THE CROATIAN PARLIAMENT

Pursuant to Article 88 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 30 May 2008.

Class: 011-01/08-01/59

Reg. No.: 71-05-03/1-08-2

Zagreb, 4 June 2008

The President of the Republic of Croatia

Stjepan Mesić, m. p.

THE MEDICAL DEVICES ACT

I GENERAL PROVISIONS

Article 1

This Act establishes the requirements for medical devices, clinical trials of medical devices, registration in the register of medical device manufacturers, conformity assessment, marking of conformity and registration in the register, distribution, advertising and notification, and vigilance and supervision of medical devices in order to ensure the quality and safety of medical devices as products of special importance for the protection of human health. The provisions of this Act shall apply to medical devices and their accessories, including *in vitro* diagnostic medical devices and active implantable medical devices.

Article 2

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

1. *Medical device* shall mean any instrument, apparatus, appliance, software, material or other article, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means and which is either used alone or in combination with the software necessary for its proper application 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.

2. *Orthopaedic and other aids* (hereinafter: aids) shall mean medical devices pursuant to item 1 of this Article whose purpose is to enable the improvement of impaired functions or to alleviate or remove physical impairments or deficiencies of organs or organ systems or to replace the anatomy or a physiological process resulting from a disease or an injury. They shall be ensured for the insurants of the Croatian Institute for Health Insurance (hereinafter: the Institute) under the compulsory health insurance scheme. These medical devices shall be custom made in accordance with the instructions of the authorised medical doctor or dental medicine doctor and intended solely for a particular user or they shall be mass produced to be subsequently adapted to a particular user or mass produced and intended for all users.

3. *Accessory* shall mean an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

4. *In vitro diagnostic medical device* shall mean 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, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles shall be 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 shall mean an article which whilst not being an *in vitro* diagnostic medical device is intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable it to be used in accordance with the use of the *in vitro* diagnostic medical device intended by the manufacturer of the device.

5. *Medical device for self-testing* shall mean an *in vitro* diagnostic medical device intended by the manufacturer for household use.

6. *Medical device for evaluation* shall mean an *in vitro* diagnostic medical device intended for evaluation in the laboratory or other appropriate environments.

7. *Calibrators and control materials* shall mean substances, materials and objects intended by their manufacturers 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.

8. *In vitro diagnostic medical device* 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.

9. *Active medical device* shall mean 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.

10. *Active implantable medical device* shall mean 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.

11. *Custom-made medical device* shall mean 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.

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

12. *A medical device intended for clinical investigation* shall mean any medical device used as an object of testing or as an additional piece of equipment in testing of medicinal products.

13. *Clinical data* shall mean the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

- clinical investigation(s) of the device concerned; or
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

14. *Protocol* shall mean a document that describes the objective(s), design, methodology, statistical considerations and organisation of a clinical trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments.

15. *Sponsor* shall mean any legal or natural person who takes responsibility for the initiation, management and/or financing of a clinical trial.

16. *Clinical trial applicant* shall mean a sponsor having the registered place of business in the Republic of Croatia or any legal person having the registered place of business in the Republic of Croatia and registered to perform mediation activities relating to clinical trials who, on behalf of the sponsor and by virtue of a power of attorney, files the application for a clinical trial.

17. *The Central Ethics Committee* shall mean 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: the Minister) shall appoint the Central Ethics Committee.

18. *Good clinical practice* shall mean a set of internationally recognised ethical and scientific requirements which must be observed for designing, conducting, recording and reporting on clinical trials.

19. *Informed consent* shall mean 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,
20. *Medical device manufacturer* shall mean any natural or legal person with responsibility for the design, manufacture, packaging, instructions for use and labelling of a 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.
The obligations of this Act to be met by manufacturers shall also apply to any natural or legal person who assembles, packages, processes, fully refurbishes and/or labels medical devices with a view to their being placed on the market under his own name. These obligations shall not apply to the person who, while not a manufacturer, assembles or adapts devices already on the market to their intended purpose for an individual patient.
21. *Intended purpose* shall mean the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.
22. *Placing on the market* shall mean the first making available of a device in the Republic of Croatia, other than a device intended for clinical investigation, regardless of whether it is new or fully refurbished.
23. *Putting into service* shall mean the stage at which a device has been made available to the final user.
24. *Device subcategory* shall mean a set of devices having common areas of intended use or common technology.
25. *Generic device group* shall mean a set of 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* shall mean a device intended to be used once only for a single patient.
27. *Medical devices manufactured utilising animal tissue which is rendered nonviable or nonviable products derived from animal tissues* shall meet the essential requirements with regard to risks of transmitting transmissible spongiform encephalopathies (BSE) under normal conditions of use to patients or others and which have been identified as such during the conformity assessment procedure.
28. Vigilance of medical devices shall mean activities comprising the 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 effects, interactions with other substances or products, contraindications, counterfeiting, decreased effects, defects and technical irregularities.
29. Person responsible for vigilance of medical devices shall mean a medical doctor, dental medicine doctor, pharmacist or medical biochemist.
30. *Adverse event relating to a medical device* shall mean 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.
31. *Holder of registration in the register of medical devices and register of medical device manufacturers* shall mean any manufacturer having the registered place of business in the Republic of Croatia or any legal person having the registered place of business in the Republic of Croatia and representing a foreign manufacturer.

