform in accordance with their intended purpose, without affecting health or safety of their users;
  - b) That during the process of their manufacturing, the quality assurance system regarding their design and manufacture has been observed.
  - c) Special requirements are those which must be met in accordance with the intended purpose of manufacturing of medical devices.
- (3) Detailed basic requirements, or general and special requirements which must be met by medical devices shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board.

**Article 101**  
**Conformity assessment of medical devices**

- (1) Conformity assessment of medical devices meeting general and special requirements in view of this Act is a procedure used to establish directly or indirectly whether a medical device meets the requirements of: General safety of products Act; Technical conditions for products and assessment of their conformity Act , in accordance with this Act and legislation derived from the aforementioned Acts.
- (2) Procedure of conformity assessment of medical device with general and special requirements shall depend on classification of the medical device in respect to the degree of potential risks, as follows:
  - a) For medical devices of Class I, the manufacturer shall assess on their own whether the medical device conforms with general and special requirements, and shall be responsible to provide a declaration of conformity, or a certificate at their own risk. Exception to this are medical devices intended for measuring as well as sterile products which shall be adjusted, which means that they shall be considered as medical devices of Class II or III for assessing of their ability to measure or of their sterile condition;
  - b) For medical devices of Classes II-a, II-b and III, conformity of medical device with the proscribed general and special requirements assessment, as well as quality assurance system supervision, shall be determined by authorised institutions.
- (3) In case that the conformity assessment of a certain type of medical devices is not performed by authorised institutions in view of Technical conditions for products and assessment of their conformity Act, then the assessment of their conformity shall be taken over by the Committee for medical devices in accordance with the authorisation provided by the Professional Board and upon recommendation by the Agency Director.
- (4) Requirements in view of conformity assessment of a certain type of medical devices with general and special requirements, based on the Act and subordinate legislation referred to in paragraph 1 of this article; marking of the medical device; and the content of the certificate on conformity of the medical device, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency, in accordance with the current legislation.
- (5) More detail regarding requirements to be complied with by professional institutions responsible for conformity assessment of certain types of medical devices, unless it has been under the authority of another



responsible state institution, shall be proscribed by the Minister of Civil Affairs upon the recommendation of the Professional Board of the Agency.

**Article 102**  
**Marking of medical devices**

- (1) Based on the conformity certificate, the manufacturer of medical device shall be required to mark their product by the proscribed conformity marking.
- (2) The conformity marking used in B-H and the content of the marking certificate issued in B-H shall be proscribed by the Department of Foreign Trade and Economic Relations of B-H, unless it has been stipulated differently by a separate Act.
- (3) An exception to paragraph 2 of this article is the condition when the manufacturer of medical devices, where the conformity assessment of general and special requirements has been determined by a body recognised by and in EU, shall mark the medical devices with a CE marking which has been recognised in B-H.
- (4) It is illegal to mark a medical device with markings referred to in this article should they not comply with the procedure referred to in article 101 of this Act, or with this Act, or with legislation derived from this Act or from the Acts referred to in article 101.

**Article 103**  
**Exemptions**

It shall not be deemed necessary to mark medical devices which are:

1. Intended for clinical trials;
2. Manufactured by order for an individual patient or user.

**Article 104**  
**Conditions for manufacturing of medical devices**

- (1) Besides adhering to general legislation, the manufacturer of medical devices shall fulfill the special requirements stipulated by this Act, which are:
  - a) The manufacturer shall register their activity prior to commencing manufacturing of medical devices;
  - b) Manufacturing activity shall have the quality assurance system and the protection of public health safety implemented;
  - c) The manufacturer shall employ a person in charge with at least level VI of medical education for medical devices of class I and II, and with level VII of medical education for medical devices of class III, who shall be responsible for monitoring and reporting about adverse effects and responding to them;
  - d) The manufacturer shall be insured against liability for potential damages caused to the user or third party.
- (2) Conditions related to criteria regarding the premises, equipment and personnel shall be proscribed by Entities or Brcko District in accordance with this Act.

**Article 105**  
**Technical procedure on conformity of medical devices**

- (1) During manufacturing of medical devices, the manufacturer shall apply technical procedures ensuring conformity of the medical device with its general and special requirements.



- (2) Regulations on basic or general and special requirements ensuring conformity of medical device or its safety, shall be proscribed by the Council of ministers upon the recommendation by the Agency.

