THE MINISTRY OF HEALTH AND SOCIAL WELFARE

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Pursuant to Article 11, paragraph 7 of the Medicinal Products Act (Official Gazette 71/07), the Minister of Health and Social Welfare hereby issues the

ORDINANCE

ON SPECIAL CONDITIONS FOR PLACING MEDICINAL PRODUCTS AUTHORISED IN THE MEMBER STATES OF THE EUROPEAN UNION ON THE MARKET OF THE REPUBLIC OF CROATIA

Article 1

This Ordinance establishes special conditions for placing medicinal products authorised in the Member States of the European Union following the Centralised Procedure, Mutual Recognition Procedure or Decentralised Procedure on the market of the Republic of Croatia.

Article 2

For the purposes of this Ordinance, the following definitions shall apply:
1. *Centralised Procedure on the granting of a marketing authorisation for a medicinal product in the European Union (hereinafter: Centralised Procedure)* means the procedure on the granting of the marketing authorisation that falls under the competence of the European Medicines Agency (hereinafter: EMEA), whose Committee for Medicinal Products for Human Use drafts the Assessment Report, while the final decision on the marketing authorisation is rendered by the European Commission (hereinafter: EC).
2. *Reference Member State* means a Member State of the European Union whose competent authority grants the marketing authorisation and drafts the Assessment Report, which is recognised by the competent authorities of other EU Member States in the Mutual Recognition Procedure or Decentralised Procedure (hereinafter: other Member States).
3. *Mutual Recognition Procedure on the granting of a marketing authorisation for a medicinal product in the European Union (hereinafter: Mutual Recognition Procedure)* means the procedure initiated by the national procedure on the granting of a marketing authorisation in a Reference Member State, after which this Reference Member State forwards the Assessment Report, along with the approved Summary of Product Characteristics, Patient Information Leaflet and labelling, to other Member States. Other Member States from the Mutual Recognition Procedure may either accept the Assessment Report or refuse it, subject to an explanation and with a possibility of solving the procedure before the EMEA in the case of their disagreement.
Mutual Recognition Procedure is compulsory for medicinal products that are not

subject to the Centralised Procedure, for which the applicant submits the marketing authorisation application in more than one Member State, and which are authorised in one Member State of the European Union.
4. *Decentralised Procedure on the granting of a marketing authorisation for a medicinal product in the European Union (hereinafter: Decentralised Procedure)* means the procedure where the applicant chooses a Reference Member State and concurrently submits the registration dossier in this Reference Member State and other Member States. The Reference Member State drafts the Assessment Report and submits it, along with a draft Summary of Product Characteristics, Patient Information Leaflet and labelling, to other Member States, which either accept the Assessment Report or refuse it, subject to an explanation and with a possibility of solving the procedure before the EMEA in the case of their disagreement.
Decentralised Procedure is compulsory for medicinal products that are not subject to the Centralised Procedure, for which the applicant submits the marketing authorisation application in more than one Member State, and which are not authorised in any EU Member State.
5. *nCADREAC* is a New Collaborative Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (supported by EU officials and encouraged by the WHO Regional Office for Europe). This Agreement lays down the conditions for the simplified procedure on the granting of the marketing authorisation for medicinal products already authorised in the European Union following the Centralised Procedure, Mutual Recognition Procedure or Decentralised Procedure, and defines the participation of the competent authority of a candidate country in any EU body and the Agency's obligations to report to the EMEA or to the Reference Member State.
6. *Common technical document (hereinafter: CTD)* is the internationally agreed upon format (between Europe, USA and Japan) for the organisation of a regulatory file in the procedure on the granting of the marketing authorisation. The CTD consists of five modules: module 1 (Administrative Information and Prescribing Information), module 2 (CTD Summaries), module 3 (Quality), module 4 (Non-clinical Study Reports) and module 5 (Clinical Study Reports).
7. *EU Dossier (hereinafter: EU-format)* means the format for the preparation of documentation in the European Union recommended by earlier guidelines for marketing authorisation applicants. The EU-format consists of four parts: Part I (summary of the dossier), Part II (chemical, pharmaceutical and biological documentation), Part III (toxico-pharmacological documentation), and Part IV (clinical documentation).
8. *Drug Master File (hereinafter: DMF)* contains the scientific information about the active substance divided into two parts: the Applicants Part that contains the information which is not regarded as confidential with respect to the applicant or the marketing authorisation holder, and the Restricted Part that contains the information which is regarded as confidential and is therefore accessible neither to the applicant nor to the marketing authorisation holder.
9. Variations to a marketing authorisation in the European Union according to the type may be: minor (types IA and IB), major (type II) and urgent safety restrictions.

1. MARKETING AUTHORISATION

Article 3

The procedure on the granting of the marketing authorisation in the Republic of Croatia for medicinal products authorised in EU Member States following the Centralised Procedure, Mutual Recognition Procedure or Decentralised Procedure shall be initiated by an application submitted by a legal person seated in the Republic of Croatia to the Agency for Medicinal Products and Medical Devices (hereinafter: Agency) in line with the Medicinal Products Act.
The application shall be filed separately for each pharmaceutical form, strength and package size(s), and it shall contain the subject, date and signature of the applicant's responsible person.
The application from paragraph 2 of this Article shall be accompanied with the completed form of the marketing authorisation application in the Republic of Croatia, which is given in Annex 1 and forms an integral part of this Ordinance.