32. *Wholesaler* shall mean any legal person holding the authorisation for the performance of wholesale activities issued by the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency).
33. *Importer/exporter of medical devices* shall mean any legal person authorised by the Agency for import/export of medical devices.
34. *Wholesale* shall cover procurement, acceptance, storage, sale, delivery, other than delivery to end users, and import and export of medical devices.
35. *Retail sale* shall cover ordering, keeping and dispensing of medical devices.
36. *Good practice in wholesale of medical devices* shall mean 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.
37. *Conformity assessment of the medical device* shall mean 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.
38. *Body responsible for conformity assessment* shall mean an independent laboratory, confirmatory body, supervisory or any other body authorised by the Minister to conduct the conformity assessment procedure for medical devices.
39. *Notified body* shall mean any body responsible for conformity assessment 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.
40. *Croatian standard* shall mean the publicly available standard accepted by the Croatian national standardisation authority.
41. *Attestation* shall mean the procedure by which an independent attestation authority officially confirms that a legal or natural person is capable of performing certain activities relating to conformity assessment.

Article 3

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

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.

Where 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 regulations.

Article 4

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 or 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,
- personal protective equipment and accessories in line with special regulations.

The main purpose of the device shall determine whether it is a medical device or not.

Article 5

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.

II REQUIREMENTS FOR MEDICAL DEVICES

Article 6

Medical devices may be placed on the market only if they do not compromise the health and safety of patients, users and other persons, and if they have been properly manufactured, installed, maintained and used in accordance with their intended purpose.

Medical devices shall meet the essential requirements taking account of their intended purpose.

Medical devices emitting ionising radiation shall also meet the requirements defined by the regulations on protection against ionising radiation.

Devices which are also machinery pursuant to a special regulation shall also meet the essential requirements of this Act.

The essential requirements for medical devices (hereinafter: essential requirements), which shall be defined in detail in an ordinance to be issued by the Minister, shall be implemented to ensure the safety and efficacy of medical devices.

Article 7

Medical devices referred to in Article 2, item 27 of this Act shall mean medical devices originating from bovine, ovine and caprine species, as well as from deer, elk, mink and cats.

In accordance with a special regulation, collagen, gelatin and tallow used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption.

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.

Article 8

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.

The list of Croatian standards for medical devices shall be published in the Official Gazette.

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

Article 9

Where it is ascertained that the medical device, which meets the requirements from Article 6 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 recall this medical device or restrict its use *ex officio* or on the request of a pharmaceutical inspector from the ministry in charge of health (hereinafter: the Ministry).

The Agency shall immediately inform the Commission of any such measures from paragraph 1 of this Article, indicating the reasons for its decision and, in particular in the case of:

(a) failure to meet the essential requirements;
(b) incorrect application of the standards referred to in Article 8 of this Act,
(c) shortcomings in the standards themselves.

When a non-complying medical device bears a marking of conformity, the Agency shall recall that medical device on the basis of notification received from the pharmaceutical inspector.

The Agency shall notify the European Commission and Member States thereof.

Article 10

With regard to a degree of user risk, medical devices shall be classified into:

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

The classification rules may be changed in the light of technical progress and any new information that becomes available.

Detailed conditions, rules and procedure for classification of medical devices and *in vitro* diagnostic medical devices shall be stipulated by an ordinance to be issued by the Minister.

Article 11

In the event of a dispute between the manufacturer and the body responsible for conformity assessment, resulting from the application of the classification rules, the matter shall be referred for decision to the Ministry.

In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred to the body competent for the notified body.

Where it is established that the classification rules set 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 Commission and ask it to take the necessary measures for adaptation of classification rules.

Article 12

Any manufacturer who assembles and places on the market medical devices, as a system or procedure pack, bearing the marking of conformity together within their intended purpose and within the limits of use specified by their manufacturers, shall draw up a declaration by which he states that:

(a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and
(b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and that
(c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions from paragraph 1 of this Article are not met, as in cases where the system or procedure pack incorporate devices which do not bear a marking of conformity 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 device that is subject to the relevant conformity assessment procedure.

Article 13

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.

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.

During the use of the medical device that should be pre-sterilised 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.

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.

The systems and procedure packs from paragraph 1 of this Article shall not have to bear an additional marking of conformity.

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.

The manufacturer shall keep the declarations from Article 12 of this Act and paragraph 4 of this Article for five years, and submit them at the request of the Agency.

Article 14

The Minister shall issue an ordinance establishing the quality systems for medical devices.

III CLINICAL TRIALS OF MEDICAL DEVICES

Article 15

A clinical trial of a medical device shall mean any trial whose purpose is to establish whether a medical device satisfies the essential requirements and thus protects public health.

Article 16

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.

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

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 a legal person requesting the clinical trial of a medical device.