**Article 106**  
**Registering manufacturing of medical devices**

- (1) Manufacturer of medical devices shall be required to submit to the Agency the documentation demonstrating that the medical device has been manufactured in such manner so that the quality assurance system and public health care safety have been implemented and that the medical devices have been manufactured in accordance with general and special requirements.
- (2) Manufacturer of medical devices shall be required to submit to the Agency the documentation specifying the design, quality control and the method of maintenance of the medical device.
- (3) Manufacturer of medical devices shall be required to report to the Agency and submit the documentation regarding any changes in the manufacturing procedure or specifications of the medical device, as well as to report any other data relating to public health.
- (4) In case where the medical device is manufactured in another country, supplier/importer of the medical device in B-H shall take the responsibility of the manufacturer.
- (5) Detailed content of the documentation referred to in paragraph 2 of this article, as well as the content and procedure for registering the activity of manufacturing of medical devices shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board. The cost of processing the application and registering the manufacturer of medical devices shall be proscribed by the Council of Ministers upon the recommendation of the Agency Director.

**Article 107**  
**Marketing of medical devices**

Marketing of medical devices includes wholesale and retail distribution, including import and export.

**Article 108**  
**Wholesale distribution of medical devices**

- (1) Wholesale distribution of medical devices includes procurement, storage, transportation and trade of medical devices, as well as their import and export.
- (2) It is illegal to distribute medical devices which do not conform with proscribed general and special requirements of the Technical conditions for products and assessment of their conformity Act derived from this Act, as well as legislation derived from these Acts; it is also illegal to market medical devices which have not been registered with the Registry of medical devices kept by the Agency.

**Article 109**  
**Conditions for the wholesale distribution of medical devices**

A legal entity engaged in the wholesale distribution of medical devices shall, besides general legal requirements, comply with special requirements stipulated by this Act. The legal entity shall be required to:

1. Register their activity with the Agency, prior to commencement of distributing medical devices. The Agency shall then process the application and keep the register of the legal entities engaged in the wholesale distribution of medical devices;
2. Perform their activity to ensure that the quality assurance system has been implemented and public health care safety observed;



3. Employ a person in charge with at least level VI of medical education, responsible for monitoring and reporting about adverse effects in the application of medical devices and responding to them, and who shall be responsible for materiovigilance;
4. Employ a person in charge of distribution of medical devices with adequate knowledge necessary for taking over such responsibility.

**Article 110**  
**Retail of medical devices**

Retail of medical devices includes procurement, storage, transportation and trade of medical devices.

**Article 111**  
**Conditions for retail of medical devices**

- (1) A legal entity or private persons engaged in retail of medical devices in shops specialising in medical devices trade shall be allowed to procure medical devices exclusively from wholesale traders of medical devices, or manufacturers registered in the Agency Registry, or shall be allowed to retail medical devices only upon condition that they have been registered with the Registry of medical devices with the Agency.
- (2) Conditions related to the criteria regarding the premises, equipment and personnel shall be proscribed by Entities or Brcko District.

**Article 112**  
**Registry of medical devices and Registry of manufacturers and wholesale traders of medical devices**

- (1) The Agency shall keep the Register of manufacturers and legal entities engaged in the wholesale trading of medical devices, as well as the Register of medical devices marketed in Bosnia and Herzegovina.
- (2) Content of the Register of manufacturers and legal entities engaged in the wholesale distribution of medical devices, as well as the content of the Register of medical devices marketed in B-H, and the accessibility to the Register, shall be proscribed by the Professional Board upon the recommendation by the Agency Director.
- (3) Content of documentation and the procedure of registering manufacturing and the wholesale distribution of medical devices and the procedure of their verification shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency. The cost of registering legal entities engaged in manufacturing and the wholesale distribution, and the cost of registering medical devices, shall be proscribed by the Council of Ministers upon the recommendation by the Agency Director.

**Article 113**  
**Labelling of medical devices**

- (1) Any medical device which is distributed in B-H must be labelled as such on the outside or immediate packaging in one of the official languages in use in Bosnia and Herzegovina, and must have instructions for use enclosed.
- (2) Packaging of medical device must contain at least the following information: information about the manufacturer or supplier; information needed for identification of the medical device and the content of the package; different markings, such as «sterile», «by order», «for one use only», «for clinical trial»; if necessary, it must have identification code, expiry date, instructions for storage, and, if necessary, special warnings or precautions measures, purpose, and any other detail concerning public health safety.



- (3) Instructions for use of the medical device must be written in one of the official languages in use in B-H and must contain, besides details referred to in paragraph 2 of this article, at least the information about any adverse effects on use, detailed instructions for installation and testing of the correct use, and any other information related to the medical device.
- (4) Content and the method of labelling the outer and immediate packaging of the medical device, as well as the content of the instructions for use leaflet, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Body of the Agency.

