

THE CROATIAN PARLIAMENT

1521

Pursuant to Article 89 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION

PROMULGATING THE MEDICAL DEVICES ACT

I hereby promulgate the Medical Devices Act, passed by the Croatian Parliament at its session on 14 June 2013.

Class: 011-01/13.01/135

Reg. No: 71-05-03/1-13-2

Zagreb, 18 June 2013

The President of
the Republic of
Croatia
Ivo Josipović, m.
p.

MEDICAL DEVICES ACT

I. GENERAL PROVISIONS

Article 1

(1) In order to ensure quality, safety and performance requirements of medical devices that are considered devices of particular importance for health protection of humans, this Act lays down the requirements for medical devices, clinical trials of medical devices, entry into the register of manufacturers of medical devices, conformity assessment and CE markings, conformity assessment bodies, registration, placing on the market, advertising, vigilance and supervision and control of medical devices.

(2) The provisions of this Act apply to medical devices and their accessories, including *in vitro* diagnostic medical devices and active implantable medical devices.

(3) The terms used in this Act and in the relevant regulations adopted pursuant to this Act equally refer to common gender - masculine and feminine gender, regardless of the fact whether they have been used in the masculine or feminine form.

Article 2

(1) This Act transposes the following directives into the legislative framework of the Republic of Croatia:

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990),
2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993),
3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998),
4. Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma (OJ L 313, 13.12.2000),
5. Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (Text with EEA relevance) (OJ L 105, 26.4.2003),
6. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance) (OJ L 247, 21.9.2007).

(2) This Act lays down the implementation of the following regulations:

1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance), (OJ L 218, 13.8.2008),
2. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (Text with EEA relevance), (OJ L 72, 10.3.2012),
3. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Text with EEA relevance) (OJ L 212/3, 9.8.2012).

Article 3

For the purposes of this Act the following definitions shall apply:

1. 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, control, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its function by such means;

2. ‘Accessory’ means an article which whilst not being a medical device is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

3. ‘*In vitro* diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state,
- concerning a congenital abnormality,
- to determine the safety and compatibility with potential recipients,
- to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

‘Accessory’ means an article which, whilst not being an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with any *in vitro* diagnostic medical device to enable that device to be used in accordance with its purpose intended by its manufacturer.

Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen shall not be considered to be accessories to *in vitro* diagnostic medical devices;

4. 'Medical device for self-testing' means an *in vitro* diagnostic medical device intended by the manufacturer for household use;

5. 'Medical device for performance evaluation' means an *in vitro* diagnostic medical device intended for evaluation in the laboratory or other appropriate environments;

6. 'Calibrators and control materials' means substances, materials and objects intended by their manufacturer for calibration and for being used as control materials in the comparison of measurement data or for testing of the performance of an *in vitro* diagnostic medical device in line with its purpose. Certified international reference materials and materials used in quality system assessment procedures in production and laboratories shall not be considered as *in vitro* diagnostic medical devices.

7. *In vitro* shall be considered as a new product if:

a) it has not been continuously marketed in the Republic of Croatia and/or the European Union over the past three years for an appropriate analyte or some other parameter,

b) the procedure includes the analytical technology that has not been continuously used relating to a particular analyte or some other parameter in the Republic of Croatia and/or the European Union over the past three years.

8. 'Active medical device' means any medical device the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

9. 'Active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

10. 'Custom-made medical device' means any device specifically made in accordance with a duly qualified medical doctor 's or dental medicine doctor 's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned written prescription may also be made out by any other person authorised by virtue of his professional qualifications to do so in line with special regulations.

Mass-produced medical devices which need to be adapted to meet the specific requirements of the medical doctor or dental medicine doctor shall not be considered to be custom-made medical devices;

11. 'Device intended for clinical investigation (clinical trial)' means any device intended for use by a duly qualified medical practitioner when conducting investigations in an adequate human clinical environment. For the purpose of conducting clinical trial, any other person who, by virtue of his professional qualifications, is authorised to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

12. 'Clinical data' means the safety and/or performance information that is generated from the use of a medical device. Clinical data are sourced from:

— clinical trial(s) of the medical device concerned;

— clinical trial (s) of the medical device concerned or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated;

— published and/or unpublished reports on other clinical experience of either the medical device in question or a similar medical device for which equivalence to the device in question can be demonstrated;

13. ‘Clinical investigation plan (protocol)’ is a document that describes the objective(s), design, methodology, statistical considerations and organisation of a medical device clinical trial. The term ‘protocol’ refers to the protocol, successive versions of the protocol and protocol amendments and supplements.

14. ‘Sponsor of the clinical trial means any legal or natural person who takes responsibility for the initiation, management and/or financing of a clinical trial.

15. ‘Clinical trial applicant’ means the sponsor of the clinical trial having the registered place of business in the European Union or any legal or natural person having the registered place of business in the European Union who has been authorised by the sponsor to file the application for a clinical trial in his name and on his behalf.

16. ‘*Central Ethics Committee*’ means an independent body consisting of medical professionals and other non-medical members whose responsibility is to ensure the protection of rights, safety and well-being of clinical trial subjects and to provide assurance of that protection by, among other things, giving opinions on trial protocols, suitability of investigators, legal persons on whose premises trials are conducted, equipment, methods and documents to be used for informing the trial subjects and obtaining their informed consents. The minister in charge of health (hereinafter “Minister”) shall appoint the Central Ethics Committee.

17. ‘Good clinical practice’ means a set of internationally recognised ethical and scientific requirements which must be observed for designing, conducting, recording and reporting on clinical trials.

18. ‘Informed consent’ means a signed and dated consent of a trial subject given in writing, which proves the subject’s willingness to participate in a clinical trial, after having received appropriately documented information on the nature and significance, as well as involved consequences and risks. If a subject is incapable of giving such a consent or is a minor, his legal representative or a guardian shall sign an informed consent. If the person concerned is illiterate or unable to write, verbal consent in the presence of at least one witness who is not a member of the clinical trial team may be given.

19. ‘Natural person’ means a person who autonomously performs an economic activity on a permanent basis in conformity with a special regulation, or a person with its registered place of business in the European Union who in conformity with the relevant regulations of the EU Member State autonomously performs a business activity.

20. 'Manufacturer of a medical device' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

21. 'Intended purpose (intended use)' means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;

22. 'Placing on the market' means the first making available in return for payment or free of charge of a medical device other than a medical device intended for clinical trial, with a view to distribution and/or use on the EU market, regardless of whether it is new or fully refurbished;

23. 'Putting into service' means the stage at which a medical device has been made available to the final user as being ready for use for the first time for its intended purpose. In the case of active implantable medical devices putting into service means making available to the medical profession for implantation;

24. 'Device subcategory' means a set of devices having common areas of intended use or common technology;

25. 'Generic device group' means a set of medical devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

26. 'Single use device' means a medical device intended to be used once only for a single patient.

27. 'Medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue' means devices that must meet essential requirements relating to the risk of transmitting transmissible animal spongiform encephalopathies (TSE), under the normal conditions of use, to patients or other persons, and which have been identified as such during the conformity assessment procedure.

28. 'Vigilance of medical devices' means activities comprising collection, assessment, understanding and reaction to any new knowledge of the risks arising from the use or administration of medical devices, and especially of adverse events, interactions with other substances or products, contraindications, counterfeiting, decreased effects, defects and technical irregularities.

29. 'Adverse event or incident relating to a medical device' means any defect, loss of value of its properties, absent or reduced efficacy of a medical device, adverse reaction of a medical device, as well as any inaccuracy in its labelling or instructions for use, where this adverse event lead or might have led to death or a serious deterioration in health of the patient, user or a third party.

30. 'Authorised representative of the manufacturer of the medical device' means any legal or natural person established in the European Union who, explicitly designated in writing by the

manufacturer with its seat in a third country, to represent him with regard to the manufacturer's obligations within the territory of the European Union;

31. 'Third countries' means countries that are not Member States of the European Union or the European Economic Area.

32. 'Wholesale of medical devices' means purchase of medical devices and their resale to natural or legal persons with the view to performing their professional and registered activity, including the purchase, receipt, storage, resale and delivery, with an exception of the delivery to the end user - intended for use by a sole customer.

33. 'Retail sale of medical devices' means ordering, storage, dispensing and resale of the medical device to the end user – intended for use by a sole customer.

34. 'Import of a medical device' means wholesale of a medical device which has been imported from third countries to the territory of the European Union.

35. 'Good practice in the wholesale of medical devices' means the standard for storage and transportation of medical devices which ensures organisation, performance and control over storage in line with prescribed conditions, as well as transport to the wholesale user.