Article 17

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.

The Minister shall grant or refuse his authorisation for the clinical trial of the medical device within 60 days of the receipt of an application and documentation to be defined by him in an ordinance.

If the Minister does not give or refuse his authorisation for the clinical trial of the medical device within the deadline from paragraph 2 of this Article, the authorisation shall be deemed granted.

The Minister shall issue or refuse the authorisation from paragraph 1 of this Article by the decision that cannot be appealed, but against which administrative proceedings may be instituted. The costs of issuance of the authorisation shall be incurred by the applicant.

The Minister shall issue an ordinance establishing the documentation, procedure and requirements for clinical trials of medical devices and the procedure for delivery of the opinion by the Central Ethics Committee.

Article 18

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

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

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.

Clinical trials shall not be conducted if potential risks of a medical device use outweigh medical justification according to the assessment made by the Minister.

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

Article 19

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.

Clinical trials of medical devices shall take place only on the premises of legal persons referred to in Article 16 of this Act who have entered into clinical trial agreements with clinical trial applicants.

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 16 of this Act and compensations to investigators and subjects.

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 20

The provisions of Articles 15–19 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 21

If necessary, the Ministry shall take any necessary measures in order to ensure protection of public health. If an authorisation for a clinical trial is refused or if a clinical trial is suspended, the Ministry shall inform all Member States and the European Commission of its decision and provide the relevant justification. When a Member State refers to significant amendments or a temporary suspension of a clinical trial, it shall notify all interested Member States of its activities and their reasons.

A clinical trial sponsor or applicant shall notify the competent authorities of the interested 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 its early termination due to safety reasons, this notification shall be forwarded to all Member States and the European Commission.

IV REGISTRATION IN THE REGISTER OF MEDICAL DEVICE MANUFACTURERS

Article 22

Legal and natural persons manufacturing or producing medical devices shall file the application for registration in the register of medical device manufacturers maintained by the Agency.

The application for registration of medical device manufacturers in the corresponding register may be filed by:

- manufacturers of medical devices having the registered place of business in the Republic of Croatia,
- representatives of foreign manufacturers having the registered place of business in the Republic of Croatia.

The Agency shall issue a decision on registration of the medical device manufacturer in the register of medical device manufacturers within 90 days of the date of receipt of the complete application.

An appeal may not be lodged against the decision from paragraph 3 of this Article, though administrative proceedings may be instituted.

Article 23

Following the registration of the medical device manufacturer in the corresponding register, the holder of registration in the register of medical device manufacturers shall notify any amendment to the documentation based on which the Agency made the registration in the register.

The registration holder shall file the application for amendment to registration with the Agency.

If the approved amendment requires an amendment to the decision on registration of the manufacturer in the register of medical device manufacturers, the Agency shall pass a decision on amendment to the decision on registration of the medical device manufacturer in the corresponding register that may not be appealed, but against which administrative proceedings may be instituted.

The Agency shall either grant or refuse an amendment, depending on its type, to the decision on registration of the manufacturer in the relevant register within maximum 30 days of the date of receipt of the complete application.

Article 24

The Agency shall cancel the registration of the manufacturer in the register of medical device manufacturers in the following cases:

- on the substantiated request of the registration holder,
- *ex officio* if it is established that the manufacturer has been registered in the register contrary to the provisions of this Act and the ensuing regulations.

The Agency shall carry out the cancellation of the medical device manufacturer from the register of medical device manufacturers by issuing a decision that cannot be appealed, but against which administrative proceedings may be instituted.

The Agency shall issue the decision on cancellation within maximum 30 days.

Article 25

If the application for registration, amendment to registration or cancellation from the register of medical device manufacturers is not complete, or if the application is not supported by the stipulated data and documents, the Agency shall invite the applicant in writing to rectify the deficiencies explicitly stated in the invitation and submit the requested data and documents within maximum 30 days of the date of receipt of the invitation.

If the Agency requires the applicant to supplement the application, the deadline from Article 22, paragraph 3, Article 23, paragraph 4 and Article 24, paragraph 3 of this Act shall not run until the date of delivery of the supplemented application.

The deadline shall neither run during the time approved to the applicant to provide a written or verbal explanation.

The Agency shall define the costs of the procedure for issuance, refusal, amendment or cancellation on the request of the holder of registration in the register of medical device manufacturers, subject to approval by the Minister, and these costs shall be incurred by either the applicant or the registration holder.

The procedure and the method for registration in the register of medical device manufacturers, amendments to registration and cancellation of the manufacturer in the register of medical device manufacturers, as well as requisite documentation, shall be stipulated by an ordinance to be issued by the Minister.

V CONFORMITY ASSESSMENT, MARKING OF CONFORMITY AND REGISTRATION IN THE MEDICAL DEVICE REGISTER

Article 26

The conformity of the medical device with the essential requirements shall be confirmed by the issuance of the conformity document (declaration, certificate).

The procedure for assessment of conformity of the medical device with the essential requirements shall be conducted in line with the class of the medical device.