**Article 114**  
**Clinical testing of medical devices**

- (1) Clinical testing of medical devices means establishing or confirming safety of a medical device, its efficacy and conformity with general and special requirements in accordance with the intended use as determined by the manufacturer.
- (2) Clinical testing of medical devices cannot be performed at the expense of the compulsory health insurance fund.

**Article 115**  
**Procedure of clinical testing of medical devices**

- (1) Procedure of clinical testing of medical devices must comply with contemporary scientific-technical advancements and principles of good clinical practice in clinical research and medical ethics. Results of the clinical testing must combine results of any available clinical testing of the medical device, either positive or negative ones.
- (2) Documentation about the clinical testing of medical devices must contain results of the clinical testing which have been described in much detail and in an objective manner, sufficient for making an objective assessment of the ratio between the benefits and risks for the patient, assessment of the safety and efficacy of the medical device, as well as the statement whether the medical device complies with general and special requirements of this Act, and with its purpose as determined by the manufacturer.

**Article 116**  
**Liability insurance**

Prior to commencement of the testing, the legal entity performing the clinical testing of the medical device and the sponsor of the clinical testing shall insure their liability against any possible damages which might be caused to the participant or participants in the clinical trial.

**Article 117**  
**Registering of clinical testing of medical device**

- (1) Prior to commencement of clinical testing of the medical device on the territory of B-H, the intended clinical testing must be registered with the Agency.
- (2) An applicant for registration of the clinical testing can be the sponsor of the clinical testing, or, on their behalf, it can be the principal researcher in the clinical trial.

**Article 118**  
**Decision on the application to perform clinical testing of medical devices**



- (1) Should the applicant for registration of clinical testing of the medical device not receive a negative response by the Agency within 30 days from the application date, it shall be considered that they may commence with the clinical testing of the medical device.
- (2) Within at least 30 days from the receipt of a complete application for the clinical testing, the Agency shall be required to inform the applicant about the reasons for rejection of their application, in the form of a decision which is final in the administrative procedure, against which a complaint shall not be permitted; however, an administrative appeal may be initiated at the relevant court.
- (3) The timeframe from paragraph 2 of this article shall be deferred from the date when the Agency makes a request for any additional information or explanation from the applicant for the clinical testing until the new requirements of the Agency shall be met.

#### **Article 119**

#### **Temporary or permanent discontinuation of clinical testing of medical devices**

In order to protect public health safety, the Agency may order a temporary or permanent discontinuation of clinical testing and impose supervision over the clinical testing and adhering to good clinical practice in clinical testing in accordance with this Act and legislation derived therefrom.

#### **Article 120**

#### **The applicant for clinical testing of medical devices**

- (1) A manufacturer, or importer of the medical device can be the applicant for clinical testing.
- (2) Cost of the clinical testing and processing of the application for the clinical testing shall be borne by the applicant.
- (3) The Agency, or Department of Health of either Entity, or Department of Health of Brcko District, or another state or Entity Ministry or other legal entities, may request the clinical testing of the medical device for the purpose of protecting public health safety.
- (4) The cost of the clinical testing referred to in paragraph 3 of this article shall be borne by the proposer of the clinical testing only in case that it has been proven that safety, efficacy and conformity of the medical device with general and special requirements have been in accordance with stipulations of this Act and legislation derived therefrom.
- (5) Should it be proven that safety, efficacy and conformity of the medical device with general and special requirements are not in accordance with stipulations of this Act and legislation derived therefrom, then the cost of the clinical testing shall be borne by the manufacturer, or importer of the medical device.
- (6) Documentation required and the application for registering the clinical testing procedure, as well as conditions to be met by the legal entities authorised to perform the clinical testing of medical devices, as well as the procedure of their verification and supervision of the clinical testing, shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board. The cost of processing the application for the clinical testing of medical devices shall be proscribed by the Council of Ministers upon the recommendation of the Agency Director.

#### **Article 121**

#### **Materiovigilance**



- (1) Regulations referred to pharmacovigilance in paragraph 1 of article 72 of this Act shall apply respectively to medical devices, or the procedure of materiovigilance.
- (2) The method and procedure of reporting about the adverse effects during the application and use of medical devices, methods of appropriate response to such effects, responsibilities of medical personnel and suppliers, and the organisation of the system of monitoring the adverse effects during the application and use of medical devices and methods of appropriate response to such effects, or the system of materiovigilance, shall be proscribed by the Professional Board upon the recommendation by the Agency Director.