36. 'Conformity assessment of a medical device' means any activity whose purpose is to determine either directly or indirectly whether the appropriate essential requirements defined by technical regulations governing a particular device have been met.

37. 'Conformity assessment body' means an independent laboratory, confirmatory body, supervisory or any other body authorised by the Minister to conduct the conformity assessment procedure for medical devices.

38. 'Notified body for conformity assessment' (hereinafter: notified body) means any body that has been notified to the European Commission by the competent central state administration authority for the performance of conformity assessment procedures and that has obtained the identification number of the European Commission.

39. 'Croatian standard' means a publically available standard which has been adopted by the Croatian national standards organisation.

40. 'Certification of conformity' means a document issued by a notified body on the basis of which it guarantees that the essential requirements, which are in line with the requirements set out in this Act and the relevant regulations adopted pursuant to this Act or the relevant EU rules, have been met concerning a particular manufacturing process or a medical device.

41. 'Declaration of conformity' means a document issued by the manufacturer of a medical device on the basis of which it guarantees that a manufacturing process or a medical device meets the essential requirements which are in line with the requirements set out in this Act and the relevant regulations adopted pursuant to this Act or the relevant EU rules.

(1) The provisions of this Act shall apply to medical devices intended for administration of medicinal products.

(2) If a device and a medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that medical device shall be governed by the provisions of the Medicinal Products Act. As far as the safety and performance-related device features of the medical device are concerned, they must comply with the essential requirements under this Act.

(3) If a medical device incorporates, as an integral part, a medicinal product which can be used separately and which is liable to act upon the body with action ancillary to that of the device, that device shall be governed by this Act, while the medicinal product shall be governed by the Medicinal Products Act and the ensuing ordinances.

(4) The provisions of this Act shall apply also to *in vitro* diagnostic medical devices manufactured from tissues, cells or substances of human origin.

Article 5

The provisions of this Act shall not apply to:

- medicinal products;
- cosmetic products;
- human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;
- transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin,
- transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue;
- products which are a combination of a medicinal product and a medical device, containing viable cells or tissues or non-viable cells or tissues, where the cells or tissues have been considered to be the principal mode of action of the combination product;
- *in vitro* diagnostic medical devices which are manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity;
- personal protective equipment and substances in conformity with special regulations.

Article 6

(1) Medical devices referred to in Article 3, item 27 of this Act are medical devices originating from bovine, ovine and caprine species, deer, elk, mink and cats.

(2) The provisions of this Article shall not apply to medical devices which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

(3) Special requirements for medical devices referred to under paragraph 1 of this Article shall be stipulated by way of an ordinance to be issued by the Minister.

Article 7

The excision, collection and utilisation of tissues, cells and substances of human origin shall be governed by ethical principles and principles relating to the application of biology and medicine given in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, as well as in line with special regulations.

Article 8

(1) The Croatian Agency for Medicinal Products and Medical Devices (hereinafter: "Agency") shall cooperate with the competent authorities of the EU Member States, the European Commission and other competent authorities and exchange information with the view to uniformity in the application of the regulations covering medical devices.

(2) The Agency shall enter into the European Database on Medical Devices (hereinafter: EUDAMED) the following data:

- data on manufactures and authorised representatives of manufacturers of medical devices with their registered place of business in the Republic of Croatia and on medical devices which they place on the market, with an exception of medical devices which have been manufactured for the sole use of a particular patient,
- data on issued, revoked, modified, complemented and suspended certifications on conformity of medical devices,
- data on vigilance of medical devices.

(3) The data on clinical trials of medical devices shall be entered into the EUDAMED data base by the ministry in charge of health (hereinafter: Ministry).

II REQUIREMENTS FOR MEDICAL DEVICES

Article 9

(1) Medical devices may be made available on the market of the Republic of Croatia (hereinafter: placing on the market) only if they do not compromise the safety and health of patients, users and other persons and only if they have been properly manufactured, correctly installed, maintained and used in accordance with their intended purpose.

(2) Medical devices must meet the essential requirements taking into account the intended use of a particular medical device.

(3) Medical devices emitting ionised radiation must also meet the conditions laid down by regulations on protection from ionising radiation.

(4) Where medical devices are also machines pursuant to a special regulation, they must accordingly comply with the essential requirements for machines.

(5) Where the intended use of a medical device is such that at the same time it is used as personal protective equipment, the medical device in question must also accordingly comply with the essential requirements for personal protective equipment.

(6) The essential requirements for medical devices shall be stipulated by way of an ordinance to be issued by the Minister.

Article 10

(1) If a medical device complies with Croatian standards, which have incorporated the harmonised European standards, it shall be considered as meeting the appropriate essential requirements.

(2) The Minister shall publish the list of the Croatian standards for medical devices in the Official Gazette.

(3) The reference to standards shall include the monographs of the Croatian Pharmacopoeia and of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products.

(4) For *in vitro* diagnostic medical devices in List A in Annex II whose intended use is for *in vitro* diagnostics and which is a constituent part of the ordinance referred to in Article 13, paragraph 2 of this Act and, where necessary, for *in vitro* diagnostic medical devices in List B in Annex II whose intended use is for *in vitro* diagnostics and which is a constituent part of the ordinance referred to in Article 13, paragraph 2 of this Act, the reference to norms shall mean at the same time the reference to common technical specifications for *in vitro* diagnostic medical devices.

(5) The common technical specifications establish appropriate performance evaluation and re-evaluation criteria for *in vitro* diagnostic medical devices, batch release criteria for *in vitro* diagnostic medical devices, reference methods and reference materials.

(6) The common technical specifications are published in the Official Journal of the European Union.

(7) Manufacturers of medical devices shall be required to comply with the common technical specifications regarding *in vitro* diagnostic medical devices.

(8) If, for duly justified reasons, manufacturers do not comply with the aforementioned common technical specifications regarding *in vitro* diagnostic medical devices, they must adopt solutions of a level at least equivalent thereto.

Article 11

(1) Where it has been ascertained that a medical device, which meets the requirements provided in Article 9 of this Act, when correctly installed and used for its intended purpose, may compromise the health and/or safety of patients, users or other persons, the Agency shall, acting upon its own initiative (*ex officio*) or upon the initiative of a pharmaceutical inspector, take the following interim measures:

- withdraw such medical device from the market,
- restrict its being placed on the market or put into service.

(2) The Agency shall immediately inform the European Commission of any such measures taken under paragraph 1 of this Article, indicating the reasons for its decision and, in particular, whether noncompliance is due to:

- failure of the medical device to meet the essential requirements,
- incorrect application of the standards referred to in Article 10 of this Act,
- shortcomings in the standards themselves.

(3) Where it has been established that a medical device does not meet the essential requirements, and where a non-complying device bears the CE marking, the pharmaceutical inspector shall take appropriate action and shall inform the Agency thereof.

(4) The Agency shall inform the European Commission on the measures taken under paragraph 3 of this Article.

Article 12

(1) Each medical device must be accompanied by information needed for its safe and proper use, taking into account the training and knowledge of potential users, and must identify the manufacturer.

(2) Information referred to in paragraph 1 of this Article shall comprise the data on the label or in the instructions for use of the medical device.

(3) By way of derogation from paragraph 1 of this Article, no such instructions for use are needed for medical devices of Class I and IIa if they can be used properly and safely without them.

(4) By way of derogation from paragraph 1 of this Article, in duly justified and exceptional cases, no such instructions for use are needed for *in vitro* diagnostic medical devices if they can be used safely without them.

(5) The instructions for use and labelling of the medical device must be in the Croatian language and appear in a visible and legible form.

(6) Where the instructions for use and labelling referred to in paragraph 5 of this Article are translated into the Croatian language, the translation of the instructions for use and marking of

the medical device must correspond to the original instructions for use and marking of the medical device.

(7) The instructions for use of medical devices exclusively intended for use by medical institutions must be supplied in a language which the user speaks.

(8) The instructions referred to in paragraph 7 of this Article for medical devices referred to in Article 3, paragraph 1 of Commission Regulation (EU) No 207/2012 may be in electronic form, in line with its provisions.

Article 13

(1) Medical devices are grouped into risk categories as follows:

- Class I - medical devices with low user risk,
- Class IIa - medical devices with moderate user risk,
- Class IIb - medical devices with high user risk,
- Class III - medical devices with the highest user risk.

(2) Detailed requirements and rules for classification of medical devices and *in vitro* diagnostic medical devices shall be stipulated by way of an ordinance to be issued by the Minister.

Article 14

(1) In the event of a dispute between the manufacturer and the notified body, resulting from the application of the classification rules, the matter shall be referred to the competent authority to which the notified body is subject.