Within the procedure for registration in the medical device register and the issuance of approval for import of the medical device, the Agency shall accept the documents and the marking of conformity issued by the competent authority of a Member State showing the conformity with defined requirements that correspond to those laid down by this Act and the ensuing regulations or the regulations of the European Union.

Article 27

Prior to placing of the medical device on the market, the manufacturer shall draw up a declaration of conformity and affix a marking of conformity.

The marking of conformity shall not be required for medical devices intended for clinical investigation and for custom-made medical devices.

The marking of conformity shall neither be required for medical devices intended for exhibitions, demonstrations, trade fairs, etc. These devices shall bear a visible sign clearly indicating that they may not be marketed or put into service.

Article 28

The marking of conformity shall 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.

It shall be accompanied by the identification number of the notified body or of the body responsible for conformity assessment, if involved in the procedure for conformity assessment.

It is prohibited to affix labels to medical devices that do not comply with the provisions of this Act.

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 marking of conformity.

Article 29

Detailed requirements for the conformity assessment procedure and for the content of the declaration of conformity and the marking of conformity shall be stipulated in an ordinance, to be issued by the Minister subject to prior opinion of the ministry in charge of the economy.

Article 30

The registration of the medical device in the register of medical devices shall mean an administrative procedure conducted by the Agency with an aim to keep the records of medical devices marketed in the Republic of Croatia and thus protect public health.

At the request of the medical device manufacturer having the registered place of business in the Republic of Croatia, the Agency shall issue a certificate of registration of the medical device in the register of medical devices.

The application for registration of the medical device in the register of medical devices may be filed by:

- manufacturers of medical devices having the registered place of business in the Republic of Croatia,
- representatives of foreign manufacturers that have the registered place of business in the Republic of Croatia and are registered in the register of medical device manufacturers.

The Agency shall issue a decision on registration of the medical device in the register of medical devices within 90 days of the date of receipt of the complete application.

An appeal cannot be lodged against the decision from paragraph 4 of this Article, but administrative proceedings may be instituted.

Article 31

Following the registration of the medical device in the register, the registration holder shall notify any amendment to the documentation based on which the Agency made the registration.

The registration holder shall file an application for amendment to the registration in the register with the Agency.

If the approved amendment requires an amendment to the decision on registration of the medical device in the register, the Agency shall pass a decision on amendment to the decision on registration of the medical device in the register that cannot be appealed, but against which administrative proceedings may be instituted.

The Agency shall approve or refuse the amendment to the decision on registration in the register or the approved amendment, depending on a type of the amendment, within maximum 30 days of the date of receipt of the complete application.

Article 32

The Agency shall cancel the medical device from the register *ex officio* in the following cases, i.e. if it has established that:

- the medical device has been registered in the register contrary to the provisions of this Act,
- the medical device is unacceptably harmful under prescribed conditions of use,
- the data in the documentation submitted for registration of the medical device in the register of medical devices are not accurate,
- the data about the registration holder are not accurate.

The Agency shall cancel the medical device from the register on the written substantiated request of the registration holder.

The cancellation of the medical device from the register shall be carried out on the basis of a decision that cannot be appealed, but against which administrative proceedings may be instituted.

The Agency shall issue the decision on cancellation of medical devices from the register within maximum 30 days.

The Agency shall notify the Institute of any cancellation of an orthopaedic aid from the register of medical devices for the purpose of its exclusion from the Institute's list of orthopaedic aids.

Article 33

In case the application for registration, amendment to registration or cancellation of the medical device from the corresponding register is not complete, i.e. required data and documents have not been submitted, the Agency shall invite the applicant in writing to rectify deficiencies explicitly stated in the invitation and furnish required data and documents within 30 days of receipt of the invitation.

Should the Agency invite the applicant to supplement the application, the time limit referred to in Article 30, paragraph 4, Article 31, paragraph 4 and Article 32, paragraph 4 shall be suspended until such time as the required supplementary information has been provided.

Likewise, the time limit shall be suspended for the time allowed to the applicant to give a written or verbal explanation.

The Agency shall define the costs of the procedure for issuance, refusal, amendment or cancellation on the request of the holder of registration in the register of medical devices, subject to approval by the Minister, and the costs shall be incurred by either the applicant or the registration holder.

The procedure and the method for registration in the register of medical devices, amendments to registration and cancellation of the medical device from the corresponding register, as well as requisite documentation, shall be stipulated by an ordinance issued by the Minister.

Article 34

The Minister may authorise the body responsible for conformity assessment, which shall conduct the conformity assessment procedures for medical devices in the territory of the Republic of Croatia until the date of accession of the Republic of Croatia to the European Union.

As at the date of accession of the Republic of Croatia to the European Union, all certificates issued by the body responsible for conformity assessment from paragraph 1 of this Article shall cease to have effect.

The criteria for issuance of the authorisation from paragraph 1 of this Article shall be stipulated by an ordinance issued by the Minister.

After the accession of the Republic of Croatia to the European Union and on the request of the body responsible for conformity assessment, the Minister shall notify the European Commission of the body responsible for conformity assessment in order to obtain the identification number and acquire the status of the notified body.