**Article 122**  
**Reporting about medical devices and their advertising**

- (1) Regulations in articles 73, 74, 75, 76 and 77 of this Act referring to advertising of medicinal products, shall apply respectively to medical devices
- (2) Conditions and methods of advertising medical devices to professionals, level of education and discipline and other conditions which are required to be met by the persons engaged in informing professionals, and conditions and methods of advertising medical devices to general public shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.

**Article 123**  
**Disposal of withdrawn medical devices**

- (1) Marketing of medical devices which have been withdrawn or out of order is not permitted.
- (2) Withdrawn medical devices shall be disposed of at the owner's expense, or at the expense of a legal entity or private persons who have been in possession of such medical devices.
- (3) Regulations from articles 93, 94 and 95 of this Act shall apply to the disposal of medical devices referred to in paragraph 1 of this article.

**V – PHARMACEUTICAL-INSPECTORIAL SUPERVISION**

**Article 124**  
**Pharmaceutical inspection and Inspection**

- (1) Pharmaceutical-inspectorial supervision over the implementation of this Act and legislation derived therefrom shall be performed by the pharmaceutical inspection, or the inspection formed within the Agency.
- (2) Duties of the pharmaceutical inspection, or inspection referred to in paragraph 1 of this article shall be performed by pharmaceutical inspectors or the Agency inspectors (hereinafter referred to as: the pharmaceutical inspector/inspector).
- (3) Methods of supervision referred to in paragraph 1 of this article shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Agency Director.
- (4) Pharmaceutical-inspectorial supervision of medicinal products and medical devices shall be determined by legislation in Entities or Brcko District.

**Article 125**  
**Pharmaceutical inspector**



- (1) Duties of a pharmaceutical inspector can be carried out by an individual who meets the following criteria: tertiary education in pharmacy, passed professional skills examination, three years of relevant professional experience, passed professional skills examination for duties of a pharmaceutical inspector, and an active command of the English language.
- (2) The program for sitting for a special professional examination for a pharmaceutical inspector, the composition of the panel of examiners, and the form of examination shall be proscribed by the Minister of Civil Affairs upon the recommendation by the Professional Board of the Agency.
- (3) In accordance with article 15 of this Act, the Professional Board may, should the need arise, engage eminent experts from the area of pharmacy, medicine or dental surgery, or other professional institutions, for the purpose of executing specific actions of importance for carrying out duties of pharmaceutical-inspectorial supervision (expert opinion, professional-medical testing, analyses, etc.) in case where the Agency does not meet professional, technical or any other requirements.

### **Article 126**

#### **Authorities of pharmaceutical inspector in the area of medicinal products**

In exercising pharmaceutical-inspectorial supervision in the area of medicinal products, the pharmaceutical inspector shall have the right and duty, besides measures stipulated in the Market supervision in B-H Act (published in «The Official Gazette of B-H», issue 45/04), to recommend initiating of a penal procedure for misdemeanor, or order and take action in the following circumstances:

- a) Temporarily suspend manufacturing, testing and marketing of medicinal products which fail to meet the proscribed authorisation requirements, or which jeopardize public health safety;
- b) Temporarily suspend manufacturing of a medicinal products or a particular batch which does not meet the proscribed authorisation requirements, or any other requirements stipulated by this Act;
- c) Temporarily suspend the work of a legal entity in case where there is no adequate quality assurance of medicinal product;
- d) Temporarily suspend the work of a legal entity in case where there is no liability insurance for potential damages caused by the medicinal products to the medicinal products users ;
- e) Carry out sampling of medicinal products for the purpose of executing quality control referred to in articles 79 and 81 of this Act;
- f) Ban marketing of incompliant medicinal products and order their appropriate disposal;
- g) Order temporary withdrawal of medicinal products or a particular batch from the market, where there is a suspicion that the medicinal products do not meet the proscribed quality requirements, until it has been finally determined by the Agency;
- h) Seize (confiscate) medicinal products manufactured or marketed by legal entities not holding an authorisation issued by the Agency, and which have been the case of a misdemeanor or criminal offence;
- i) Ban marketing of a medicinal product or a particular batch which fails to meet the labelling requirements of this Act;
- j) Ban advertising of medicinal products which fail to adhere to the requirements of this Act;
- k) Ban the legal entity from running business which fails to meet the requirements of this Act in respect to the organisation of business within the stipulated timeframe, or where the business is operated without the necessary authorisation by the Agency;
- l) Declare that the medicinal product, which has been found incompliant, be pharmaceutical waste and order its disposal;
- m) Order that the incompliances or shortcomings that have been detected be corrected within a given timeframe;
- n) Prohibit carrying out actions which are contrary to this Act and legislation derived therefrom;
- o) Order taking other measures as authorised by inspectorial rights and duties stipulated by this Act and legislation derived therefrom.