(2) Where it is considered that the classification rules for medical devices require adaptation in the light of technical progress and any information which becomes available, the Agency may submit a duly substantiated request to the European Commission in view to taking the necessary measures for adaptation of classification rules for medical devices.

Article 15

The Agency shall submit a request to the European Commission and ask it to take the necessary measures if it considers:

- that the application of the classification rules requires a decision with regard to the classification of a given medical device or category of devices;
- that a given medical device or family of medical devices should be classified in another class;
- that the conformity of a medical device or an *in vitro* diagnostic medical device should be established by applying some other conformity assessment procedure;

- that a decision is required as to whether a particular product should be classified into a particular product group.

Article 16

(1) Any manufacturer who assembles medical devices bearing the CE marking within their intended purpose and within the limits of use specified by their manufacturer, in order to make them available, i.e. place them on the market as a system or procedure pack, shall draw up a declaration in which he states that:

(a) he has verified mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions;

(b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturer;

(c) the whole activity is subjected to appropriate methods of internal control and inspection.

(2) The systems and the procedure packs referred to in paragraph 1 of this Article do not have to bear a CE marking.

(3) Where the conditions referred to above in paragraph 1 of this Article are not met, as in cases where the system or procedure pack incorporates devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a medical device in its own right and as such be subjected to the relevant conformity assessment procedure.

Article 17

(1) Any manufacturer who, for the purpose of placing on the market, sterilises systems or procedure packs, shall carry out the sterilisation procedure in line with the quality system for sterilisation procedures.

(2) The manufacturer shall guarantee the sterility of medical devices from paragraph 1 of this Article until their opening or any possible damage to the packaging.

(3) During the use of the medical device that should be presterilised in line with the manufacturer's instructions, any legal or natural person shall carry out the sterilisation procedure in line with the manufacturer's instructions and the quality system for the sterilisation procedure.

(4) Any manufacturer of a system or a procedure pack shall draw up a declaration stating that sterilisation has been carried out in line with the instructions of manufacturers of individual medical devices forming integral parts of systems or procedure packs.

(5) Systems and procedure packs referred to in paragraph 1 of this Article do not have to bear an additional CE marking.

(6) The systems and procedure packs from paragraph 1 of this Article shall not have to be equipped with instructions for use, including the instructions for use of manufacturers of medical devices incorporated in the system or the procedure pack.

(7) The declarations referred to in paragraph 4 of this Article and Article 16 of this Act shall be kept by the manufacturer for a period of five years and be made available to the competent authority upon request.

Article 18

The Agency shall provide professional advice upon request submitted by legal or natural persons relating to the following:

- translations of instructions for use and marking of medical devices,
- classification of devices in categories of medical devices,
- classification of medical devices in appropriate classes according to the degree of risk.

III CLINICAL INVESTIGATION OF MEDICAL DEVICES (CLINICAL TRIALS)

Article 19

(1) A clinical investigation (clinical trial) of a medical device shall mean any trial undertaken to assess the safety and performance of a medical device in accordance with its intended purpose.

(2) Safety and performance of *in vitro* diagnostic medical devices shall be assessed on the basis of performance evaluation studies.

Article 20

(1) A clinical trial of a medical device shall be conducted in a legal person satisfying the conditions established by an ordinance to be issued by the Minister.

2) A clinical trial of a medical device may be conducted by a natural or a legal person authorised to conduct this particular trial by the Minister.

(3) A clinical trial of a medical device shall be conducted in the legal person from paragraph 1 of this Article and at the cost of and on the request of the person applying for the clinical trial of the medical device (clinical trial applicant).

Article 21

(1) A clinical trial of the medical device shall be authorised by the Minister on the basis of the complete documentation and the positive opinion of the Central Ethics Committee.

(2) The Minister shall grant or refuse his authorisation for the clinical trial of the medical device within 60 days of the receipt of the duly filed application.

(3) If the Minister does not give or refuses his authorisation for the clinical trial within the time period referred to in paragraph 2 of this Article, the authorisation shall be deemed granted.

(4) The Minister shall issue or refuse the authorisation from paragraph 1 of this Article by a decision that cannot be appealed, but against which administrative proceedings may be instituted.

(5) The costs of issuance of the authorisation shall be incurred by the applicant.

(6) The criteria for the conduct of the clinical trial of a medical device, necessary documentation and the opinion of the Central Ethics Committee shall be stipulated by way of an ordinance to be issued by the Minister.

Article 22

(1) After the commencement of the clinical trial, the sponsor of the clinical trial shall be required to notify any revisions of the documentation or the clinical trial procedure.

(2) The revisions of the clinical trial shall be authorised or refused by the Minister within a time period which may not exceed 30 days from the day of the receipt of the duly filed application by way of a decision that cannot be appealed, but against which administrative proceedings may be instituted.

Article 23

(1) Clinical trials of medical devices may be conducted only subject to the informed consent of clinical trial subjects.

(2) Clinical trials of medical devices in children may be conducted only if the trial conducted in adults cannot provide satisfactory results.

(3) In exceptional cases, informed consent shall be granted by a legal representative or a guardian of a person who is unconscious, has severe mental difficulties, is under a legal incapacity or is a minor.

(4) Persons referred to in paragraphs 1 and 3 of this Article may revoke the informed consent to participate in a clinical trial at any time.

(5) Clinical trials shall not be conducted if potential risks of a medical device use outweigh medical justification of the clinical trial.

(6) Prisoners or persons who might be coerced into giving consent to participate in clinical trials shall not be trial subjects.

Article 24

(1) The principles of medical ethics as well as compulsory protection of subjects' privacy and data shall be observed during clinical trials of medical devices in line with an ordinance on clinical trials of medical devices and good clinical practice issued by the Minister.

(2) Clinical trials of medical devices shall take place only on the premises of legal persons referred to in Article 20 of this Act who have entered into clinical trial agreements with clinical trial applicants.

(3) The agreement from paragraph 2 of this Article shall specify total costs of the clinical trial of the medical device and the costs to be incurred by a clinical trial sponsor or applicant, including costs of medical and other services incurred by legal persons from Article 20 of this Act and compensations to investigators and subjects.

(4) The clinical trial applicant or sponsor shall pay compensations for investigators and subjects from paragraph 3 of this Article to a legal person with whom he concluded the agreement on a clinical trial of the medicinal product.

Article 25

The provisions of Articles 19 – 24 of this Act shall apply to clinical trials when they are conducted on a medical device possessing a conformity certificate and if their purpose is the use of this medical device for any purpose other than that given in the relevant conformity assessment procedure.

Article 26

(1) If it deems it necessary, the Ministry shall take appropriate measures to assure safety and health of humans. If an authorisation for a clinical trial is refused or if a clinical trial is suspended, the Ministry shall communicate to all EU Member States and the European Commission its decision and provide the relevant justification.

(2) Where a clinical trial has been substantially amended or suspended, the Ministry shall inform the interested EU Member States on the measures taken and indicate the reasons for its actions.

(3) The sponsor of the clinical trial shall notify the competent authorities of the interested EU Member States about the completion of the clinical trial, or provide the relevant justification in the event of its early termination. In the event of early termination of the clinical trial due to safety reasons, the notification concerned shall be forwarded to all EU Member States and to the European Commission.

IV MANUFACTURE OF MEDICINAL PRODUCTS

Article 27

(1) A legal or natural person with its registered place of business in the Republic of Croatia who manufactures or makes a medical device, including medical devices referred to in Articles 16 and 17 of this Act (hereinafter: manufacturer of a medical device) shall: :

– ensure that the medical device which he manufactures has been designed and manufactured in accordance with the requirements provided by this Act,

- carry out the classification of the medical device according to the associated risk, draw up the relevant technical documentation and conduct or ensure the conduct of an applicable conformity assessment procedure for the medical device concerned,
 - draw up the conformity declaration and affix the CE marking to the medical device in question,
 - keep available the technical documentation and the conformity declaration for at least five years after the medical device has been placed on the market,
 - ensure the procedures with the view to pertaining the conformity of the batch or serial,
 - properly label and mark the medical device and supplement it with the instructions for use referred to under Article 12 of this Act,
 - undertake corrective actions where it can be assumed or where there is reason to believe that the medical device which has been placed on the market does not comply with the provisions of this Act.
- (2) The manufacturer of a medical device shall be insured from the harmful effects which might occur by the use of the medical device.
- (3) The responsibilities of the manufacturer of a medical device laid down by the provisions of this Act refer both to a legal and a natural person who assembles, packages, processes, fully refurbishes and/or labels medical products with a view to their being placed on the market under his own name.
- (4) The responsibilities referred to under paragraphs 1 and 2 of this Article do not apply to the person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

Article 28

- (1) The manufacturer of a medical device shall, within the period not exceeding 15 days from the start of performing its economic activity, file an application for entry into the register of manufacturers of medical devices kept by the Agency.
- (2) The application for entry into the register of manufacturers of medical devices shall be submitted by:
- the manufacturers of medical devices with their place of establishment in the Republic of Croatia,
 - the authorised representatives of manufacturers from third countries, who have their seat in the Republic of Croatia.
- (3) The decision of the Agency on the entry of a manufacturer of a medical device into the register of manufacturers of medical devices shall be adopted within the time period of 60 days from the day of the receipt of the duly filed application.