The Minister shall withdraw the notification from paragraph 4 of this Article if the body responsible for conformity assessment no longer meets the criteria from paragraph 3 of this Article, and it shall immediately inform Member States and the European Commission thereof.

The bodies responsible for conformity assessment, which have the certificate of attestation, shall issue the certificate of conformity of a medical device with regard to the scope of activities and devices covered by the attestation.

Article 35

The documentation received by the Agency and all data relating to medical devices, other than those registered in the Agency’s registers, shall represent a business secret.

The provision of paragraph 1 of this Article shall not apply to the exchange of information, i.e. to warnings exchanged between third countries and competent authorities.

VI DISTRIBUTION OF MEDICAL DEVICES

Article 36

Medical devices can be marketed or they can be put into service only if they fulfil the essential requirements, if their conformity has been established by applying the relevant procedure, if they bear the marking of conformity in a stipulated manner and if they have been entered in the register of medical devices.

All legal and natural persons and state authorities that come into possession of medical devices in any way whatsoever shall ensure the compliance of their transport, keeping and storage with stipulated requirements.

The ordinance on good practice in wholesale of medical devices shall be issued by the Minister.

Article 37

Wholesale of medical devices may be carried out by:

- legal persons holding the Agency's authorisation for wholesale distribution of medical devices (wholesales of medical devices),
- manufacturers of medical devices having the registered place of business in the Republic of Croatia for those devices they manufacture and that have been entered in the register of medical devices.

Article 38

Wholesale distributors shall be allowed to procure medical devices directly from manufacturers, or from importers or from other wholesale distributors.

Article 39

Wholesale distributors and manufacturers shall be allowed to supply medical devices to:

- pharmacies and pharmacy depots,
- healthcare institutions,
- other wholesale distributors,
- private surgeries.

Wholesale distributors may supply other legal and natural persons with medical devices in line with this Act, the ensuing regulations, or special regulations in the event of medical devices for which the Agency has granted approval on the basis of the decision on their registration in the register of medical devices.

The importer may supply medical devices to wholesalers only.

Article 40

Wholesale distribution of medical devices may be carried out only by legal persons holding the Agency's wholesale distribution authorisation.

The Minister shall issue an ordinance specifying the requirements, the procedure, documents and data for obtaining the wholesale distribution authorisation for medical devices.

Article 41

Retail sale of medical devices shall be carried out by legal and natural persons with authorisation to engage in pharmacist activities granted under a separate act, as well as specialised retail stores holding the authorisation for retail sale of medical devices.

Specialised retail stores for medical devices may sell only those medical devices holding the Agency's authorisation issued on the basis of decision on their registration in the register of medical devices.

The Minister shall issue an ordinance specifying conditions, procedure, documents and data for obtaining the retail distribution authorisation for medical devices.

Article 42

Wholesale distributors and importers of medical devices shall carry out the import and export of medical devices.

Legal persons holding the Agency’s wholesale distribution authorisation or import and export licence for medical devices shall import and export medical devices.

The Minister shall issue an ordinance establishing the conditions to be met by legal persons for obtaining the import and export licence for medical devices.

Article 43

The Agency shall grant the marketing authorisation referred to in Article 40, paragraph 1, Article 41, paragraph 1, and Article 42, paragraph 2 of this Act within 90 days of receipt of the complete application.

In case the application is not complete, i.e. required data and documents have not been submitted, the Agency shall invite the applicant in writing to rectify deficiencies explicitly stated in the invitation and furnish required data and documents within 30 days of receipt of the invitation.

Should the Agency invite the applicant to supplement the application, the time limit referred to in paragraph 1 of this Article shall be suspended until such time as the required supplementary information has been provided. Likewise, the time limit shall be suspended for the time allowed to the applicant to give a written or verbal explanation.

The authorisation for the wholesale of medical devices, retail sale of medical devices in specialised retail stores and for import and export of medical devices shall be granted by a decision which cannot be appealed, but against which administrative proceedings may be instituted.

The Agency, subject to the approval by the Minister, shall determine the costs of issuance, refusal, amendment or revoking of the authorisations from paragraph 1 of this Article. The costs shall be settled by applicants or authorisation holders.

Article 44

The Agency shall revoke the authorisation for wholesale of medical devices, the authorisation for retail sale of medical devices in specialised retail stores, and the import and export licence for medical devices if the data and documents supporting the application are found to be inaccurate or if the authorisation holder no longer fulfils the conditions based on which the authorisation was issued.

On the basis of the written request of the authorisation holder, the Agency shall issue a decision revoking the authorisations from paragraph 1 of this Article if the authorisation holder discontinues his operations.

The authorisation for wholesale of medical devices, for retail sale of medical devices in specialised retail stores and the import and export licence shall be withdrawn and revoked by a decision which cannot be appealed, but against which administrative proceedings may be instituted.

The list of authorisations for wholesale distribution of medical devices and the list of decisions on withdrawal and revoking of authorisations for wholesale distribution of medical devices shall be published once a year in the Official Gazette.