**Article 127**  
**Authorities of pharmaceutical inspectors in the area of medical devices**

In exercising pharmaceutical-inspectorial supervision in the area of medical devices, the pharmaceutical inspector shall have the right and duty, besides measures stipulated in the legislation governing market supervision, to recommend initiating of misdemeanor penalty procedure, or order and take action in the following circumstances:

- a) Carry out supervision over system of quality control of manufacturing of medical devices and, should the need arise, over the premises of the supplier or another contractual partner of the manufacturer;
- b) Order carrying out of suitable testing and checking of medical devices after marketing or prior to commencement of their use for the purpose of assessing their conformity with this Act and legislation derived therefrom;
- c) Carry out sampling of medical devices and order carrying out of assessing their conformity with the stipulated requirements;
- d) Temporarily suspend manufacturing, testing and marketing of medical devices which fail to meet the proscribed authorisation requirements, or which jeopardize public health safety;
- e) Temporarily suspend marketing of medical devices which fail to meet labelling or marking requirements stipulated by this Act and legislation derived therefrom;
- f) Temporarily suspend marketing of medical devices which fail to meet the requirements, or in other circumstances as stipulated by this Act;
- g) Temporarily suspend the work of a legal entity in case where there is no adequate quality assurance of the medical device;
- h) Temporarily suspend the work of a legal entity in case where there is no liability insurance for potential damages caused by the medical device to its users;
- i) Seize (confiscate) medical devices manufactured or marketed by legal entities not holding an authorisation issued by the Agency, and which have been the case of a misdemeanor or criminal offence;
- j) Ban advertising of medical devices which fail to adhere to the requirements of this Act;
- k) Ban the legal entity from running business which fails to meet the requirements of this Act in respect to the organisation of business within the stipulated timeframe;
- l) Order disposal of medical devices which have been withdrawn in accordance with this Act;
- m) Order that the incompliances or shortcomings that have been detected be corrected;
- n) Prohibit carrying out actions which are contrary to this Act and legislation derived therefrom;
- o) Order taking other measures as authorised by the inspectorial rights and duties stipulated by this Act and legislation derived therefrom.

**Article 128**  
**Executing of pharmaceutical-inspectorial supervision**

- (1) Executing of inspectorial supervision shall be initiated and carried out by the inspector within their line of duty or on request of an interested party. In executing of the inspectorial supervision, the pharmaceutical inspector and inspector have the right and duty to directly inspect business premises and other facilities, work process, products and other goods, authorisations and other documents and perform any other actions in accordance with the purpose of inspectorial supervision.
- (2) After each supervision, the pharmaceutical inspector and inspector shall be required to prepare a report stating factual findings of the inspectorial supervision.
- (3) Actions referred to in articles 126 and 127 of this Act shall be defined in a decision.



- (4) The pharmaceutical inspector and inspector shall be authorised to bring a verbal decision only in the following circumstances:
  - a) In case where the imminent danger posed to the health or lives of people necessitates that the required action be taken without delay;
  - b) In case where there is a possibility that the evidence may be hidden, substituted or destroyed should the action not be taken immediately.
- (5) The pharmaceutical inspector and inspector shall be authorised to order immediate executing of the verbal decision.
- (6) The pharmaceutical inspector and inspector shall be required to prepare a decision in writing referring to paragraph 4 of this article in accordance with regulations about the administrative procedure.
- (7) An appeal against the decision made by the pharmaceutical inspector or inspector can be submitted to the Agency Director within eight days after the receipt of the decision.
- (8) An appeal shall not defer carrying out of the decision.
- (9) The Agency Director's decision is final in the administrative procedure; however the appeal against it can be initiated at the relevant court.

**Article 129**  
**Consistency in legislation**

Should certain issues be not stipulated by this Act, then the regulations governing administrative and/or government procedures in Bosnia and Herzegovina shall apply on the actions taken by the pharmaceutical inspector or inspector.