(4) The decision referred to in paragraph 3 of this Article cannot be appealed, but administrative proceedings may be instituted against it.

Article 29

(1) Following the registration of the manufacturer of a medical device in the register of manufacturers of medical devices, the holder of the enrolment in the register filing for entry into the register of manufacturers of medical devices shall notify to the Agency any amendments to the documentation on the basis of which the Agency has authorised the entry into the register.

(2) If the amendment to the documentation referred to in paragraph 1 of this Article requires also an amendment to the entry into the register, the Agency shall take a decision thereon. This decision cannot be appealed, but administrative proceedings may be instituted against it.

(3) The decision referred to in paragraph 2 of this Article shall be rendered or refused by the Agency, depending on the subject and scope of the amendment, within a time period not exceeding 30 days from the day of receipt of the duly filed application.

Article 30

(1) The Agency shall remove the manufacturer from the register of manufacturers of medical devices:

- upon a substantiated request of the holder of the enrolment in the register,
- acting on its own initiative where it has been established that the manufacturer has been registered into the register in contravention of the provisions of this Act and the regulations adopted pursuant to this Act,
- on the basis of other justified reasoning.

(2) The removal of the manufacturer of the medical device from the register of manufacturers of medical devices shall be based on the decision of the Agency that cannot be appealed, but against which administrative proceedings may be instituted.

(3) The decision on removal of the manufacturer from the register of manufacturers shall be issued by the Agency within a time period not exceeding 30 days.

(4) The fees relating to the entry into the register of manufacturers of medical devices, refusal of entry, amendments to the entry and removal from the register of manufacturers of medical devices on the request of the holder of the enrolment in the register shall be set by the Agency, subject to prior approval by the Minister, whereas the costs relating to the above mentioned procedures shall be borne by the applicant or the holder of the enrolment in the register.

(5) The method of the registration into the register of manufacturers, the amendments to the entry, the removal of a manufacturer from the register of manufacturers and the documentation necessary for the registration shall be stipulated by way of an ordinance to be issued by the Minister.

V CONFORMITY ASSESSMENT AND CE MARKING

Article 31

(1) The conformity assessment procedure relating to a medical device is a procedure on the basis of which it is established and assessed whether the medical device or the manufacturing of the medical device meets the requirements laid down by this Act and the ordinances adopted pursuant to this Act.

(2) The conformity assessment procedure relating to a medical device establishing its conformity with the essential requirements shall be conducted in accordance with the classification of the medical product concerned.

(3) Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer may apply to a body of his choice of an appropriate scope of competence and with the seat in any EU Member State.

Article 32

(1) Before placing on the market of a medical device the manufacturer shall draw up a declaration on conformity with respect to the medical device in question and affix the CE marking of conformity.

(2) The CE marking of conformity does not have to be affixed to medical devices intended for clinical trials, custom-made devices and *in vitro* diagnostic medical devices for performance evaluation.

(3) The medical devices at trade fairs, exhibitions and demonstrations also need not bear the CE marking. Such devices must be provided a visible sign clearly indicating that such devices are not intended to be marketed or put into service.

Article 33

(1) The CE marking of conformity must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.

(2) The CE marking shall be accompanied by the identification number of the notified body responsible for conformity assessment if the body concerned has been involved in the conformity assessment procedure.

(3) It is prohibited to affix CE marks of conformity to medical devices if the medical device concerned does not meet the criteria laid down by this Act.

(4) It is prohibited to affix CE marks within the meaning of this Act if the device concerned does not constitute a medical device.

(5) It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking.

Article 34

The Agency may, acting on its own initiative or based on the duly justified request of the applicant, with prior approval by the Minister, authorise making available on the market, i.e. placing on the market and putting into service, also the medical devices that have not been subject to conformity assessment in exceptional cases such as epidemics, poisoning, nuclear or radiological accident or similar, but also under other circumstances where human health must be protected.

Article 35

The conformity assessment procedures, the content of the declaration on conformity and the CE marking shall be stipulated by way of an ordinance to be issued by the Minister in accordance with the previously obtained opinion of the minister in charge of the economy.

VI CONFORMITY ASSESSMENT BODIES

Article 36

(1) Before it becomes operative, a conformity assessment body with the place of establishment in the Republic of Croatia carrying out the activities relating to conformity assessment of medical devices must have the authorisation issued by the Minister.

(2) The criteria for the authorisation referred to in paragraph 1 of this Article shall be stipulated by way of an ordinance to be issued by the Minister.

Article 37

(1) The conformity assessment body shall:

- have available sufficient scientific staff that possesses adequate experience and knowledge necessary to assess the medical functionality and performance of medical devices and their quality and quality systems in the manufacturing process,
- have adequate premises, instruments and equipment,
- have a quality assurance system in place,
- keep the necessary documentation record on conformity assessment procedures and verification of medical devices as well as documentation on manufacturers of medical devices.

(2) A conformity assessment body may, in the supplement to its application for authorisation referred to in Article 36, paragraph 1 of this Act, provide the certificate of accreditation issued by the Croatian national accreditation body.

(3) The certificate of accreditation referred to in paragraph 2 of this Article shall prove the competence of the conformity assessment body and its compliance with the requirements set by the Croatian standards which have incorporated relevant harmonised European standards.

Article 38

(1) The authorisation referred to in Article 36, paragraph 1 of this Act shall be granted to the conformity assessment body by the Minister within 60 days from the day of the receipt of the duly filed application, whereas a prior opinion thereon shall be given by the expert committee.

(2) The expert committee referred to in paragraph 1 of this Article shall be appointed by the Minister.

(3) Where the application is not duly filed, i.e. if it does not contain the relevant statutory data and documentation, the Minister shall, by means of a procedural order, request from the applicant to rectify the problem within a time period which shall not exceed 30 days from the day of the receipt of the procedural order.

(4) Where the Minister requests from the applicant to supply additional data to the application concerned, the time limit referred to in paragraph 1 of this Article shall not run as long as the additional data have been received. Also the time limit shall not run during the period granted to the applicant with the view to submitting his written or verbal argumentation.

(5) The authorisation shall be given to the conformity assessment body by means of a decision that cannot be appealed, but against which administrative proceedings may be instituted.

(6) The costs of issuance of authorisation, refusal of authorisation or the revocation of authorisation referred to in paragraph 1 of this Article shall be borne by the applicant.

(7) The Ministry shall, within the time period of 15 days from the day of the adoption of the decision referred to in paragraph 5 of this Article, notify the European Commission of the bodies which they have designated for carrying out the tasks pertaining to the conformity assessment to enable the European Commission to assign identification numbers to these bodies who may then be referred to as 'notified bodies'.

Article 39

(1) The Ministry shall carry out supervision of the operation of the notified bodies referred to in Article 38, paragraph 1 of this Article.

(2) Where the notified body ceases to meet the requirements laid down in Article 37 of this Act and the regulations adopted pursuant to this Act, the Minister shall revoke the decision referred to in Article 38, paragraph 5 of this Act.

(3) The Ministry shall notify the EU Member States and the European Commission on the revocation of the decision referred to in paragraph 2 of this Article.

Article 40

(1) The notified body shall perform its duties guaranteeing impartiality and within the competence assigned to it.

(2) The notified body shall not be the designer, manufacturer, supplier or user of the medical devices which are subject to conformity assessment.

(3) The staff of the notified body is bound to observe that there shall not be any conflict of interest which would result in favouring certain manufacturers and it is also bound to observe professional secrecy with regard to the medical device technical data and other information relating to the manufacturer.

(4) The notified body shall:

– notify the Agency on the issued, modified or supplemented certificates on conformity within the time period which may not exceed 30 days from the day on which the certificate was issued;

– notify the Agency and the competent authorities in other EU Member States on suspended or revoked certificates of conformity, on applications for obtaining a certificate of conformity that have been refused, and supply other information on request of the competent authorities,

– revoke the certificate of conformity where it establishes that the pertinent requirements are no longer met by the manufacturer or suspend the certificate of conformity until the appropriate corrective measures taken by the manufacturer have been completed, of which it shall inform the Agency,

– enable the competent inspection in the Ministry to perform supervision and supply all relevant information and documents.