Article 45

Holders of wholesale distribution authorisations, authorisations for retail sale of medical devices in specialised retail stores and of import and export licences shall notify the Agency in writing about all changes in conditions, documents and data based on which the authorisation was granted.

The Agency shall issue the decision on amendment to authorisations from paragraph 1 of this Article within 90 days of receipt of a complete application.

Where an application is not complete, i.e. required data and documents have not been submitted, the Agency shall invite the applicant to rectify deficiencies, i.e. to submit the required documents and data within 30 days of receipt of the invitation.

Should the Agency invite the applicant to supplement the application, the time limit referred to in paragraph 2 of this Article shall be suspended until such time as the required supplementary information has been provided. Likewise, the time limit shall be suspended for the time allowed to the applicant to give a verbal or written explanation.

Amendment to the authorisation for the wholesale distribution of medical devices, retail sale of medical devices in specialised retail stores and to import and export licences shall be granted by a decision which cannot be appealed, but against which administrative proceedings may be instituted.

Article 46

Legal persons from Articles 40 and 42 of this Act shall not be required to have an import licence for medical devices entered in the register of medical devices.

Legal persons from paragraph 1 of this Article shall be required to have an import licence for medical devices that are not entered in the register of medical devices provided that there is an urgent medically justified need as well as in the following cases:

- for purposes of research,
- for clinical trials,
- in case of natural disasters or other emergencies.

The Minister shall issue an ordinance establishing more detailed conditions for granting the import licence referred to in paragraph 2 of this Article.

Article 47

The Institute shall adopt a list of aids covered by the compulsory health insurance that shall be established in line with a special act.

The criteria for inclusion of aids in the list from paragraph 1 of this Article shall be established by an ordinance issued by the Minister.

The pricing criteria for aids from paragraph 1 of this Article shall be established by an ordinance issued by the Minister.

Article 48

The distribution of medical devices via the Internet shall be prohibited.

Certain medical devices may be sold, in addition to pharmacies and specialised retail stores, outside of them in line with a decision on registration of medical devices in the register of medical devices.

Article 49

Medical devices that can no longer be used shall be disposed of at the cost of their owners.

The regulations governing waste management shall apply to disposal of medical devices from paragraph 1 of this Article.

Article 50

The Agency shall charge an annual fee for the decision on registration of medical devices in the register of medical devices, the decision on registration in the register of medical device manufacturers, wholesale and retail sale authorisations for medical devices and import and/or export licences for medical devices.

The amount of the annual fee from paragraph 1 of this Article shall be defined by the Agency subject to approval by the Minister, and incurred by the registration or authorisation/licence holder.

VII ADVERTISING AND NOTIFICATIONS RELATING TO MEDICAL DEVICES

Article 51

The advertising and notifications relating to medical devices without certificates of conformity, markings of conformity or registration in the register of medical devices shall be prohibited.

The method for advertising and notifications relating to medical devices shall be established by an ordinance issued by the Minister.

VIII VIGILANCE

Article 52

A healthcare professional in contact with the user of a medical device shall notify the Agency in writing and within the shortest possible about any adverse event or any suspected adverse event relating to the medical device.

A healthcare professional, wholesaler, manufacturer or holder of the registration of the medical device in the register of medical devices shall immediately notify the Agency in writing about the following adverse events:

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

When the Agency receives a notification about an adverse event from a healthcare professional, a healthcare institution or a wholesale distributor, it shall notify the manufacturer or the registration holder thereof.

Following the analysis of the adverse event, the Agency shall notify the European Commission and Member States about the measures taken to mitigate its consequences.

Article 53

The holder of registration in the register of medical devices shall:

1. appoint a vigilance expert who shall be at his disposal at all times,
2. keep detailed records of all adverse events occurring in the Republic of Croatia or any other country,

3. report all adverse events that have caused death or serious aggravation of the health status of a user to the Agency no later than 10 days of their knowledge,
4. report all adverse events that have resulted in the recall of the medical device in the Republic of Croatia and other countries to the Agency within 10 days of their knowledge,
5. report all adverse events that could have resulted, but that due to favourable conditions did not result in death or serious deterioration of the health status of users, to the Agency within 30 days of their knowledge.

Article 54

If a healthcare professional participates 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 protocol and investigator's instructions.

The holder of the clinical trial authorisation shall:

1. maintain detailed records of all adverse events notified by the investigator, and submit the information on request to the Agency and the Central Ethics Committee,
2. report all adverse events that have resulted in death or serious deterioration of the health status of users to the Agency within 10 days of their knowledge,
3. report any adverse events that could have resulted, but that did not result in death or serious deterioration of the health status of users due to favourable circumstances, to the Agency within 30 days of their knowledge,
4. notify investigators of any adverse events from items 2 and 3 of this paragraph that occurred during the clinical trials of medical devices.

The Minister shall issue an ordinance establishing the monitoring of adverse events relating to medical devices.

In the event of a suspected counterfeited medical device, the persons from Article 52, paragraphs 1 and 2 of this Act shall notify the Agency and the holder of registration in the register of medical devices within 24 hours.