Article 4

The Agency shall grant or refuse the marketing authorisation within 150 days for the medicinal product already authorised in EU Member States by the Centralised Procedure or within 180 days for the medicinal product already authorised in EU Member States by the Mutual Recognition Procedure or Decentralised Procedure, calculating as from the date of receipt of a valid application.
The application from Article 3 of this Ordinance shall be valid if the applicant also attaches the documentation containing the following information and documents:
– completed application form for a marketing authorisation for the Republic of Croatia separately for each pharmaceutical form, strength and package size(s);
– agency agreement (the original document or a notarised copy) and proof of the applicant's registration in the court register of the competent commercial court (the original document or a notarised copy, not older than six months following the date of application submission);
– proof of the paid administrative fee;
– documentation in line with the Medicinal Products Act and the documentation stipulated by this Ordinance.
The documentation from paragraph 2 of this Article shall be submitted as a copy, unless this Ordinance stipulates that it should be submitted as the original document or as a notarised copy.
The Agency may require the applicant to make the original document available.
The application shall be accompanied with samples of the medicinal product.
In the case of electronic submission, the documentation shall at the same time submitted in a paper copy.

Article 5

If the Agency establishes that the application is not valid, it shall require the applicant to supplement the application within 30 days following the date of receipt of the Agency's notification.
During the procedure on the granting of the marketing authorisation, the Agency may require the applicant in writing to provide the additional documentation or the appropriate explanation within 30 days.
If the applicant does not supplement the application or submit the additional documentation or the appropriate explanation within the deadline from paragraphs 1 and 2 of this Article, the Agency shall issue a decision refusing the application that

cannot be appealed, but against which administrative proceedings may be instituted. The provisions of paragraphs 1, 2 and 3 of this Article shall appropriately apply to the procedures for renewal of marketing authorisations and their variations.

Article 6

The applicant shall submit the application and the completed application form for marketing authorisation in the Republic of Croatia in Croatian. Other stipulated documents may be submitted either in Croatian or English, with the exception of documents to be submitted in both languages as stipulated by this Ordinance.

Article 7

For medicinal products authorised in the European Union by the centralised procedure, the applicant shall also submit the following documents in addition to the application from Article 3 of this Ordinance:
– documentation referred to in Article 4, paragraph 2 of this Ordinance;
– Part I and Part II of the registration dossier (EU-format) or module 1, module 2 and module 3 (CTD format) accepted by the EMEA;
– a detailed list of contents of Part III and Part IV (EU-format) or modules 4 and 5 (CTD format), or integral parts thereof on the Agency's request;
– a draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian;
– the latest Summary of Product Characteristics, Patient Information Leaflet and labelling in English approved by the Centralised Procedure;
– declaration by the applicant that the draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian are translations of the texts of the latest Summary of Product Characteristics, Patient Information Leaflet and labelling approved by the Centralised Procedure(the original document);
– declaration by the responsible person of the applicant that the dossier submitted, or, where appropriate, the parts submitted thereof are identical to the dossier of a product authorised in the EU by the Centralised Procedure, including all information submitted to support any variation which has been applied for and accepted until the date of submission of the application for marketing authorisation to the Agency, as well as information concerning post-authorisation commitments, if any, following the Centralised Procedure (the original document);
– declaration by the responsible person of the applicant that all subsequent variations to and renewals of this dossier, once accepted in the EU, will also be submitted without delay to the Agency (the original document);
– declaration by the responsible person of the applicant that all urgent safety measures will be immediately notified to the Agency and implemented according to regulations in force in the Republic of Croatia (the original document);
– declaration by the responsible person of the applicant that he shall, in the case where the marketing authorisation will be suspended or withdrawn in the EU (either by the initiative of the marketing authorisation holder or by the European Commission Decision), immediately notify the Agency (the original document);
– a copy of the declaration by the responsible person of the marketing authorisation holder in the European Union sent to the EMEA and the European Commission that an application is being submitted for authorisation of the medicinal product in the Republic of Croatia, pertaining to the name of the product and the marketing

authorisation number in the European Union, and that he agrees that the EMEA and the European Commission may make available to the Agency any information to the quality, safety and efficacy of the product concerned (the extent of this information shall not exceed that which is made available to EU Member States by the EMEA);
– Assessment Report of the EMEA's Committee for Medicinal Products for Human Use, including all annexes;
– the final decision of the European Commission on the granting of the marketing authorisation, including all annexes (Annexes I, II and III);
– list of all resolved/outstanding post-marketing commitments following the Centralised Procedure;
– if the application is submitted to the Agency six months after the date of the European Commission Decision, then the latest available Periodic Safety Update Report (PSUR), which should include any new pharmacovigilance data;
– certificate of the medicinal product issued by the EMEA.
If any variations to the marketing authorisation in the EU have been applied for and accepted at the time of submission of the application for marketing authorisation to the Agency, the information submitted to the EMEA to support these variations shall be also provided, as well as:
– list of all variations to the marketing authorisation that have been approved in the European Union, safety, transfer or renewal procedures approved in the period between the authorisation of the medicinal product in the European Union and the date of application submission to the Agency;
– European Commission Decisions amending the marketing authorisation as a consequence of an approved type II variation, as well as for an approved type IA and IB variation, European Commission Decisions renewing marketing authorisations for medicinal products, Annual Reassessment, transfer of the marketing authorisation or safety procedure, if issued by the European Commission;
– notifications on a type IB variation to the terms of the marketing authorisation, issued by the EMEA;
– notifications of the minor changes in labelling or Patient Information Leaflet not connected with the Summary of Product Characteristics;
– acknowledgement of receipt of a valid notification for type IA variation to the terms of the marketing authorisation;
– Variation Assessment Report or the declaration by the responsible person of the applicant that there is no Variation Assessment Report for the type of variation concerned.