**Article 130**  
**Accountability of the pharmaceutical inspector and inspector**

The pharmaceutical inspector and inspector shall be accountable for their work to the Agency Director. The pharmaceutical inspector and inspector shall be suspended or removed from their position should it be confirmed that:

- a) They have failed to take or order measures which they have been required to take or order by this Act during their supervision;
- b) They have overstepped their legal authorities;
- c) They have failed to report misdemeanor, to initiate legal procedure regarding misdemeanor, or have failed to report to the Agency about the detected irregularities or shortcomings.

**VI- PENAL PROVISIONS**

**Article 131**  
**Breach of regulations in articles 29, 40, 57, 93, 123, 126 and 127 of this Act**

- (1) A legal entity shall be fined for misdemeanor between KM 30,000 and KM 100,000 for:
  - a) Placing a medicinal product on the market in Bosnia and Herzegovina for which the Agency for medicinal products and medical devices B-H has not issued a marketing authorisation (article 29, paragraph 1, clause a));



- b) Placing a medicinal product on the market where each batch has not been manufactured in accordance with the documentation which was used for issuing a current marketing authorisation, and if the quality control for each batch has not been performed (article 29, paragraph 1, clause b));
  - c) Placing a medicinal product on the market after the marketing authorisation had been revoked for the following reasons: it was established that the medicinal product had been marketed contrary to the marketing authorisation; or the medicinal product had been harmful when used as instructed; or the qualitative and/or quantitative composition of the medicinal product was not in accordance with the composition declared in the documentation; or the facts in the supporting documentation did not represent the actual facts (article 40, paragraph 3, clauses a), b), d) and e);
  - d) Manufacturing a medicinal product without a manufacturing authorisation or contrary to the manufacturing authorisation issued by the Agency for medicinal products and medical devices (article 57, paragraphs 2 and 3);
  - e) Placing an incompliant medicinal product or medical device on the market (article 93, paragraph 1, and article 123, paragraph 1);
  - f) Not complying with, or acting against the decision made by the pharmaceutical inspector or inspector (articles 126 and 127).
- (2) For misdemeanors referred to in paragraph 1 of this article, a responsible person within the legal entity shall be fined between KM 5,000 and KM 10,000.

### **Article 132**

#### **Implementation of regulations in articles. 44, 59, 63, 68, 74, 102, 104, 106, 108, 109 and 117 of this Act**

- (1) A legal entity, marketing authorisation holder or other legal entities shall be fined between KM 20,000 and KM 50,000 for:
- a) Failing to submit an application to the Agency for implementing major changes (changes type II) in the marketing of medicinal products authorisation (article 44, paragraph 3);
  - b) Failing to report any changes regarding changes in manufacturing of medicinal products conditions (article 59 paragraph 3);
  - c) Selling the medicinal product to a legal entity or private persons who do not hold a marketing of medicinal products authorisation (article 63 paragraph 3);
  - d) Placing a medicinal product with attributed healing properties on the market, which is not classified as a medicinal product according to this Act and regulations derived therefrom (article 68, paragraph 1);
  - e) Placing an expired medicinal product on the market, or the medicinal product for which it has been proven that the quality, safety or efficacy are inadequate, or the medicinal product does not conform with the marketing of medicinal product authorisation or an emergency import authorisation (article 68, paragraph 2);
  - f) Offering direct or indirect material benefits to the person prescribing or dispensing the medicinal product (article 74, paragraph 4);
  - g) Commencing manufacturing of medical devices prior to registering it with the Agency (article 104, paragraph 1, clause a), and paragraph 106);
  - h) Commencing marketing of medical devices prior to registering it with the Agency (article 109, paragraph 1, clause a));
  - i) Marketing a medical device which does not conform with the proscribed general and special requirements (article 108, paragraph 2);
  - j) Failing to report clinical testing of medical device which has already commenced (article 117, paragraph 1);
  - k) Marking a medical device with a conforming mark, while it has not conformed with general and special requirements of technical regulations (article 102, paragraph 4).
- (2) For misdemeanor referred to in paragraph 1 of this article, a responsible person within the legal entity shall be fined between KM 3,000 and KM 10,000.

### **Article 133**



### **Breach of regulations in articles 33, 72 and 121 of this Act**

- (1) A legal entity, a marketing of medicinal products or medical devices authorisation holder or other legal entities shall be fined between KM 10,000 and KM 20,000 for:
- a. Submitting false documentation in the process of obtaining a marketing of medicinal products authorisation (article 33, paragraph 2);
  - b. Failing to inform the Agency about the adverse effects of medicinal products or for being suspicious about them (article 72, paragraph 1);
  - c. Failing to submit a periodical report on safety of the medicinal product or medical device (article 121, paragraph 1).
- (2) For misdemeanor referred to in paragraph 1 of this article, a responsible person within the legal entity shall be fined between KM 2,000 and KM 7,000.

### **Article 134**

#### **Breach of regulations in articles 61, 76, 81 and 94 of this Act**

- (1) A legal entity shall be fined for misdemeanor between KM 5,000 and KM 15,000 for:
- a) Failing to enable inspectorial supervision upon the Agency's request (article 61);
  - b) Failing to enable the Agency to exempt a necessary quantity of medicinal products for the purpose of quality control (article 81, paragraph 1);
  - c) Advertising the prescription-only medicinal product to the general public, contrary to regulations of this Act; or for advertising the medicinal product to the general public in which the medicinal product has been attributed non-existing properties, or the positive effects of the medicinal product have been exaggerated, or the medicinal product users have been misled in any other manner; or for addressing children directly in advertising the medicinal products (article 76, paragraphs 1, 3 and 4);
  - d) Providing free samples of medicinal products to the general public (article 76, paragraph 5);
  - e) Advertising the medicinal product for which a marketing authorisation has not been issued (article 76, paragraph 6);
  - f) Failing to dispose of pharmaceutical waste in accordance with stipulations of this Act (article 94, paragraphs 1 and 2).
- (2) For misdemeanor referred to in paragraph 1 of this article, a responsible person within the legal entity shall be fined between KM 3,000 and KM 6,000.

### **Article 135**

#### **Breach of regulations in articles 43, 44 and 69 of this Act**

A legal entity, private persons, or a professional institution and professional body shall be fined for misdemeanor between KM 1,500 and KM 3,000 for:

- a) Failing to handle the medicinal product which has come into their possession within their line of business in accordance with the ordering party's instructions for the purpose of preventing the changes in quality of the medicinal product or preventing its misuse (article 69);
- b) Failing to notify the Agency about discontinuation of manufacturing or marketing the medicinal product (article 43);
- c) Failing to notify the Agency about the minor changes (changes of the type I.A and I.B) in the documentation, or in the marketing authorisation, i.e. introducing minor changes earlier than 30 days from the date of notification (article 44, paragraph 2).



## VII – TRANSITIONAL AND FINAL PROVISIONS

### Article 136

#### Appointing the Director and members of the Professional Board of the Agency

- (1) Within 60 days from the date this Act enters into force, the Council of Ministers shall appoint the Director, Deputy Director and members of the Professional Board of the Agency. Department of Health of either Entity and the Department of Health of Brcko District shall submit their recommendations for members of the Board within 30 days from the date this Act enters into force.
- (2) The constituting session of the Professional Board shall be held 30 days after the appointment of its members, at the latest.

### Article 137

#### Regulations on internal organisation and job classification of the Agency

Within 30 days from his/her appointment, the Director shall be required to provide recommendations for the Regulations on internal organisation and job classification of the Agency and submit it without delay to the Professional Board for consideration. The Professional Board shall provide their recommendations within 30 days from the constituting session, at the latest. The Director shall submit the proposal of the Regulations, supported by the recommendations provided by the Professional Board, to the Council of Ministers for their approval.

### Article 138

#### Appointing the Agency committees members

Within 60 days from his/her appointment, the Agency Director shall appoint committee members of the Agency upon recommendations provided by the Professional Board and in accordance with this Act.

### Article 139

#### Implementation of regulations

- (1) Upon the recommendation by the Professional Board of the Agency, the Council of Ministers shall proclaim the policy on medicinal products and medical devices in Bosnia and Herzegovina within 90 days from entering this Act into force.
- (2) The Council of Ministers shall declare the regulations on implementation of regulations from their authority within 90 days from entering this Act into force.
- (3) The Professional Board, or the Agency Director, shall be required to provide the recommendations of regulations referred to in paragraph 2 of this article within 60 days from the date of their appointment.
- (4) The Professional Board of the Agency shall adopt Regulations on implementation of regulations from their authority within 90 days from the date of the constituting session.
- (5) Proposal of the Regulations on activities of the Professional Board shall be established and submitted for approval to the Department of Civil Affairs within 60 days from the date of the constituting session.