Article 55

The Agency may require the manufacturer or the holder of registration of the medical device in the register to provide the report on the experience acquired during the use of a new *in vitro* diagnostic medical device referred to in Article 2, paragraph 8 of this Act as from its placing on the market until the lapse of two years following the date of its registration in the register of medical devices.

IX SUPERVISION

Article 56

Supervision of the implementation of provisions of this Act and the ensuing regulations shall be carried out by the pharmaceutical inspection of the Ministry.

The method of supervision from paragraph 1 of this Article shall be established by an ordinance issued by the Minister.

Article 57

In the framework of supervision, a pharmaceutical inspector shall have the following rights and obligations:

- to conduct supervision of the body authorised for conformity assessment of medical devices,
- to conduct supervision of the quality assurance system of the medical device manufacturer and, as necessary, of his suppliers and other contractors,
- to require all necessary information from the manufacturer, holder of registration in the register, wholesale distributor or importer, and the insight into issued conformity documents and technical documentation,
- to order the performance of the relevant tests and the control of the medical device in order to check on the regulatory compliance after its placing on the market or putting into service,
- to perform sampling of the medical device, and if it does not comply with the provisions of this Act and the ensuing regulations, order its bringing into compliance,
- to order the appropriate labelling of medical devices, or submit the request for recall of the inappropriately labelled medical device,
- to prohibit or restrict distribution or submit the request to the Agency for recall of the medical device that has not been harmonised with statutory requirements,
- to prohibit or restrict use or order termination of use of medical devices that have not been harmonised with statutory requirements,
- to temporarily prohibit delivery, putting into service or advertising or notifications relating to medical devices in the event of a justified doubt regarding their incompliance with statutory requirements,
- to order destruction of the medical device that does not comply with statutory requirements when necessary in order to protect human health,
- to order the performance of the activity in line with the conditions set out in this Act and other regulations,
- to order the rectifying of established irregularities and deficiencies within the stipulated deadline,
- to prohibit the performance of activities that are contrary to this Act and other regulations,
- to temporarily prohibit the work to legal and natural persons who do not fulfil the requirements relating to employees, equipment and premises stipulated by the ordinance issued on the basis of this Act,
- to prohibit the work to legal and natural persons if they are engaged in conformity assessment procedures, manufacturing, production and distribution without the Minister's approval or Agency's authorisation.
- to order the performance of other measures as authorised by this Act and other regulations.

Article 58

In addition to rights and obligations referred to in Article 57 of this Act, pharmaceutical inspectors shall also have the right and obligation to temporarily suspend the decision on registration of the medical device in the register in the event of all medical devices the manufacturing of which, as found out during supervision, does not comply with statutory requirements.

Article 59

Where established during supervision that a sampled medical device is defective, the costs of testing, recall or disposal shall be covered either by legal persons responsible for its placing on the market or import, or legal or natural persons responsible for its defects on account of its incorrect storage or handling.

Article 60

Pharmaceutical inspectors are persons with university degree in the field of healthcare or other related fields, and a five-year experience on corresponding jobs, who have passed the civil service examination and who fulfil other requirements to be established by an ordinance issued by the Minister.

Article 61

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 62

Pharmaceutical inspectors shall have official identity cards in evidence of their official capacity, identity and authority.

The Minister shall issue an ordinance establishing the form and contents of official identity cards as well as the manner of issuance and maintenance of the register of issued official identity cards.

Article 63

Where during supervision a pharmaceutical inspector discovers that a misdemeanour or criminal act was committed by breach of regulations, he shall immediately, within maximum 15 days after supervision, submit a claim or report to the competent judicial authority.

The competent authority to which the claim or report referred to in paragraph 1 of this Article was submitted shall inform the Ministry about the outcome of the relevant proceedings.

Article 64

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

Article 65

During inspectional supervision, pharmaceutical inspectors shall examine business premises, buildings, equipment, facilities and documentation.

Article 66

In carrying out inspectional supervision, pharmaceutical inspectors shall observe confidentiality regulations.

Legal and natural persons shall inform pharmaceutical inspectors about the information falling under their confidentiality regulations.

Article 67

Pharmaceutical inspectors shall pass verbal decisions in the following cases:

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

Pharmaceutical inspectors may order immediate execution of a verbal decision. The decision shall be entered into the supervision report.

Pharmaceutical inspectors shall draw up a written communication of verbal decision within eight days of passing of the verbal decision.

Article 68

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

Article 69

Pharmaceutical inspectors shall draw up reports on completed supervision, established status and taken or ordered measures, as well as on performed activities.

Pharmaceutical inspectors shall send a copy of the report to a natural person or a legal person whose premises were inspected.

Article 70

Activities of pharmaceutical inspectors shall be governed by the provisions of the Act on General Administrative Procedure, unless otherwise regulated by this Act.

Article 71

Pharmaceutical inspectors shall keep registers of performed inspectional supervisions.

The method of keeping the register shall be prescribed by the Minister in an ordinance.