Article 8

For medicinal products authorised in the European Union by the Mutual Recognition Procedure or Decentralised Procedure, the applicant shall also submit the following documents in addition to the application from Article 3 of this Ordinance:
– documentation from Article 4, paragraph 2 of this Ordinance;
– Part I, Part II, Part III and Part IV of the registration dossier (EU-format) or module 1, module 2, module 3, module 4 and module 5 (CTD format) accepted by the Reference Member State and other Member States in the Mutual Recognition Procedure or Decentralised Procedure;
– a draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian;
– the latest Summary of Product Characteristics, Patient Information Leaflet and

labelling in English approved in the Mutual Recognition Procedure or Decentralised Procedure;
– consolidated list of questions raised by other Member States within the Mutual Recognition Procedure or Decentralised Procedure and applicant response document in the Mutual Recognition Procedure or Decentralised Procedure;
– declaration by the responsible person of the applicant that the dossier submitted is identical to the dossier of the same medicinal product submitted to the competent authorities in other Members States in the Mutual Recognition Procedure, including all information submitted to support any variation which has been applied for and accepted until the time of submission of the application for marketing authorisation to the Agency, as well as information concerning post-authorisation commitments, if any, established in the Mutual Recognition Procedure and Decentralised Procedure, or that the submitted registration dossier is valid in EU Member States at the time of receipt of the application in the Republic of Croatia (the original document);
– declaration by the responsible person of the applicant that he will cooperate with the Agency similarly as the marketing authorisation holder cooperates in the Mutual Recognition Procedure or Decentralised Procedure with the competent authorities of EU Member States, especially that he will keep the product authorised by the Agency identical with that in EU Member States, i.e. in the post-authorisation phase he will notify and implement all urgent safety measures simultaneously in the EU Member States and the Republic of Croatia, and that he will submit all variations to marketing authorisations and renewals thereof, once accepted in the EU Member States, without unnecessary delay (the original document);
– declaration by the responsible person of the applicant, that the draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian are translations of the texts of the latest Summary of Product Characteristics, Patient Information Leaflet and labelling approved by the Mutual Recognition Procedure or Decentralised Procedure (the original document);
– a copy of the declaration by the responsible person of the marketing authorisation holder in the Reference Member State sent to the competent authority in that Sate ,that an application is being submitted for authorisation of the concerned medicinal product to the Agency, and that he agrees that the competent authority in the Reference Member State may make available to the Agency any information to the quality, safety and efficacy of the product concerned;
– a copy of the declaration by the responsible person of the DMF holder for an active substance contained in the medicinal product authorised under the Mutual Recognition Procedure or Decentralised Procedure and sent to the competent authority in that State that an application is being submitted for authorisation of the concerned medicinal product to the Agency, and that he agrees that the competent authority in the Reference Member State may make available to the Agency any information from the DMF to the quality, safety and efficacy of the product concerned, if appropriate;
– Assessment Report of the competent authority in the Reference Member State;
– list of other Member States in the Mutual Recognition Procedure or Decentralised Procedure;
– a description of the course of the Mutual Recognition Procedure or Decentralised Procedure;
– break out session minutes or the declaration by the responsible person of the applicant that there has been no break out session (the original document);
– information about the reasons for withdrawal(s) or declaration by the responsible person of the applicant that there has been no withdrawal (the original document);

– letter of the Reference Member State about the completion of the procedure with the Summary of Product Characteristics, Patient Information leaflet and labelling attached;
– in case that variations have been accepted after conclusion of the Mutual Recognition Procedure or Decentralised Procedure, a list of these variations for the period between the date of completion of the Mutual Recognition Procedure or Decentralised Procedure and the date of application submission to the Agency, as well as the documentation to support these variations, Assessment Report if available, the letter of the Reference Member State on completion of the variation procedure with the Summary of Product Characteristics, Patient Information Leaflet and labelling attached;
– if the application is submitted to the Agency 9 months after the date of the authorisation of the medicinal product in the Reference Member State, then the latest available Periodic Safety Update Report (PSUR), which should include any new pharmacovigilance data;
– list of all post-marketing commitments established in the Mutual Recognition Procedure or Decentralised Procedure;
– certificate of the medicinal product from the Reference Member State or any other Member State in the Mutual Recognition Procedure or Decentralised Procedure.

Article 9

After granting of the marketing authorisation in the Republic of Croatia for the medicinal product authorised in the European Union under the Centralised Procedure, the Agency shall notify the EMEA about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.
After granting of the marketing authorisation in the Republic of Croatia for the medicinal product authorised in the European Union under the Mutual Recognition Procedure or Decentralised Procedure, the Agency shall notify the Reference Member State and the Administrative Secretariat of nCADREAC about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.