(5) The Agency shall notify the European Commission and other EU Member States about the measures taken within the meaning of paragraph 4, subparagraph 3 of this Article.

VII REGISTRATION OF MEDICAL DEVICES IN THE REGISTER OF MEDICAL DEVICES

Article 41

(1) Registration of a medical device in the register of medical devices is an administrative procedure which is performed by the Agency with the aim of protection of human health and with the objective to establish a list of medical devices which are available on the market in the Republic of Croatia.

(2) The registration of a medical device in the register of medical devices shall not be a condition for placing a medical device on the market.

(3) Any manufacturer of a medical device who has his registered place of business in the Republic of Croatia and any authorised representative of the manufacturer of the medical device with its registered place of business in the Republic of Croatia who place a medical device classified as Class I on the market shall inform the Agency and thereby apply for the registration of the medical device concerned in the register of the medical devices within the time period not exceeding 15 days from the day on which the medical device was first placed on the market.

(4) The Agency shall decide on the registration of a medical device in the register of medical devices on the basis of a decision which must be adopted within a time period of 60 days from the day of receipt of the duly filed application.

(5) The decision referred to in paragraph 4 of this Article cannot be appealed, but administrative proceedings may be instituted against it.

(6) The way in which the registration in the register of medical devices is carried out, modifications in the registration and the removal of a medical device from the register of medical devices, the content of the notification referred to in Article 42 of this Act and the necessary documentation that should be submitted shall be stipulated by way of an ordinance to be issued by the Minister.

Article 42

(1) Legal and natural persons who place on the market of the Republic of Croatia medical devices classified as Class IIa, IIb and III, *in vitro* diagnostic medical devices and active implantable medical devices shall notify the Agency thereof within a time period not exceeding 15 days from the day on which these products are placed on the market.

(2) On the request of the manufacturer of a medical device with its registered place of business in the Republic of Croatia, the Agency may issue a certificate certifying the conformity of the medical device or a family of medical devices concerned with the relevant regulations in effect and declaring that the medical device in question is not subject to any restrictions with regard to its placing on the market.

(3) Legal and natural persons referred to in paragraph 1 of this Article shall notify the Agency about any modifications of data and documentation relating to medical devices referred to in paragraph 1 of this Article.

Article 43

(1) After a medical device has been registered into the register referred to in Article 41 of this Act the holder of the enrolment in the register shall notify the Agency about any additional information and modifications of the documentation on the basis of which the Agency has carried out the registration into the register.

(2) Where additional information and modifications of the documentation referred to in paragraph 1 of this Article require modifications of the entry into the register, the Agency shall adopt a decision that cannot be appealed, but against which administrative proceedings may be instituted.

(3) The Agency shall adopt or reject the decision on modifications of the entry into the register referred to in paragraph 2 of this Article, depending on the nature of the modification concerned, within a time period not exceeding 30 days from the day of the receipt of the duly filed application.

Article 44

(1) The Agency shall remove a medical device from the register of medical devices:

– on a substantiated request of the holder of the enrolment in the register,

– on its own initiative where it finds that the medical device has been registered in the register of medical devices in contravention of the provisions of this Act and the regulations adopted pursuant to this Act,

– based on other justified reason.

(2) The removal of the medical device from the register shall be based on the decision that cannot be appealed, but against which administrative proceedings may be instituted.

(3) The decision on removal of the medical device from the register shall be adopted by the Agency within a time period not exceeding 30 days.

(4) The fees related to the registration, refusal of registration, modification of information and removal of the medical device from the register of medical devices on the request of the holder of the enrolment in the register, subject to prior approval by the Minister, shall be set by the Agency whereas the applicant or the holder of the enrolment in the register shall bear the costs in question.

Article 45

(1) The documentation received by the Agency as well as all the data relating to medical devices, except the data which have been registered in the registers of the Agency, shall be covered by the business secrecy clause.

(2) The provision of paragraph 1 of this Article shall not apply to exchange of information and warnings between competent authorities and other states.

VIII PLACING ON THE MARKET OF MEDICAL DEVICES

Article 46

(1) Medical devices may be made available on the market, i.e. placed on the market and administered if they meet the essential requirements, have been issued a certification of conformity and have been affixed the CE marking.

(2) Any legal or natural person and state bodies who in any way come into possession of medical devices must ensure their transport, storage and handling conditions in line with the relevant requirements.

(3) The Ordinance on good practice in the wholesale of medical devices shall be adopted by the Minister.

Article 47

(1) The following persons may be engaged in the wholesale of medical devices:

– legal and natural persons with their place of business registered in the Republic of Croatia and who are registered in the register of wholesalers of medical devices with the Agency (hereinafter: wholesale distributors),

– legal and natural persons with their place of business registered in the European Union who meet the requirements relating to wholesale of medical devices in the Member State in which they have their seat.

(2) Manufacturers of medical devices may also be engaged in the wholesale of medical devices they manufacture and which meet all the requirements stipulated by this Act.

(3) Legal and natural persons engaged exclusively in the wholesale of medical devices referred to in Article 49, paragraph 3 of this Act do not have to be registered in the register of wholesalers of medical devices.

(4) The criteria and the documentation and data necessary for registration in the register of wholesalers of medical devices shall be stipulated by way of an ordinance to be issued by the Minister.

Article 48

Legal and natural persons engaged in the wholesale of medical devices shall carry out this activity in accordance with the good practice in the wholesale of medical devices.

Article 49

(1) Legal and natural persons who, in accordance with a special law, have been authorised to carry out pharmacist activity and specialised retail sale outlets selling medical devices who have been licenced by the Agency to carry out activities involving retail sale of medical devices shall be engaged in the retail sale of medical devices.

(2) Legal and natural persons referred to in paragraph 1 of this Article may sell only medical devices which meet all the requirements stipulated in this Act and which are considered appropriate to dispense medical devices taking into account their intended use and the environment in which the medical device concerned is intended to be used.

(3) Particular medical devices may be sold outside pharmacies and specialised retail sale outlets selling medical devices.

(4) The list of medical devices referred to in paragraph 3 of this Article shall be drawn up by the Agency and made available on the web site of the Agency.

(5) The Ordinance specifying the criteria for retail sale of medical devices, and on documents and information necessary for the issuance of a licence to specialised retail sale outlets selling medical devices shall be adopted by the Minister.

Article 50

(1) Legal and natural persons engaged in pharmacist activity in the Republic of Croatia, specialised retail sale outlets selling medical devices and wholesale distributors may offer for sale medical devices over the Internet (distance selling) in line with their line of business and in compliance with a special regulation.

(2) Legal and natural persons performing pharmacist activity in the Republic of Croatia and specialised retail sale outlets selling medical devices offering for sale medical devices over the Internet (distance selling) shall communicate to the Agency the following data:

- name and permanent address of the point of sale from which they sell medical devices,
- the starting date of the sales activities,
- the address of the website used for sale over the Internet and all relevant information necessary to identify that web site.

(3) The web page referred to in paragraph 2 of this Article which offers selling of medical devices shall contain the following:

- name and address of the company,
- the address of the point of sale of medical devices,
- name and surname of the owner or the relevant responsible person,
- the contact details of the Agency,
- a hyperlink to the website of the Agency with data about legal and natural persons offering distance selling of medical devices.

(4) The Ordinance setting the conditions for distance retail sale of medical devices shall be issued by the Minister.

Article 51

(1) Legal and natural persons engaged in the import of medical devices from third countries shall import only medical devices that meet all the requirements stipulated by this Act and for which the manufacturer has an authorised representative in the European Union.

(2) The import of medical devices shall be carried out by legal and natural persons who have been registered in the register of wholesalers of medical devices.

Article 52

Legal and natural persons engaged in the import of medical devices from third countries shall have to:

- ensure that the manufacturer has carried out appropriate conformity assessment procedure relating to the imported medical device,
- ensure that the manufacturer has prepared proper technical documentation on the imported medical device,
- identify the contact name and the permanent contact address on the device, packaging or in the technical documentation attached to the device concerned,

– be in possession of the declaration of conformity at the point of import and, if necessary, keep available for inspection other relevant documentation certifying the conformity of the medical device concerned.

Article 53

(1) The Agency shall enter a wholesale distributor in the register of wholesalers of medical devices and issue a licence for retail sale of medical devices in a specialised store within a time period of 60 days from the day of the receipt of a duly filed application.

(2) Where the application is not duly filed, i.e. the application is not supplemented by the requested data and documentation, the Agency shall, by means of a procedural order, request the applicant to rectify the problem within a time period not exceeding 30 days.

(3) Where the Agency requests that the applicant supply additional data to its application, the time period referred to in paragraph 1 of this Article shall not run until the day of the receipt of the additional data. The time period shall also not run during the time which has been granted to the applicant to provide a written or verbal explanation.

(4) The registration in the register of wholesalers of medical devices and the licence for retail sale of medical devices referred to in paragraph 1 of this Article shall be based on the decision that cannot be appealed, but against which administrative proceedings may be instituted.

(5) The fees relating to the registration, modifications of the registration and removal from the register of wholesalers of medical devices as well as the fees for issuing, modifications or revocation of licences referred to in paragraph 1 of this Article, subject to prior approval by the Minister, shall be laid down by the Agency, whereas the applicant or the holder of the enrolment in the register or the licence holder shall bear the costs in question.

Article 54

(1) The Agency shall remove the wholesale distributor from the register of wholesalers of medical devices or revoke the licence for retail sale of medical devices granted to a specialised store where it finds that the holder of the enrolment in the register or the licence holder no longer meet the criteria on the basis of which the registration in the register was carried out or the licence issued.

(2) On the basis of a written request submitted by the holder of the enrolment in the register or the licence holder the Agency shall, by means of a decision, remove the wholesaler from the register of wholesalers of medical devices or revoke the licence referred to in paragraph 1 of this Article, if the holder of the enrolment in the register or the licence holder ceases to perform the activity concerned.

(3) The entry into the register of wholesalers of medical devices and the licence for retail sale of medical devices in a specialised store shall be revoked and removed from the register by means of a decision that cannot be appealed, but against which administrative proceedings may be instituted.

Article 55

(1) The holder of the enrolment in the register registered in the register of wholesalers of medical devices or the licence holder for retail sale of medical devices in a specialised store shall inform the Agency in writing of any modifications with respect to the criteria, documentation and information on the basis of which the registration in the register of wholesalers has been carried out or on the basis of which the licence has been issued.

(2) Where the additional data and modifications of the documentation referred to in paragraph 1 of this Article give rise to the modifications of the entry into the register of wholesalers or licences referred to in paragraph 1 of this Article, the Agency shall adopt the decision thereon within 30 days from the day of the receipt of a duly filed application.

(3) Where the application is not duly filed, i.e. the relevant data and documentation have not been delivered in the supplement to the application, the Agency shall, by means of a procedural order, request the applicant to rectify the problem within a time period not exceeding 15 days from the receipt of the procedural order.

(4) If the Agency requires additional data from the applicant, the time period referred to in paragraph 2 of this Article shall not run until the day the additional data to the application have been submitted. The time period shall also not run during the time period granted to the applicant to submit a verbal or written explanation.

(5) Modifications to the entry into the register of wholesalers of medical devices or to the licence for retail sale of medical devices in a specialised store shall be authorised on the basis of a decision that cannot be appealed, but against which administrative proceedings may be instituted.

Article 56

(1) The Croatian Institute for Health Insurance shall adopt the basic and supplementary reimbursement lists of medical devices covered by the compulsory health insurance which shall be drawn up in compliance with a special law.

(2) The criteria for the inclusion of the medical devices in the lists referred to in paragraph 1 of this Article shall be determined by the Minister.

(3) The criteria for the pricing of medical devices referred to in paragraph 1 of this Article shall be stipulated by way of an ordinance to be issued by the Minister.

Article 57

Medical devices which are no longer intended for use shall be considered waste and shall be subject to waste management regulations.

Article 58

(1) The Agency shall charge an annual fee for the decision on entry into the register of the manufacturers of medical devices, on issuance of a retail sale licence and on the registration in the register of wholesalers of medical devices.

(2) The amount of the annual fee referred to in paragraph 1 of this Article shall be determined by the Agency, subject to the prior approval of the Minister. The annual fee shall be paid by the holder of the enrolment in the register or the licence holder.

IX ADVERTISING OF MEDICAL DEVICES

Article 59

(1) Advertising of medical devices within the meaning of this Act shall mean any activity designed to promote the prescription, sale or consumption of a medical device, in any written or oral form, pictorial, audio, electronic, digital or any other form.

(2) It shall be prohibited to advertise any medical device which does not meet the requirements laid down by this Act, with the exception of medical devices intended to be used in exhibitions, demonstrations, fairs etc. Such devices must be provided with a visible sign clearly indicating that they are not intended to be marketed or put into service.

(3) Misleading advertising of medical devices shall be prohibited.

(4) Medical devices which are intended for use exclusively by healthcare practitioners may be advertised but the advertising in such a case must be targeted exclusively to healthcare professionals.

Article 60

Advertising of medical devices shall not contain any information which:

- gives the impression that a medical device can guarantee recovery from illness and that the health of the patient can be improved exclusively by using the advertised medical device, whereas the objective claims must be supported by evidence,
- suggests that the health of the patient could deteriorate without the use of the advertised medical device ;
- encourages patients to abandon generally accepted treatments;
- is directed exclusively or principally at children;
- confuses by using scientific terms unknown to general public for common health conditions;
- refers to statements by scientists, health professionals or persons with influence on the public, who by their reputation could encourage the use of the medical device;
- suggests that the medical device is safety because of its natural origin;
- could, because of detailed description of a pathological state or a case history, lead to erroneous self-diagnosis;
- uses inappropriate, alarming or misleading claims of the possibility of recovery;

- uses inappropriate alarming or misleading pictorial presentations of changes on the human body caused by disease;
- assaults human dignity.

X VIGILANCE

Article 61

(1) Health practitioners, manufacturers or authorised representatives of the manufacturer and legal and natural persons engaged in the wholesale or imports of medical devices shall inform the Agency in writing on any adverse incidents relating to medical devices:

- any malfunction, failure or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labelling or the instructions for use which might lead to the death of a patient or user or to serious deterioration in their state of health;
- any technical or medical reason in relation to the characteristics or performance of a medical device for the reasons referred to in subparagraph 1 of this paragraph, leading to a recall of the medical device by the manufacturer.

(2) The persons referred to in paragraph 1 of this Article shall report an adverse event to the Agency:

1. where there is a serious threat to public health: immediately, but not later than two calendar days after gaining knowledge of the event;
2. where death or unanticipated serious deterioration in health status occurred: immediately after the connection between the medical device and the event has been established, but not later than ten calendar days after the date of gaining knowledge of the event;
3. other: immediately after the connection between the medical device and the event has been established but not later than 30 calendar days after the date of gaining knowledge of the event.

(3) Where the Agency receives information on an adverse event from a health practitioner, medical institution or wholesale distributor, it shall without delay inform of the event the manufacturer or the authorised representative of the manufacturer.

(4) The manufacturer or the authorised representative of the manufacturer of the medical device shall inform the Agency in writing on any corrective measures they intend to implement so as to minimise the possibility of reoccurrence of the adverse event.

(5) After having carried out the analysis of the adverse event, the Agency shall inform the European Commission and the EU Member States of the measures undertaken to minimise the possibility of reoccurrence of the adverse event.

Article 62

The manufacturer or the authorised representative of the manufacturer of medical devices shall:

1. appoint a responsible reference person for vigilance of medical devices, who shall be permanently available,
2. establish and maintain its own vigilance system for medical devices ensuring the collection, evaluation and dissemination of data relating to adverse events in respect of medical devices and cooperate with the Agency,
3. in an appropriate scope, keep a detailed record on all adverse events that occurred in the Republic of Croatia and in other states.

Article 63

(1) Where a health practitioner takes part in a clinical trial as investigator he shall immediately notify the holder of the clinical trial authorisation of any adverse event or suspected adverse event relating to medical devices, except in the case of adverse events for which this is not required in line with the clinical trial protocol and investigator's instructions.

(2) The holder of the clinical trial authorisation shall:

1. keep a detailed record of all adverse events notified to him by the investigator, and submit the information on request to the Agency and the Central Ethics Committee,
2. report to the Agency all adverse events that have resulted in death or serious deterioration of the health status of users immediately after the connection between the medical device and the event has been established, but not later than ten days after the date of gaining knowledge of the event,
3. report to the Agency any adverse events that could have but did not result in death or that could have but did not lead to serious deterioration of the health status of users due to favourable circumstances, immediately after the connection between the medical device and the event has been established, but not later than 30 days after the date of gaining knowledge of the event,
4. notify the investigators of any adverse events referred to in items 2 and 3 of this paragraph that occurred during the clinical trial of a medical device.

Article 64

(1) In case of suspicion that a medical device has been counterfeited, persons referred to in Article 61, paragraph 1 of this Act shall inform the Agency of their suspicion within 24 hours.