Article 72

Pharmaceutical inspectors shall be responsible for:

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

X PENAL PROVISIONS

Article 73

Legal persons shall be liable to a fine from HRK 70,000.00 to HRK 100,000.00 for the following misdemeanours:

1. manufacturing of the medical device in the Republic of Croatia without its registration in the Agency's register of medical device manufacturers (Article 22),
2. provision of inaccurate data in the application for registration in the register of manufacturers and failure to notify the Agency about the amendments to documentation based on which the Agency made the registration (Article 25),
3. affixing a label to a medical device that does not comply with the provisions of this Act (Article 28, paragraph 3),
4. affixing marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the marking of conformity (Article 28, paragraph 4),
5. failure to notify any amendment to documentation following the registration of the medical device in the register on the basis of which the Agency has made the registration (Article 31, paragraph 1),
6. provision of inaccurate data in the documentation supporting the application for registration of the medical device in the register of medical devices (Article 33),
7. wholesale of medical devices without the relevant authorisation (Article 40, paragraph 1),
8. retail sale of medical devices contrary to Article 41 of this Act,
9. import or export of medical devices contrary to Article 42 of this Act,
10. distribution of medical devices via the Internet (Article 48, paragraph 1),
11. disposal of medical devices that are no longer suitable for use contrary to the provisions of Article 49 of this Act,
12. advertising and notifications relating to medical devices contrary to this Act and the ensuing ordinance (Article 51),
13. failure to notify the Agency about any adverse event in writing (Article 52, paragraph 2),
14. acting contrary to Article 53 of this Act,
15. acting contrary to Article 54, paragraphs 2 and 4 of this Act,

16. failure to allow the pharmaceutical inspector to perform the supervision in line with the provisions of this Act and the ensuing regulations (Article 64),
17. failure to act within the deadline following the valid decision of the pharmaceutical inspector ordering certain measures or activities or prohibiting work (Article 68).

For misdemeanours referred to in paragraph 1, natural persons and qualified employees of legal persons shall be liable to a fine from HRK 7,000.00 to HRK 10,000.00.

Article 74

Legal persons shall be liable to a fine from HRK 50,000.00 to HRK 80,000.00 for the following misdemeanours:

1. performance of clinical trials of the medical device without the approval by the Minister (Article 16, paragraph 2),
2. performance of conformity assessment procedures without the authorisation by the Minister (Article 34, paragraph 1),
3. placing the medical device on the market contrary to Article 36, paragraph 1 of this Act,
4. failure to ensure the compliance of transport, keeping and storage of the medical device with statutory requirements (Article 36, paragraph 2).

For misdemeanours referred to in paragraph 1, natural persons and qualified employees of legal persons shall be liable to a fine from HRK 5,000.00 to HRK 8,000.00.

Article 75

Legal persons shall be liable to a fine from HRK 40,000.00 to HRK 60,000.00 for providing inaccurate data in the procedure for issuance of authorisation for the import of the medical device that has not been entered in the register of medical devices in the Republic of Croatia, (Article 46, paragraph 2).

For the misdemeanour referred to in paragraph 1 of this Article, the qualified employee of the legal person shall be liable to a fine from HRK 4,000.00 to HRK 6,000.00.

XI TRANSITIONAL AND FINAL PROVISIONS

Article 76

The Minister shall issue the ordinances placed under his competence by this Act within a year from the date of entry into force of this Act.

Article 77

Until the entry into force of ordinances referred to in Article 76 of this Act, the following ordinances shall remain in force:

1. Ordinance on pharmacovigilance of medicinal products and medical devices (Official Gazette 29/05), in a part relating to medical devices,

2. Ordinance on advertising and providing information on medicinal products, homeopathic products and medical devices (Official Gazette 62/05), in a part relating to medical devices,
3. Ordinance on clinical trials and good clinical practice (Official Gazette 121/07), in a part relating to medical devices,
4. Ordinance on the licensing requirements for specialised stores for retail sale of medicinal products and medical devices (Official Gazette 29/05, 81/06 and 5/07), in a part relating to medical devices,
5. Ordinance on classification, placing on the market, essential requirements, conformity assessment procedures and the register of medical devices (Official Gazette 54/05), and
6. Ordinance on good practice and conditions for issuing marketing authorisations for medical devices (Official Gazette 54/05 and 81/06).

Article 78

Procedures for the entry in the register of medical devices and manufacturers and the procedures for granting of marketing authorisations and import and export licences for medical devices, which have been initiated before the entry into force of this Act, shall be completed in conformity with the provisions of this Act.

Article 79

Manufacturing authorisations issued on the grounds of regulations valid until the entry into force of this Act shall remain in force until expiry of their original term.

Article 80

This Act shall enter into force on 1 October 2008, except for the provisions of Article 9, paragraphs 2 and 4, Article 11, paragraph 3, Article 21, Article 34, paragraphs 4 and 5, and Article 52, paragraph 4, which shall take effect as of the date of accession of the Republic of Croatia to the European Union.

Class: 530-08/08-01/01
Zagreb, 30 May 2008

THE CROATIAN PARLIAMENT
The President of the Croatian Parliament
Luka Bebić, m. p.