2. VARIATION TO A MARKETING AUTHORISATION AND/OR A REGISTRATION DOSSIER

Article 10

The marketing authorisation holder in the Republic of Croatia shall file an application for approval of the variation to the Agency within 60 days following the date of approval of the variation in the European Union in accordance with Article 24 of the Medicinal Products Act.
The applicant shall attach the completed variation application form, which is given in Annex 2 and forms an integral part of this Ordinance, to the application for approval of the variation.
The application shall be considered as valid if the applicant also attaches the documentation containing the following information and documents:
– completed application form for approval of the variation for each pharmaceutical form, strength and package size/s;

– proof of payment of the administrative fee;
– documentation stipulated by this Ordinance.
The documentation from paragraph 3 of this Article shall be given as a copy, unless this Ordinance stipulates that it should be provided as the original document or as a notarised copy.
The Agency may require the applicant to make the original document available.
In the case of electronic submission, the documentation shall be also submitted in a paper copy.
The Agency shall either approve or refuse the variation to the marketing authorisation or the dossier, depending on a type of variation, within the deadline stipulated by the Medicinal Products Act.

Article 11

For medicinal products authorised in the European Union by the Centralised Procedure, the applicant shall submit the following documents in addition to the application and documentation referred to in Article 10, paragraph 3 of this Ordinance:
– documentation on variation approved by the EMEA; in the case of non-clinical and/or clinical documentation, i.e. module 4 and/or module 5, only a detailed list of contents of non-clinical and/or clinical documentation, i.e. module 4 and/or module 5, shall be submitted, or the integral parts of the documentation on the Agency's request;
– European Commission Decision on type II variation amending the terms of marketing authorisation of a medicinal product, including all annexes;
– letter of European Commission on type II variation not amending the terms of marketing authorisation of a medicinal product;
– opinion on type II variation, issued by the EMEA, including all annexes;
– notification on a type IB variation, issued by the EMEA, including all annexes;
– notification of the minor changes in labelling or Patient Information Leaflet not connected with the Summary of Product Characteristics;
– notification of the submitted and approved type IA variation;
– Variation Assessment Report or the original declaration by the responsible person of the applicant that the Variation Assessment Report has not been issued for the concerned type of variation.

Article 12

For medicinal products authorised in the European Union by the Mutual Recognition Procedure of Decentralised Procedure, the applicant shall also submit the following documents in addition to the application and documentation referred to in Article 10, paragraph 3,of this Ordinance:
– letter of acceptance of the variation in question, sent by the Reference Member State to the marketing authorisation holder and other Member States in the Mutual Recognition Procedure or Decentralised Procedure;
– Variation Assessment Report or declaration by the responsible person of the applicant that the Variation Assessment Report has not been issued for the concerned type of variation (the original document);
– the supporting documentation identical with that submitted in the Mutual Recognition Procedure or Decentralised Procedure;
– updated Summary of Product Characteristics, Patient Information Leaflet or labelling with the approved variation in English, a draft Summary of Product Characteristics,

Patient Information Leaflet or labelling in Croatian with track changes and as a clean copy.

Article 13

Once a year, the Agency shall submit to the EMEA the overview of all completed variation approval procedures for medicinal products authorised in the Republic of Croatia and authorised in the European Union by the Centralised Procedure.

3. RENEWAL OF THE MARKETING AUTHORISATION

Article 14

In the renewal procedure, the marketing authorisation holder in the Republic of Croatia shall file an application for renewal of the marketing authorisation to the Agency in accordance with Article 23 of the Medicinal Products Act.
The marketing authorisation holder shall attach the completed renewal application form, which is given in Annex 1 and forms an integral part of this Ordinance, to the application for renewal of the marketing authorisation.
The application referred to in paragraph 1 of this Article shall be considered as valid if the applicant also attaches the documentation containing the following information and documents:
– completed renewal application form in the Republic of Croatia for each pharmaceutical form, strength and package size/s;
– agency agreement (the original document or a notarised copy) and the proof of registration of the applicant in the court register of the competent commercial court (the original document or a notarised copy, not more than six months old as from the date of application submission);
– proof of payment of the administrative fee;
– documentation stipulated by this Ordinance.
The documentation from paragraph 3 of this Article shall be given as a copy, unless this Ordinance stipulates that it should be provided as the original document or as a notarised copy.
The Agency may require the applicant to make the original document available.
The application shall be accompanied with samples of the medicinal product.
In the case of electronic submission, the documentation shall be also submitted in a paper copy.
Pursuant to the provisions of this Ordinance, the Agency shall issue a decision, either approving or refusing the renewal of the marketing authorisation, within the deadline stipulated by the Medicinal Products Act.