(2) The surveillance reporting system relating to adverse events of medical devices shall be stipulated by way of an ordinance to be issued by the Minister.

Article 65

The Agency may request the manufacturer to provide a report on the experience acquired during the use of a new *in vitro* diagnostic medical device referred to in Article 3 item 7 of this Act within two years from its placing on the market.

XI SUPERVISION

Article 66

(1) Supervision of the implementation of provisions of this Act and the regulations adopted on pursuant to this Act shall be carried out by the Ministry.

(2) Pharmaceutical inspections regarding the implementation of the provisions of this Act and the regulations adopted pursuant to this Act shall be performed by pharmaceutical inspectors of the Ministry.

Article 67

When conducting an inspection, the pharmaceutical inspector shall have the following rights and duties:

- to inspect business premises, facilities, installations, devices and equipment,
- to inspect contracts, records, notes and other documents. If documents are supplied electronically, he may require to see them and to have their printout,
- to take copies of certain documents, subject to making the relevant note in the inspection report,
- to require any necessary information from the manufacturer, holder of the enrolment in the register, wholesale distributor or importer and inspect the documents on conformity and technical documentation on the medical device concerned,
- to sample the medical device concerned,
- to inspect personal documents for the purpose of identification,
- take photographs or record data on other visual media about persons, premises, facilities, installations, equipment and so on from subparagraph 1 of this paragraph for the purpose of presentation of evidence,
- to order appropriate inspections and check-ups on medical devices after their placing on the market or putting into service,
- to order recall of medical devices from the market or from service,
- to order proper labelling of medical devices,
- to order that medical devices which do not meet the statutory requirements be properly disposed of where this is necessary for the protection of health of humans,

- to order legal and natural persons to perform their activities in conformity with the criteria set out by this Act and other regulations,
- to order rectification of established irregularities and deficiencies within a set time period,
- to order implementation of other measures in accordance with the powers conferred on them under this Act and other regulations,
- to order suspension or termination of a clinical trial where it has not been carried out in conformity with the provisions of this Act and the ordinance adopted pursuant to this Act,
- to restrict or suspend placing on the market or putting into service or prohibit the use of a medical device which is not in conformity with the requirements stipulated by the provisions of this Act and other regulations adopted pursuant to this Act,
- to temporarily prohibit placing on the market, putting into service or advertising of a medical device where there is reasonable doubt regarding the conformity of the medical device with statutory requirements,
- to prohibit placing on the market and putting into service of a medical device if it is suspected that the medical device or documentation has been counterfeited,
- to prohibit distance sale of the medical devices over the Internet by natural and legal persons where they do not meet the requirements stipulated under this Act,
- to temporarily prohibit the operation of legal and natural persons if they do not meet the requirements stipulated under this Act and the regulations adopted pursuant to this Act,
- to prohibit the operation of legal and natural persons where they are engaged in conformity assessment, manufacturing, designing and placing on the market without the authorisation of the Minister or without having been licenced to do so by the Agency,
- to prohibit advertising of medical devices which are in contravention of the provisions of this Act,
- to prohibit carrying out of the activities which are in contravention of this Act and other regulations.

Article 68

(1) Where the pharmaceutical inspector, in the process of carrying out inspections referred to in Article 67, subparagraph 5 of this Act, decides to ask for verification of a medical device, the verification costs shall be borne by the natural or legal person which has placed the medical device on the market or put the device concerned into service.

(2) The Agency may carry out verification of a particular medical device under the relevant rules established by the Croatian Pharmacopoeia and the European Pharmacopoeia.

Article 69

The tasks of the pharmaceutical inspector may be performed by a person who holds an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in health care or related studies, who has three years of work experience in relevant jobs and who has passed the state licence exam.

Article 70

For the performance of certain activities relating to pharmaceutical inspection requiring special expertise, the Minister shall appoint the relevant experts if the pharmaceutical inspector does not have the necessary expertise or the equipment for the check on or testing of the medical device or he can entrust the qualified institution with the performance of certain activities within the inspectional supervision.

Article 71

(1) The pharmaceutical inspector shall be issued an identity card proving his official status, identity and powers.

(2) The form and content of the identity card and the criteria for the issuance and keeping the register of issued identity cards shall be stipulated by way of an ordinance to be issued by the Minister.

Article 72

Where during the inspection the pharmaceutical inspector finds that the infringement has been committed that constitutes a misdemeanour or a criminal offence, he shall, without delay, within a time period not exceeding 15 days from the day on which the inspection was completed, submit a claim or report to the competent authority.

Article 73

Legal and natural persons shall enable pharmaceutical inspectors to carry out supervision and shall, on his request, provide a required quantity of samples for testing as well as necessary data and information.

Article 74

(1) During inspectional supervision, the pharmaceutical inspector shall examine business premises, buildings, equipment, facilities and documentation.

(2) When conducting inspections referred to in paragraph 1 of this Article the pharmaceutical inspector shall have the right to:

– inspect contracts, records, notes or other quality system documents or other business documentation. If documents are supplied electronically, he may require to see them and have their printout,

– take copies of documents, subject to making the relevant note in the inspection report,

- take free samples of medical devices and raw materials for quality control purposes,
- take and use free data from official records and other databases related to persons, if necessary for inspection,
- recall or withdraw medical devices from the market if they do not comply with the provisions of this Act,
- inspect personal documents for the purpose of identification,
- take photographs or record data on other visual media about persons, premises, facilities, installations, equipment and so on from subparagraph 1 of this paragraph for the purpose of presentation of evidence.

(3) The pharmaceutical inspector shall have the right to conduct unannounced inspections at any time.

Article 75

If the pharmaceutical inspector is physically prevented from carrying out the inspection, he may request help from the police.

Article 76

The pharmaceutical inspector may undertake an inspection also on request of the Agency or the European Commission, within the territory of the Republic of Croatia, other EU Member States or third countries.

Article 77

(1) In carrying out inspections the pharmaceutical inspector shall act in line with the regulations relating to professional secrecy and confidentiality of data.

(2) Legal and natural persons shall inform the pharmaceutical inspector about the information falling under their confidentiality regulations.

Article 78

(1) The pharmaceutical inspector shall pass a verbal decision in the following cases:

1. where threat to human health or life requires immediate implementation of a certain measure,
2. where some evidence could be hidden, replaced or destroyed unless a measure is immediately taken.

(2) The pharmaceutical inspectors may order immediate execution of a verbal decision. The decision shall be entered into the supervision report.

(3) The pharmaceutical inspector shall draw up a written communication of verbal decision within eight days of passing of the verbal decision.

Article 79

An appeal cannot be lodged against a decisions of the pharmaceutical inspector, but administrative proceedings may be instituted .

Article 80

(1) The pharmaceutical inspector shall draw up reports on completed inspections, established status and taken or ordered measures, as well as on performed activities.

(2) A copy of the inspection report shall be sent by the pharmaceutical inspector to the natural or legal person who has been subjected to inspection.

Article 81

Activities of pharmaceutical inspectors shall be governed by the provisions of the General Administrative Procedures Act.

Article 82

(1) Pharmaceutical inspectors shall keep registers of the performed control inspections.

(2) The method of keeping the register shall be stipulated by way of an ordinance to be issued by the Minister.

Article 83

The pharmaceutical inspector shall be responsible for:

1. any failure to take or order measures under his competence,
2. exceeding his authorities,
3. any failure to submit a claim or report to competent authorities about established irregularities or defects.

XII PENAL PROVISIONS

Article 84

(1) A fine in the amount ranging from HRK 70.000,00 to 100.000,00 shall be imposed on a legal and natural person for a misdemeanour if they:

1. place on the market medical devices systems or procedure packs in contravention of Article 16, paragraphs 1 and 3 and Article 17, paragraphs 1, 3, 4, 6 and 7 of this Act,

2. conduct a clinical trial of a medical device without authorisation of the Minister (Article 21, paragraph 2),
3. start a clinical trial without an informed consent of the person subject to the clinical trial concerned (Article 23),
4. conduct a clinical trial in contravention of Article 23, paragraphs 2, 3 and 5 of this Act,
5. conduct a clinical trial in contravention of the provision of Article 24, paragraph 1 of this Act,
6. do not meet the requirements referred to in Article 27, paragraph 1 of this Act,
7. if the manufacturer of the medical devices has not been insured against the harmful effects which might occur by the use of a medical device (Article 27, paragraph 2),
8. do not carry out the conformity assessment procedure relating to the medical device on the basis of the classification of the medical device concerned (Article 31, paragraph 2),
9. place a medical device on the market in contravention of the provision of Article 32, paragraph 1 of this Act,
10. label the medical device in contravention of the provision of Article 33, paragraphs 1 and 2 of this Act,
11. affix a CE marking on the medical device which does not meet the requirements laid down by this Act (Article 33, paragraph 3),
12. label a product which is not a medical device with the CE marking (Article 33, paragraph 4),
13. put any marks or inscriptions on the medical device which could be misleading (Article 33, paragraph 5),
14. perform the activity relating to conformity assessment without authorisation of the Minister (Article 36, paragraph 1),
15. perform the jobs partially and outside their competence (Article 40, paragraph 1),
16. act against the provision of Article 40, paragraphs 2 and 3 of this Act,
17. place on the market or put into service a medical device in contravention of the provision of Article 46, paragraph 1 of this Act,
18. do not ensure transport, storage and handling conditions of medical devices within the meaning of the statutory requirements (Article 46, paragraph 2),
19. engage in the wholesale of medical devices in contravention of the provision of Article 47, paragraphs 1 and 2 of this Act,

20. engage in the wholesale of medical devices but fail to meet the statutory requirements (Article 48, paragraph 1),
21. engage in retail sale of medical devices in contravention of Article 49, paragraphs 1, 2 and 3 of this Act,
22. engage in distance selling of the medical devices over the Internet in contravention of the provision of Article 50, paragraphs 2 and 3 of this Act,
23. engage in the import of the medical devices from third countries in contravention of the provisions of Articles 51, and 52 of this Act,
24. dispose of medical devices no longer in use in contravention of the provisions of Article 57 of this Act,
25. advertise medical devices in contravention of the provision of Article 59, paragraphs 2, 3 and 4 of this Act,
26. if the advertisement on medical device contains information referred to in Article 60, paragraph 1 of this Act,
27. do not notify in writing the Agency on adverse events and undertaken corrective actions under Article 61 of this Act,
28. fail to meet the requirements relating to vigilance of medical devices (Article 62),
29. fail to notify the adverse events in clinical trials (Article 63),
30. do not ensure the pharmaceutical inspector to carry out the inspection within the meaning of the provisions of this Act and the regulations adopted pursuant to this Act (Article 73),
31. do not act within the prescribed time period in accordance with the enforceable decision of the pharmaceutical inspector on the basis of which the imposition of certain measures and actions has been ordered or the operation has been prohibited (Article 79).

(2) For the misdemeanour referred to in paragraph 1 of this Article the responsible person in the legal person shall also be fined the amount ranging from HRK 7.000,00 to 10.000,00.

Article 85

(1) A fine in the amount ranging from HRK 50.000,00 to 80.000,00 shall be imposed on a legal and natural person for a misdemeanour if they:

1. place a medical device on the market or put a medical device into service without the instruction for use or where the instruction for use or the labelling contravene the provisions of this Act (Article 12, paragraphs 1, 2, 4, 5 and 6),
2. do not notify the Ministry on any modification of the documentation or the clinical trial procedure on the basis of which the clinical trial has been authorised (Article 22, paragraph 1),

3. do not carry out the clinical trial within the meaning of Article 26, paragraph 3 of this Act,
4. do not file an application for the registration in the register of manufacturers of the Agency (Article 28, paragraph 1),
5. do not notify the Agency on the modifications or additional material supplemented to the documentation on the basis of which the Agency made the entry into the register (Article 29, paragraph 1),
6. do not communicate information referred to in Article 40, paragraph 4, subparagraphs 1 and 2 of this Act,
7. do not file the application for registration in the register of medical devices with the Agency (Article 41, paragraph 3),
8. do not notify the Agency on the modifications and additional information supplemented to the documentation on the basis of which the Agency made the entry into the register (Article 43, paragraph 1),
9. do not file the application for the modification of the entry into the register of wholesalers of medical devices or for the modification of the licence for retail sale of medical devices (Article 55, paragraph 1),
10. do not notify a suspicion of a counterfeited medical device (Article 64, paragraph 1).

(2) For the misdemeanour referred to in paragraph 1 of this Article the responsible person in the legal person shall also be fined the amount ranging from HRK 5.000,00 to 8.000,00.

XIII TRANSITIONAL AND FINAL PROVISIONS

Article 86

The ordinances referred to in Article 6, paragraph 3, Article 9, paragraph 6, Article 13, paragraph 2, Article 20, paragraph 1, Article 21, paragraph 6, Article 24, paragraph 1, Article 30, paragraph 5, Article 35, Article 36, paragraph 2, Article 41, paragraph 6, Article 46, paragraph 3, Article 47, paragraph 4, Article 49, paragraph 5, Article 50, paragraph 4, Article 56, paragraphs 2 and 3, Article 64, paragraph 2, Article 71, paragraph 2 and Article 82, paragraph 2 of this Act, shall be adopted by the Minister, in accordance with the authority assigned to him within the meaning of this Act, within a time period of one year from the entry into force of this Act.

Article 87

Until the entry into force of the ordinances referred to in Article 86 of this Act, the following ordinances shall remain in force:

1. Ordinance on clinical trials and good clinical practice (Official Gazette 121/07), in the part thereof relating to medical devices,

2. Ordinance on the criteria for issuing permits to specialised stores for retail sale of medicinal products and medical devices (Official Gazette 29/05, 81/06 and 5/07), in the part thereof relating to medical devices,
3. Ordinance on adverse events reports relating to medical devices (Official Gazette, no. 74/09),
4. Ordinance on essential requirements, classification, quality system, entry into the register of manufacturers and register of medical devices and on conformity assessment of medical devices (Official Gazette 43/10),
5. Ordinance on good practice and criteria for granting a licence for placing of medical devices on the market (Official Gazette 54/05 and 81/06),
6. Ordinance on good practice, criteria for granting a licence for the wholesale and import and export of medical devices (Official Gazette 38/10),
7. Ordinance on the criteria for the inclusion of orthopaedic and other aids on the List of aids of the Croatian Institute for Health Insurance (Official Gazette 138/09 and 43/13),
8. Ordinance on the criteria for pricing of orthopaedic and other aids (Official Gazette 138/09 and 29/12).

Article 88

- (1) The decisions on the registration of manufacturers with their registered place of business in the Republic of Croatia in the register of manufacturers of medical devices which have been issued before the adoption of this Act shall remain in effect.
- (2) On the day of entry into force of this Act the Agency shall open the proceedings for revocation of decisions on the registration of the manufacturers - representatives of foreign manufactures in the register of manufacturers of medical devices issued before the entry into force of this Act.

Article 89

- (1) The decisions on the registration of medical devices of Class I in the register of medical devices, which have been manufactured by the manufacturers with their registered place of business in the Republic of Croatia issued before the entry into force of this Act shall remain in effect.
- (2) For medical devices of Class IIa, IIb and III, *in vitro* diagnostic medical devices and active implantable medical devices that have been registered in the register of medical devices of foreign manufacturers and manufacturers with the registered place of business in the Republic of Croatia until the entry into force of this Act, it shall be considered that they have been placed on the market in the territory of the Republic of Croatia in compliance with Article 42, paragraph 1 of this Act, if they meet the requirements laid down by this Act.

Article 90

The manufacturing licences issued on the basis of regulations that have been in effect before this Act enters into force shall remain valid until the date of their expiration.

Article 91

(1) Medical devices that have been licenced for the wholesale of medical devices on the basis of regulations in effect before this Act enters into force shall be considered as having been registered in the register of wholesalers of medical devices in accordance with this Act.

(2) Licences for retail sale of medical devices issued on the basis of regulations in effect until the entry into force of this Act shall remain valid after the entry into force of this Act.

Article 92

Legal persons performing the activities of import and export of medical devices on the day of entry into force of this Act shall bring their operations in compliance with the provisions of this Act within a time period not exceeding 90 days from the day of entry into force of this Act.

Article 93

The Medical Devices Act (Official Gazette 67/08 and 124/11) shall cease to have effect on the day of entry into force of this Act.

Article 94

This Act shall enter into force on the eighth day from the day of its publication in the Official Gazette, with an exception of Articles 1 to 5, Article 6, paragraphs 1 and 2, Articles 7 and 8, Article 9, paragraphs 1 to 5, Articles 10 to 12, Article 13, paragraph 1, Articles 14 to 29, Article 30, paragraphs 1 to 4, Articles 31 to 34, Articles 36 to 40, Article 41, paragraphs 1 to 4, Articles 42 to 63, Article 64, paragraph 1, and Articles 65 to 93, which shall enter into force on the day of accession of the Republic of Croatia to the European Union.

Class: 022-03/13-01/123

Zagreb, 14 June 2013

THE CROATIAN PARLIAMENT

President of the
Croatian
Parliament
Josip Leko, m.p.