### Article 140

#### Timeframe for harmonisation



- (1) Legal entities, manufacturing of medicinal products and/or medical devices authorisation holders, wholesale of medicinal products and/or medical devices authorisation holders, shall be required to harmonise their organisations and businesses with the regulations stipulated by this Act within six months from entering this Act into force.
- (2) Legal entities from paragraph 1 of this article shall be required to harmonise their businesses with good practices within 12 months from entering this Act into force.
- (3) Harmonisation of organisation and business of legal entities referred to in paragraph 1 of this article implies registering of current authorisations issued by institutions in either Entity or Brcko District within a set timeframe. Current authorisations for marketing of medicinal products, manufacturing, wholesale or import of medicinal products, issued by relevant authorities from either Entity and Department of Foreign Trade and Economic Relations of B-H, shall be deemed valid until such authorities expire on the territory of either Entity and Brcko District. In circumstances where the same marketing of medicinal products authorisation holder has a valid authorisation in both Entities, but with a different expiry date, both current authorisations shall be registered, however the latest expiry date shall be deemed valid.
- (4) Within the timeframe stipulated in paragraph 1 of this article, relevant Entity authorities which prior to entering this Act into force had issued marketing of medicinal products as well as other manufacturers or wholesale of medicinal products authorisations shall be required to submit to the Agency any relevant documentation based on which individual authorisations had been issued, as well as submit a certificate certifying that from the date of issue of the authorisation until the submission of the aforementioned documentation no changes in circumstances regarding the named authorisations had occurred.
- (5) In case where the documentation referred to in paragraph 4 of this article has not been complete, or has not been harmonised with regulations at the time of its submission to the Agency, the Agency shall be entitled to suspend the validity of individual authorisations, requesting at the same time that the authorisation holder provide the additional supporting documentation in accordance with legislation. In such circumstances, the Agency shall be required to carry out the procedure of assessment and verification of the authorisation, in accordance with the timeframe stipulated by this Act.
- (6) On applications for marketing of medicinal products as well as other manufacturers or wholesale of medicinal products authorisations which had already been submitted prior to entering this Act into force, then legislation from either Entity, or legislation from Brcko District B-H, shall apply.
- (7) Within 18 months from entering this Act into force, the Agency shall issue a certificate confirming the existence of the authorisation, its date of validity in accordance with this Act; such certificate shall be issued to individual holders of authorisations related to manufacturing or wholesale marketing of medicinal products and medical devices. Relevant Entity authorities shall be required to complete any previously commenced procedures regarding the issue of authorisations within 90 days from the date of entering this Act into force; or if unable to complete them, they are required to submit the already received applications to the Agency for further processing by the Agency.
- (8) Regulations referred to in article 34, paragraph 1, clause c), in the section related to the exclusivity of the data, shall not apply for at least five years from the date of entering this Act into force. After the period of five years, upon the recommendation by the Director, the Professional Board of the Agency shall re-consider re-introducing the application of principles of exclusivity of the data.
- (9) Within 90 days from the date of entering this Act into force, the Professional Board shall put forward the proposal, and the Council of Ministers shall make a decision about the proposal which shall include essential financial funds for establishing the database of medicinal products and medical devices, or linking the Agency office in the unique information system as stipulated by article 11 of this Act.



- (10) Within 90 days from entering this Act into force, the Agency shall take over employees of the Agency for medicinal products and medical devices of RS, employees of Department for control of medicinal products of Federation of Bosnia and Herzegovina, and employees of Pharmacy Office of the Department of Health of Federation of Bosnia and Herzegovina, who had been employed until entering this Act into force and until the Agency job classification has been adopted in accordance with the Regulations on internal organisation and job classification. In case that due to the new job classification an employee shall be made redundant as the result of the new requirements for the position which the employee had been previously required for, consequently the employee shall be entitled to the redundancy payment in the amount of three average salaries of employees in public services in Bosnia and Herzegovina.

**Article 141**  
**Harmonisation of legislation in Entities**

- (1) Both Entities and Brcko District shall be required to harmonise legislation regarding medicinal products and medical devices, in accordance with this Act, within 90 days after entering this Act into force.
- (2) Until relevant sub-legislation has been adopted as stipulated by this Act, sublegislation of each Entity and of Brcko District shall remain in force, unless they are contrary to stipulations of this Act.

**Article 142**  
**Entering of the Act into force**

This Act shall enter into force on the eighth day after it has been published in the «Official Gazette of Bosnia and Herzegovina».

Parliamentary Assembly, number 217/08  
17th June 2008  
Sarajevo

Chair of House of Representatives  
of Parliamentary Assembly of B-H

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**Mr Niko Lozancic, signed**

Chair of the House of Peoples  
of Parliamentary Assembly of B-H

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**Mr Sulejman Tihic, signed**