Article 15

For medicinal products authorised in the European Union by the Centralised Procedure, the applicant shall also submit the following documents in addition to the application and documentation referred to in Article 14, paragraph 3 of this Ordinance:
– European Commission Decision on the renewal of marketing authorisation of the medicinal product, including all annexes;
– opinion on renewal of marketing authorisation of the medicinal product, issued by the EMEA, including all annexes;

– Renewal Assessment Report issued by the EMEA's Committee for Medicinal Products for Human Use;
– documentation accepted by the EMEA for renewal of the marketing authorisation, including the Periodic Safety Update Report;
– declaration by the responsible person of the marketing authorisation holder, that at the time of renewal of the marketing authorisation, the product is identical with the product marketed in the European Union (the original document);
– list of all submitted and/or approved variations in the Republic of Croatia in the period between the date of authorisation in the Republic of Croatia and the date of renewal submission to the Agency;
– list of all approved variations in the European Union in the period between authorisation in the Republic of Croatia and the date of renewal submission to the Agency;
– the latest Summary of Product Characteristics, Patient Information Leaflet and labelling in English approved by the Centralised Procedure;
– a draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian with track changes and as a clean copy.

Article 16

For medicinal products authorised in the European Union by the Mutual Recognition Procedure or Decentralised Procedure, the applicant shall also submit the following documents in addition to the application and documentation referred to in Article 14, paragraph 3 of this Ordinance:
– declaration by the responsible person of the marketing authorisation holder in the Republic of Croatia, that at the time of renewal of the marketing authorisation in the Republic of Croatia, the product is identical with the product marketed in the Reference Member State (the original document), which is given in Annex 3 and forms an integral part of this Ordinance;
– list of all submitted and/or approved variations in the Republic of Croatia in the period between the date of authorisation in the Republic of Croatia and the date of renewal submission to the Agency;
– list of all approved variations by the Mutual Recognition Procedure or Decentralised Procedure in the period between authorisation in the Republic of Croatia and the date of renewal submission to the Agency;
– the latest Periodic Safety Update Report submitted in the Reference Member State;
– Renewal Assessment Report in the Mutual Recognition Procedure or Decentralised procedure;
– written responses of marketing authorisation holders in the European Union to requests for supplementary information from renewal procedure under the Mutual Recognition Procedure or Decentralised Procedure;
– documentation submitted/approved in the renewal procedure in the Reference Member State;
– the latest approved Summary of Product Characteristics, Patient Information Leaflet and labelling in English in the Mutual Recognition Procedure or Decentralised Procedure;
– a draft Summary of Product Characteristics, Patient Information Leaflet and labelling in Croatian with track changes and as a clean copy.

Article 17

After renewal of the marketing authorisation for the medicinal product authorised in the European Union under the Centralised Procedure, the Agency shall notify the EMEA about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.
After renewal of the marketing authorisation for the medicinal product authorised in the European Union under the Mutual Recognition Procedure or Decentralised Procedure, the Agency shall notify the Reference Member State and the Administrative Secretariat of nCADREAC about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.

4. PERIODIC SAFETY UPDATE REPORT AFTER GRANTING OF THE MARKETING AUTHORISATION

Article 18

For medicinal products authorised in the European Union by the Centralised Procedure after granting of the marketing authorisation in the Republic of Croatia, the marketing authorisation holder shall submit the Periodic Safety Update Reports concomitantly to the Agency and the EMEA.
For medicinal products authorised in the European Union by the Mutual Recognition Procedure or Decentralised Procedure after granting of the marketing authorisation in the Republic of Croatia, the marketing authorisation holder shall submit the Periodic Safety Update Reports concomitantly to the Agency and the competent authority of the Reference Member State.
Exceptionally, the marketing authorisation holder shall submit the Periodic Safety Update Report on the Agency's request.
For medicinal products authorised in the European Union by the Centralised Procedure, Mutual Recognition Procedure or Decentralised Procedure, the marketing authorisation holder shall submit a copy of the plan of drafting of Periodic Safety Update Reports in the European Union within 60 days following the granting of the marketing authorisation in the Republic of Croatia.

5. HARMONISATION OF THE DOSSIER IN THE REPUBLIC OF CROATIA WITH THE ACCEPTED DOSSIER IN THE EUROPEAN UNION

Article 19

When filing an application for renewal of the marketing authorisation in the Republic of Croatia for the medicinal product which has a marketing authorisation in the Republic of Croatia that has not been granted on the basis of provisions of this Ordinance, and which is authorised in the European Union under the Centralised Procedure, Mutual Recognition Procedure or Decentralised Procedure, the marketing authorisation holder shall file an application for renewal of the marketing authorisation and attach the dossier harmonised with the registration dossier accepted in the European Union.

Prior to renewal of the marketing authorisation in the Republic of Croatia and at the time of submission of the application for approval of the variation, the marketing authorisation holder may request from the Agency the harmonisation with the approved registration dossier in the European Union.
The provisions of this Ordinance shall apply to all subsequent procedures for renewal of the marketing authorisation and approval of variations from paragraphs 1 and 2 of this Article.

Article 20

For medicinal products authorised in the European Union following the Centralised Procedure, the marketing authorisation holder shall submit, in addition to the application for renewal of the marketing authorisation or for approval of the variation, the completed form and the documentation referred to in Article 7 of this Ordinance, which was not submitted to the Agency in the procedure on the granting of the marketing authorisation, the declaration by the responsible person of the marketing authorisation holder in the Republic of Croatia on the status of harmonisation of the registration dossier in the Republic of Croatia with that authorised under the Centralised Procedure (the original document).

Article 21

For medicinal products authorised in the European Union under the Mutual Recognition Procedure or Decentralised Procedure, the marketing authorisation holder shall submit, in addition to the application for renewal of the marketing authorisation or for approval of the variation, the completed form and the documentation referred to in Article 8 of this Ordinance, which was not submitted to the Agency in the procedure on the granting of the marketing authorisation, the declaration by the responsible person of the marketing authorisation holder in the Republic of Croatia on the status of harmonisation of the registration dossier in the Republic of Croatia with that authorised under the Mutual Recognition Procedure or Decentralised Procedure (the original document).

Article 22

After renewal of the marketing authorisation and approval of the variation for the medicinal product authorised in EU Member States under the Centralised Procedure, the Agency shall notify the EMEA about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.
After renewal of the marketing authorisation and approval of the variation for the medicinal product authorised in EU Member States under the Mutual Recognition Procedure or Decentralised Procedure, the Agency shall notify the Reference Member State and the Administrative Secretariat of nCADREAC about the outcome of the procedure (the notification is sent in line with the procedure based on nCADREAC).
The Agency shall forward a copy of the notification to the marketing authorisation holder in the Republic of Croatia.

6. TRANSITIONAL AND FINAL PROVISIONS

Article 23

The procedures for granting, variation and renewal of the marketing authorisation initiated before the entry into force of this Ordinance shall be finished in accordance with the provisions of the Ordinance on special conditions for placing on the market of the Republic of Croatia drug products with a marketing authorisation in EU Member States (Official Gazette 86/04).

Article 24

On the date of entry into force of the Ordinance on special conditions for placing on the market of the Republic of Croatia drug products with a marketing authorisation in EU Member States (Official Gazette 86/04) shall cease to have effect.

Article 25

This Ordinance shall enter into force on the eighth day after the day of its publication in the Official Gazette.

Class: 011-02/08-01/02
Reg. No.: 534-07-1-07-1
Zagreb, 9 January 2008

The Minister
Prof. Neven Ljubičić, m.p.

ANNEX 1

APPLICATION FORM UNDER THE ORDINANCE ON SPECIAL CONDITIONS FOR PLACING THE MEDICINAL PRODUCT AUTHORISED IN THE EU MEMBER STATES ON THE MARKET OF THE REPUBLIC OF CROATIA[1]

Name of the medicinal product _____
Active substance: _____
Pharmaceutical form: _____
Strength: _____
Package size/s: _____

Name and address of the applicant:
Name: _____
Address: _____
Telephone: _____
Fax: _____
E-Mail: _____

Signature and seal of the applicant _____

First and last name of the contact person:
Name: _____
Address: _____
Telephone: _____
Fax: _____
E-Mail: _____

1. TYPE OF APPLICATION:
(Please specify)
□ granting of the marketing authorisation
□ renewal of the marketing authorisation
□ harmonisation of the dossier in the Republic of Croatia with the approved dossier in the European Union

2. PROCEDURE ON THE GRANTING OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION
(Please specify)
□ Centralised Procedure[2]
□ Mutual Recognition Procedure[2]
Reference Member State:
Procedure number:
Date of completion of the Mutual Recognition Procedure:
Other Member States in the procedure:

[1] Complete the application form separately for each pharmaceutical form and each strength

AT	□	BE	□	BG	□	CY	□	CZ	□	DE	□	DK	□	EE	
EL	□	ES	□	FI	□	FR	□	HU	□	IE	□	IS	□	IT	
LI	□	LT	□	LU	□	LV	□	MT	□	NL	□	NO	□	PL	
PT	□	RO	□	SE	□	SI	□	SK	□	UK					

□ Decentralised Procedure[2]
Reference Member State:
Procedure number:
Date of completion of the Decentralised Procedure:
Other Member States in the procedure:

AT	□	BE	□	BG	□	CY	□	CZ	□	DE	□	DK	□	EE	
EL	□	ES	□	FI	□	FR	□	HU	□	IE	□	IS	□	IT	
LI	□	LT	□	LU	□	LV	□	MT	□	NL	□	NO	□	PL	
PT	□	RO	□	SE	□	SI	□	SK	□	UK					

2.1. **HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?**
□ NO
□ YES

3. THE APPLICATION REFERS TO:
(Please specify)
□ proprietary (original) medicinal product
□ new active substance
□ already authorised active substance (new pharmaceutical form/strength/package size)
□ essentially similar (generic) medicinal product (Article 15.a of the Medicinal Products Act)

Reference medicinal product
Name of the medicinal product, strength, pharmaceutical form:
Date of first authorisation in the Republic of Croatia or the European Union:

Medicinal product used for the demonstration of bioequivalence
Name of the medicinal product, strength, pharmaceutical form:
□ medicinal product with well-established use (Article 15.b of the Medicinal Products Act)
□ medicinal product pursuant to Article 15.c of the Medicinal Products Act
□ biosimilar medicinal product

2 tick where appropriate for an EU Member State according to the abbreviation given in the list of EU Member States

Abbreviated name	Member State	Abbreviated name	Member State

CY	Cyprus	LI	Lichtenstein
CZ	Czech Republic	LT	Lithuania
DE	Germany	LU	Luxembourg
DK	Denmark	LV	Latvia
EE	Estonia	MT	Malta
EL	Greece	NL	The Netherlands
ES	Spain	NO	Norway
FI	Finland	PL	Poland
FR	France	PT	Portugal
HU	Hungary	SE	Sweden
IE	Ireland	SI	Slovenia
IS	Iceland	SK	Slovakia
IT	Italy	UK	United Kingdom

Reference medicinal product
Name of the medicinal product, strength, pharmaceutical form:
Date of first authorisation in the Republic of Croatia or the European Union:

Medicinal product used for the demonstration of bioequivalence
Name of the medicinal product, strength, pharmaceutical form:
□ combination of known active substances
□ traditional herbal medicinal product

ADMINISTRATIVE INFORMATION

1. PROPOSED NAME OF THE MEDICINAL PRODUCT IN THE REPUBLIC OF CROATIA

1.1. NAME OF THE ACTIVE SUBSTANCE(S) (common name)

1.2. PHARMACOTHERAPEUTIC CLASSIFICATION (ATC classification)

2. PHARMACEUTICAL FORM AND STRENGTH

2.1. METHOD OF ADMINISTRATION

2.2. PACKAGE SIZE AND PACKAGING

Package size(s): _____
Container: _____
External packaging: _____
Additional accessories: _____

2.3. PROPOSED SHELF LIFE

Proposed shelf life: _____

Proposed shelf life after dissolution, reconstitution or dilution: _____

Proposed shelf life after first opening: _____

2.3. PROPOSED STORAGE CONDITIONS:

Proposed storage conditions:

Proposed storage conditions after first opening:

3. PROPOSED DISPENSING AND PRESCRIPTION

(Please specify)

Proposed dispensing:

□ subject to medical prescription

□ not subject to medical prescription

- □ supply through pharmacies only
- □ supply through non-pharmacy outlets

Proposed prescription

□ product on prescription which may be renewed

□ product on prescription which may not be renewed

□ product on special prescription

□ product on restricted prescription

4. QUALIFIED PERSON OF THE MARKETING AUTHORISATION HOLDER RESPONSIBLE FOR PHARMACOVIGILANCE IN THE REPUBLIC OF CROATIA

First and last name: _____

Address: _____

Telephone: _____

Fax: _____

E-Mail: _____

□ The attached declaration by the responsible person of the applicant stating that the applicant has the qualified person responsible for pharmacovigilance and that he fulfils the conditions with regard to reporting on all suspected adverse reactions recorded either in the Republic of Croatia or in other countries. (Appendix 1)

□ The attached curriculum vitae of the person responsible for pharmacovigilance in the Republic of Croatia (Appendix 2)

□ A detailed description of the pharmacovigilance system in the Republic of Croatia and, if available, an additional risk management plan that the applicant plans to implement in the Republic of Croatia (Appendix 3).

5. MANUFACTURER(S) AUTHORISED FOR BATCH RELEASE (RESPONSIBLE FOR QUALITY CONTROL) IN THE REPUBLIC OF CROATIA

Name: _____
Address: _____
Country: _____
Manufacturing authorisation number (GMP Certificate):
_____
□ Attached copy of the manufacturing authorisation (GMP Certificate) (Appendix 4):
_____
Batch testing site:

5.1. OTHER MANUFACTURERS

Name: _____
Address: _____
Country: _____
Brief description of functions performed:
_____
Manufacturing authorisation number (GMP Certificate):
_____

□ Attached copy of the manufacturing authorisation (GMP Certificate) (Appendix 4):
_____
□ Attached flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process (Appendix 5)

5.2. MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)

Name of the active substance: _____
Name: _____
Address: _____
Country: _____
□ Attached flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process of the active substance (Appendix 6)

6. QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)

(A note should be given as to which quantity the composition refers (e.g. 1 capsule)

Medicinal product	Quantity	Unit	Quality requirements (e.g. European Pharmacopoeia, etc.)
- active			

substances:			
- excipients:			

7. LIST OF COUNTRIES WHERE THE MEDICINAL PRODUCT IS AUTHORISED OR IS PENDING AUTHORISATION

Attached:

□ YES

□ NO

8. APPENDICES

1. The attached declaration by the responsible person of the applicant stating that the applicant has the qualified person responsible for pharmacovigilance and that he fulfils the conditions with regard to reporting on all suspected adverse reactions recorded either in the Republic of Croatia or in other countries.
2. The attached curriculum vitae of the person responsible for pharmacovigilance in the Republic of Croatia.
3. A detailed description of the pharmacovigilance system in the Republic of Croatia and, if available, an additional risk management plan that the applicant plans to implement in the Republic of Croatia.
4. A copy of the manufacturing authorisation (GMP Certificate)
5. Flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process of the medicinal product
6. Flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process of the active substance

10. DOCUMENTATION

The documentation was used in the following format:

□ EU-FORMAT

□ COMMON TECHNICAL DOCUMENT

ANNEX 2

APPLICATION FORM FOR A VARIATION TO THE DOSSIER OF THE MEDICINAL PRODUCT AUTHORISED IN EU MEMBER STATES UNDER THE CP, MRP AND DP[1]

BASIC INFORMATION[2]	
Name of the medicinal product	
Active substance: (INN)	
Pharmaceutical form:	
Strength:	
Package size(s):	
Manufacturer:	
MARKETING AUTHORISATION HOLDER for the Republic of Croatia	
Name:	
Address:	
Marketing authorisation number:	
Date of marketing authorisation:	
Marketing authorisation valid until:	

Community authorisation procedure:	
1. Centralised Procedure (CP)	☐
2. Mutual Recognition Procedure (MRP) / Decentralised Procedure (DC)	☐
2.1. Reference Member State in MRP/DC Procedure[3a]	
2.2. Other EU Member States in the Mutual Recognition Procedure/Decentralised Procedure[3b] AT BE CY CZ DE DK EE EL ES FI FR HU IE IS ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ IT LI LT LU LV MT NL NO PL PT SE SI SK UK ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

[1] complete the application form separately for each pharmaceutical form and each strength

[2] the information approved by the Decision on the Granting of the Marketing Authorisation in the Republic of Croatia

[3a] enter the EU Reference Member State according to the abbreviation given in the list of EU Member States

Abbreviated name	Member State	Abbreviated name	Member State
CY	Cyprus	LI	Lichtenstein
CZ	Czech Republic	LT	Lithuania
DE	Germany	LU	Luxembourg
DK	Denmark	LV	Latvia
EE	Estonia	MT	Malta
EL	Greece	NL	The Netherlands

ES	Spain	NO	Norway
FI	Finland	PL	Poland
FR	France	PT	Portugal
HU	Hungary	SE	Sweden
IE	Ireland	SI	Slovenia
IS	Iceland	SK	Slovakia
IT	Italy	UK	United Kingdom

[3b] specify other Member States in the Mutual Recognition Procedure

TYPE OF VARIATION: [4]
Minor variation Number □ [4a]
Major variation (*Variation Type II*) □ Safety □ Indication □ Following urgent safety restrictions □ Quality □ Other □ Annual variation for human influenza vaccines

VARIATION ACCEPTED:
Yes □ No □

DATE/NUMBER OF ACCEPTANCE OF VARIATION [5]**:**

Manufacturer/s (address)	**Function in the manufacturi process:** [6]

CONTACT PERSON OF THE MARKETING AUTHORISATION HOLDER IN THE REPUBLIC OF CROATIA:[7]	
First, last name, position:	
Telephone:	
Fax:	
E-Mail:	

QUALIFIED PERSON RESPONSIBLE FOR PHARMACOVIGILANCE (MARKETING AUTHORISATION HOLDER IN THE REPUBLIC OF CROATIA):[8]	
First, last name, position:	
Telephone:	
Fax:	
E-Mail:	
Status:	□ Employee of the marketing

	authorisation holder □ Contractor Name: Address:

[4] complete according to a type of variation
[4b] enter the variation number from the EU application
[5] if applicable, give number and date
[6] function in the manufacturing process, e.g. manufacture of semi-finished products (bulk), packaging, quality control, release
[7] must be completed
[8] must be completed

MAJOR VARIATIONS (*Variation Type II*)[9]

a. Variations in Part I/ Modules 1 and 2	□		Explanation □ Expert report: Supplemented □ Added □
b. Variations in Part II/ Module 3	□		
c. Variations in Part III/ Module 4	□		
d. Variations in Part IV/ Module 5	□		
A summary description of the variation:			

MAIN CHANGE (in the case of consequential changes) Major change is given in the application under number _____

A brief description of reasons for the proposed change/ explanation of consequential changes:

Documentation attached to the application for variation: [10]

CURRENT STATUS[11]	PROPOSAL[11]

I hereby declare that this change(s) will not adversely affect quality, efficacy or safety of the product and that the attached information supports the proposed change. I also declare that there are no other changes than those identified in this application.
First and last name of the responsible person _____ _____ Date Signature of the responsible person

The variation given in the application requires changes in: □ Decision □ Summary of Product Characteristics □ Patient Information Leaflet □ Labelling

Overview/chronological list of applied variations/renewals not accepted so far by the Agency:

[9] specify the part of documentation to which the major variation refers
[10] provide the number and titles of volumes:
[11] summarise the approved and proposed variations or refer to applications in the EU

Instructions for completion of Appendix 2

- submit the completed form in both paper and electronic copy (on CD)
- the application refers to variations that do not require the submission of the new marketing authorisation application
- complete the form for one variation only, except in the case when the main change requires one or more consequential changes or when more concomitant changes refer to the same part of the documentation
- the main change and the reasons for consequential changes should be clearly given in the appropriate parts of the form.

ANNEX 3

Name of the medicinal product:
Mutual Recognition/Decentralised Procedure number:

Declaration of the marketing authorisation holder in the Republic of Croatia that, at the time of renewal of the marketing authorisation, the medicinal product placed on the market in the Republic of Croatia is identical to the medicinal product placed on the market in EU Member States

I, ... (*Name and address of the marketing authorisation holder*), the holder of the marketing authorisation in the Republic of Croatia, hereby confirm that, at the time of renewal of the marketing authorisation, the medicinal product placed on the market in the Republic of Croatia is identical to the medicinal product placed on the market in the Reference Member State.....(*name of the Reference Member State*).
This declaration is submitted to the Agency for Medicinal Products and Medical Devices in the Republic of Croatia for the purpose of renewal of the marketing authorisation for ..... (*name of the medicinal product, pharmaceutical form, strength*) in line with the valid legal regulations and subordinate legislation and in order to ensure the safe administration of the medicinal product in the Republic of Croatia.
This declaration is valid for the period in which the medicinal product is authorised in EU Member States or in the Republic of Croatia.

Date:

Signature of the marketing authorisation holder
First and last name:
Address of the head office: