MINISTRY OF HEALTH AND SOCIAL WELFARE

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Pursuant to Article 14, paragraph 4; Article 19, paragraph 7; Article 23, paragraph 8; Article 24, paragraph 10; Article 25, paragraph 2; Article 41, paragraph 5; Article 46, paragraph 2; Article 47, paragraph 3; Article 48 and Article 111, paragraph 6 of the Medicinal Products Act (Official Gazette 71/07 and 45/09), the Minister of Health and Social Welfare hereby issues the

ORDINANCE

ON AMENDMENTS TO THE ORDINANCE ON THE PROCEDURE AND METHOD FOR GRANTING MARKETING AUTHORISTIONS FOR MEDICINAL PRODUCTS

Article 1

In the Ordinance on the procedure and method of granting marketing authorisations for medicinal products (Official Gazette 113/08), after Article 1, a new Article 1a is added and reads:

"Article 1a

The terms below, in the sense of this Ordinance, shall have the following meaning:

Centralised procedure for granting marketing authorisation of a medicinal product is the procedure of granting marketing authorisation for a medicinal product in the European Union, pursuant to the provisions of Regulation 726/2004/EC[1].

Decentralised procedure for granting marketing authorisation of a medicinal product is the procedure of granting marketing authorisation for a medicinal product which is initiated simultaneously in the reference country and other Member States that are participants in the process. It is mandatory for all medicinal products not subject to the centralised procedure pursuant to Regulation 726/04/EC which do not yet have marketing authorisation in any European Union Member State and which will be marketed in more than one European Union Member State pursuant to the provisions of Directive 2001/83/EC[2].

Mutual recognition procedure for granting marketing authorisation of a medicinal product is the procedure of granting marketing authorisation for a medicinal product which, after approval is granted in the reference country, begins in other Member States that are participants in the same process, and which is mandatory for medicinal products not subject to the centralised procedure pursuant to Regulation 726/04/EC or the decentralised procedure for granting marketing authorisation and which will be marketed in more than one European Union Member State, pursuant to the provisions of Directive 2001/83/EC.

Reference country is the European Union Member State which compiles the medicinal product assessment report in the mutual recognition procedure or the decentralised procedure, pursuant to which the participant countries decide on the acceptability of the benefit to risk ratio of the medicinal product, i.e. assessment of quality, safe use and efficacy of the medicinal product, pursuant to the provisions of Directive 2001/83/EC.

Participating country in the mutual recognition procedure and decentralised procedure is a country which decides on the acceptability of the benefit to risk ratio for a medicinal product, i.e. the assessment of quality, safe use and efficacy of a medicinal product in the mutual recognition procedure or decentralised procedure based on the assessment report for the medicinal product that was compiled by the referent country of the European Union, pursuant to the provisions of Directive 2001/83/EC.

Coordination Group for the Mutual Recognition and Decentralised Procedures, Human Medicinal Products (hereinafter: CMD(h) is a group that operates on behalf of the competent body for medicinal products in the European Union Member States and is seated with the European Medicines Agency (hereinafter: EMEA). This group addresses issues relating to grating marketing authorisation in two or more European Union Member States participating in the mutual recognition procedure or decentralised procedure.

Committee for Medicinal Products for Human Use (hereinafter: Committee) is a committee comprised of representatives of European Union Member States and appointed experts entrusted with preparing the opinion of the EMEA on all issues pertaining to medicinal products for human use in accordance with Regulation 726/2004/EC.

National procedure for granting marketing authorisation for a medicinal product in the Republic of Croatia is the procedure for granting marketing authorisation for a medicinal product only in the Republic of Croatia and for which the centralised procedure is not mandatory."

Article 2

In Article 4, after paragraph 2, paragraph 3 is added and reads:

"If the application pertains to several sizes of the same type of packaging of the medicinal product, only one application form is submitted for the granting of authorisation for all sizes."

The previous paragraphs 3 and 4 become paragraphs 4 and 5.

Article 3

In Article 5, paragraph 2 is amended and reads:

"The costs of the procedure of granting or rejecting marketing authorisation for a medicinal product shall be borne by the applicant."

Article 4

In Article 6, after paragraph 4, paragraph 5 is added and reads:

“The Agency shall give the prior consent from paragraph 3 of this Article if it is possible to ascertain from the explanation by the applicant that this is a medicinal product with active compounds not in use in the Republic of Croatia, and the medicinal product is justifiably useful for the treatment or prevention of disease, or pertains to a medicinal product having clinical advantages for the treatment or prevention of the same diseases in comparison with the approved medicinal products in the Republic of Croatia.”

The previous paragraph 5 becomes paragraph 6.

Article 5

In Article 7, paragraph 4 the words: “Module 1” are replaced by the words: “Modules 1 and 2”.

Article 6

Article 8 is amended and reads:

“The sections of the medicinal product documentation in CTD form, e.g. Modules 1, 2 and 3 or the appropriate sections of the documentation in STD form (Sections I and II), shall be submitted in written form. The filled-in application form, proposed Summary of Product Characteristics, product leaflet and labelling shall be submitted in electronic form.

The sections of the medicinal product documentation in CTD form, e.g. Modules 4 and 5 or the appropriate sections of the documentation in STD form (Sections III and IV) may be submitted in electronic form.

The Agency may request sections of the documentation, i.e. Modules 4 and 5 or the appropriate sections of the documentation in STD form, to also be submitted in written form.

Medicinal product documentation in electronic form may be submitted in non-eCTD form (temporary electronic form of the CTD without advanced search options and scanning through the medicinal product documentation) or in eCTD form (electronic form of the CTD with advanced search options and scanning through the medicinal product documentation).

The Agency shall determine the number of electronic and written copies of the medicinal product documentation or individual sections of the documentation to be submitted by the applicant with the application.

The applicant may submit the prescribed medicinal product documentation in Croatian or in English, with the exception of the documentation prescribed by this Ordinance to be submitted in Croatian.”

Article 7

In Article 9, after item 1.8.2, item 1.8.3 is added and reads:

“1.8.3. request for a change in the submission interval of the PSURs, where such a need exists;”

After item 1.9, item 1.10 is added and reads:

“1.10. data pertaining to medicinal products for use by children;”

The previous items 2.0, 2.1, 2.2, 2.3 and 2.4 become items 9.10, 9.11, 9.12, 9.13 and 9.14.

Article 8

In Article 20, paragraph 2 is amended and reads:

“The applicant for the marketing authorisation is obliged to enclose the expert statement from paragraph 1 of this Article which shall by its signature and date confirm the appropriate qualifications of the expert who compiled the report on the individual sections of the documentation.”

Article 9

In Article 21, after paragraph 2, paragraph 3 is added and reads:

“The applicant may propose a change to the submission periodicity of the PSUR during the procedure for granting marketing authorisation for the medicinal product or during the renewal of the authorisation, whereby it is necessary to submit an explanation for the request for the change in submission periodicity of the PSURs.”

Article 10

In Article 22, paragraph 2 is amended and reads:

“In addition to the application for the marketing authorisation for the medicinal product pursuant to Article 14 of the Act, the applicant shall also submit the complete medicinal product documentations (Modules 1 to 5 or, exceptionally, Modules 1 and 2, with all prescribed parts of the STD) pursuant to Appendix I and III of this Ordinance.”

Article 11

In Article 31, paragraph 1 is amended and reads:

“The documentation for medicinal products from human blood or human plasma must also contain information on the original material – human plasma in Module 3, or in the separate Plasma Master file (PMF).”

Paragraph 2 is amended and reads:

“The separate Plasma Master File contains the required information on the characteristics of human plasma that are used as original material or raw materials for the production of fractions as parts of excipients and/or active compounds in the medicinal product.”

Paragraph 4 is amended and reads:

“The documentation for vaccines must contain information on the vaccine antigen in Module 3 or in the separate Vaccine Antigen Master File (VAMF), with the exception of influenza vaccinations.”

Article 12

In Article 36, after paragraph 1, paragraph 2 is added and reads:

“Prior to the accession of the Republic of Croatia to the European Union, the Agency may participate in the centralised procedure for granting authorisation in the part of the procedure pertaining to a verification of the translation of the Summary of Product Characteristics, product leaflet and labelling into Croatian.”

Article 13

In Article 37, paragraph 2 is added and reads:

“If several sizes of packaging of a medicinal product are approved in the authorisation procedure, the Agency may list all the approved packaging sizes of the medicinal product in the list which is an integral part of the decision.”

Article 14

In Article 38, after paragraph 2, paragraphs 3 and 4 are added and read:

“After the marketing authorisation is granted for a medicinal product, the authorisation holder is obliged to inform the Agency in writing of the date of marketing the medicinal product in the Republic of Croatia.

The authorisation holder is obliged to inform the Agency in writing no later than two months prior to the temporary or permanent removal of the medicinal product from the market or disturbances in the supply of the market with the medicinal product, except in cases of a force majeure.”

Article 15

In Article 39, paragraph 2, a spelling error of the Croatian word: “pharmaceutical” is corrected.

Article 16

In Article 41, paragraph 1, the words: “List of variations (IA, IB)” are replaced by the words: “List of type I variations (IA and IB)”.

Paragraph 2 is amended and reads:

“The variations not listed in the List of type I variations (IA and IB) shall be type II variations.”

Paragraph 3 is amended and reads:

“Major variations may be:

1) variations that do not require the initiation of a new procedure to grant authorisation (II), or

2) variations requiring the initiation of a new procedure to grant authorisation.”

Article 17

After Article 41, a new Article 41a is added and reads:

“Article 41a

The marketing authorisation holder is obliged to submit the application for approval of variation concerning the medicinal product labelling and/or product leaflet that do not require variation to the Summary of Product Characteristics of the medicinal product.

In addition to the application from paragraph 1 of this Article, the marketing authorisation holder is obliged to submit written explanation for the proposed variation, the approved labelling of the inner and/or outer packaging of the medicinal product and/or product leaflet, and the proposed new labelling of the inner and/or outer packaging of the medicinal product and/or product leaflet.”

Article 18

In Article 43, paragraphs 1 and 3, the word: “amendment” is replaced by the word: “change”.

Paragraph 5 is deleted.

Article 19

In Article 44, paragraph 1 is amended and reads:

“Amendments to data listed in the Description of the pharmacovigilance system and changes to the responsible person for pharmacovigilance shall be major variation (II).”

After paragraph 1, a new paragraph 2 is added and reads:

“The marketing authorisation holder is obliged to inform the Agency in writing of changes to information pertaining to the responsible person for pharmacovigilance.”

The previous paragraphs 2, 3 and 4 become paragraphs 3, 4 and 5.

Article 20

In Article 46, paragraph 1 is amended and reads:

“The procedure for approval of variation(s) is initiated at the written request submitted by the authorisation holder in the Republic of Croatia to the Agency.”

Paragraph 2 is amended and reads:

“In addition to the written request for approval of variation(s), the applicant shall enclose:

1. a filled-in form for each variation;

2. documentation on the variation(s);

3. proof that the variation has been approved in the European Union (for medicinal products having approval in European Union Member States);

4. confirmation of payment of the administrative fee.”

Paragraph 3 is amended and reads:

“The costs of the procedure for approval or rejection of variations and the issuance or rejection of the decision on the approval shall be borne by the applicant.”

Paragraph 5 is amended and reads:

“The application for approval of variation and filled-in form for the reporting of variation shall be submitted in Croatian.”

Article 21

Article 47 is amended and reads:

“The form for reporting variation shall be submitted separately for each variation.

Exceptionally from paragraph 1 of this Article, in the case of multiple variations (I or II), which are the consequence of a single variationa, the applicant shall submit one form for reporting variation, with a list of all the consequential variations and explanation of their interconnectedness.

The applicant is obliged in the form from paragraph 1 of this Article to indicate the minor or major variation, and for the approval of major variation, it is necessary to mark the section of the documentation to which the major variation pertains.”

Article 22

In Article 49, after paragraph 1, paragraph 2 is added and reads:

“If the request pertains to several sizes of the same packaging of the medicinal product, a single form shall be filled in for all sizes.”

The previous paragraph 2 becomes paragraph 3.

Article 23

Article 50 is amended and reads:

“Documentation on variation in CTD form shall be submitted in written form with the application for the approval of variation and the filled-in form. The content of the documentation depends on the proposed variation. The filled-in form and the proposed Summary of Product Characteristics, product leaflet and labelling if the approved variation results in an amendment of the Summary of Product Characteristics and/or product leaflet and/or labelling are submitted in electronic form.

If the request for approval of a variation pertains to variations in the clinical or non-clinical documentation, the applicant shall be required to submit documentation on the amendments as an electronic copy and, exceptionally at the request of the Agency, in written form.

The documentation on the variation from paragraph 1 of this Article may be delivered in non-eCTD or eCTD form.

If the documentation on the medicinal product in the procedure of granting or renewing the marketing authorisation was submitted in non-eCTD or eCTD form, the documentation on the variation shall be submitted in the same form or in eCTD form.

The applicant shall submit the documentation on the variation in written form, together with the electronic copy of the non-eCTD or eCTD documentation from paragraph 3 of this Article.

The number of copies of the documentation for the variation shall be determined by the Agency.

The documentation on the variation may be in Croatian or in English, except for those parts of the documentation for which it is specified that they must be in Croatian.

If the approved variation pertains to several different pharmaceutical forms, doses or sizes of packaging or types of packaging of a medicinal product, the Agency may exceptionally list all the pharmaceutical forms, doses or sizes of packaging and/or types of packaging of a medicinal product on the list, which is an integral part of the notification of approval of the variation(s) in the medicinal product documentation.”

Article 24

In Article 52, paragraph 2 is added and reads:

“Following the approval of variation from paragraph 1 of this Article, pursuant to significant non-clinical or clinical research, the Agency may not use any results from those trials for a period of one year from its approval in acting on the request of another authorisation holder for change of the manner of prescribing medicinal products with the same active compound.”

Article 25

Article 53 is amended and reads:

“The Agency shall decide on the request for approval of minor variation (IA, IB) within 30 days, and on requests for approval of major variation (II) within 90 days from the date of receipt of the valid request.

The Agency shall give written notification on the approval of variation from paragraph 1 of this Article (Appendix IV).

The Summary of Product Characteristics and/or product leaflet and/or labelling of the medicinal product approved in the variation approval procedure shall be submitted as an enclosure to the notification from paragraph 2 of this Article."

Article 26

In Article 54, the words: "its integral parts" are replaced by the words: "the Summary of Product Characteristics and/or product leaflet and/or labelling of the medicinal product".

After paragraph 1, paragraph 2 is added and reads:

"If the Agency, within 90 days from receipt of the valid request for approval of variation pertaining to the medicinal product labelling and/or product leaflet not requiring an amendment of the Summary of Product Characteristics, does not contest the proposed variation, the same shall be considered approved."

Article 27

In Article 58, after paragraph 1, paragraphs 2, 3 and 4 are added and read:

"The medicinal product documentation from paragraph 1 of this Article in CTD form shall be submitted in written form with the request for authorisation renewal and the filled-in form. The filled-in application form, proposed Summary of Product Characteristics, product leaflet and labelling shall also be submitted in electronic form.

The applicant may submit the medicinal product documentation in non-eCTD or eCTD form.

In addition to submitting the documentation from paragraph 3 of this Article, the applicant shall submit Modules 1, 2 and 5, and Module 3 in cases from Article 66 and 67 of the Ordinance, in written form."

The previous paragraph 2, which becomes paragraph 5, is amended and reads:

"The costs of the procedure of granting or rejecting the renewal of the marketing authorisation for a medicinal product shall be borne by the applicant."

Article 28

In Article 59, paragraph 1 is deleted.

The previous paragraphs 2 and 3 become paragraphs 1 and 2.

Article 29

In Article 66, paragraph 1 is amended and reads:

“In the renewal procedure, the authorisation holder is obliged, if so requested by the Agency, to submit the complete documentation on medicinal product quality in Module 3 or, exceptionally, Section II of the STD if the complete documentation was not submitted in the previous authorisation issuance/renewal procedure.”

Article 30

In Article 73, paragraph 5 is amended and reads:

“The documentation from paragraph 4 of this Article may be in CTD form, and exceptionally in STD form, with written explanation.”

Article 31

After Title VII, Title VIIa and Articles 74a to 74n are added and read:

“VIIa PROCEDURE FOR GRANTING MARKETING AUTHORISATION FOR A MEDICINAL PRODUCT

Types of procedures

Article 74a

Procedures for granting marketing authorisation for a medicinal product are:

– national procedure,

– mutual recognition procedure,

– decentralised procedure.

In the procedures from paragraph 1, subparagraphs 2 and 3 of this Article, the Republic of Croatian may be a reference country or participating country.

National procedure

Article 74b

The national procedure for granting authorisation is carried out pursuant to Article 20 of the Act.

Simultaneous consideration of the application in multiple European Union Member States

Article 74c

When the Agency establishes that an application for granting authorisation for the same medicinal product is already under consideration by another European Union Member State, it shall terminate the authorisation granting procedure and propose the applicant to act in line

with the provisions of this Ordinance prescribing the mutual recognition procedure and decentralised procedure.

Marketing authorisation in another European Union Member State

Article 74d

When the Agency establishes that another European Union Member State has granted marketing authorisation for the medicinal product for which the application for marketing authorisation has been submitted in the Republic of Croatia, it shall reject the authorisation or terminate the procedure, except in cases when the application was submitted pursuant to the provisions of Articles 74e to 74m of this Ordinance.

Mutual recognition procedure and decentralised procedure

Article 74e

The mutual recognition procedure is implemented if a medicinal product has already received marketing authorisation in one of the European Union Member States, and the applicant intends to request marketing authorisation for the same medicinal product in another European Union Member State or States.

The decentralised procedure is carried out if the applicant intends to simultaneously request marketing authorisation for the medicinal product in several European Union Member States.

When requesting marketing authorisation in the Republic of Croatia and in a European Union Member State, the applicant is obliged to submit the application with identical documentation on the medicinal product in all those European Union Member States. The applicant shall request one of the European Union Member States to act as the reference country and to prepare the assessment report on the medicinal product.

The Republic of Croatia as a reference country in the mutual recognition procedure

Article 74f

If the authorisation holder has already received marketing authorisation for the same medicinal product in the Republic of Croatia, and intends to initiate the mutual recognition procedure in other European Union Member States, the Republic of Croatia shall be the reference country. The applicant must reach agreement with the Agency prior to the initiation of the procedure in which the Republic of Croatia is the reference country.

If the Agency will be the reference state, the authorisation holder shall request the Agency to prepare the medicinal product assessment report or, if necessary, to update the existing assessment report. The authorisation holder is obliged to inform the Agency of all updates to previously submitted medicinal product documentation. During the course of the procedure, the Agency may request that the applicant align the documentation with the most recent valid information and documents.

The Agency shall prepare or supplement the medicinal product assessment report with the most recent data within 90 days of the date of receipt of the request for supplementation. The

medicinal product assessment report, with the approved Summary of Product Characteristics, labelling and product leaflet shall be delivered to participating countries and the applicant.

If the participating country, within 90 days of the data of receipt of the document from paragraph 3 of this Article accepts the medicinal product assessment report, Summary of Product Characteristics, labelling and product leaflet, it shall inform the Agency thereof. Following receipt of the notification of acceptance from the participating country, the Agency shall complete the procedure and inform the applicant thereof.

If the participating country is unable to accept the medicinal product assessment report, Summary of Product Characteristics, labelling and product leaflet due to a possible serious risk for public health, the provisions of Article 74j of this Ordinance shall apply.

Republic of Croatia as the reference country in the decentralised procedure

Article 74g

The applicant shall be required to reach an agreement with the Agency prior to initiating the decentralised procedure in which the Republic of Croatia is to be the reference country.

The applicant shall submit its request to the Agency to prepare the proposed medicinal product assessment report, proposed Summary of Product Characteristics, labelling and product leaflet.

The Agency is obliged to prepare the documents from paragraph 2 of this Article within 120 days of the date of receipt of the valid request for authorisation and to submit the documents to the participating countries and the applicant.

If the participating country accepts the Summary of Product Characteristics, labelling and product leaflet within 90 days of the data of receipt of the documents from paragraph 3 of this Article, it shall inform the Agency thereof. After the Agency receives notification from the participating countries of the acceptance, it shall complete the international part of the procedure and inform the applicant thereof.

The applicant is obliged within five calendar days from the date of completion of the international part of the procedure to deliver the appropriate Croatian translation on the product leaflet, taking the expert terminology used in the Republic of Croatia into consideration. Within 30 days of the date of completion of the international part of the decentralised procedure, the Agency shall grant the marketing authorisation for the medicinal product.

If the participating country cannot accept the medicinal product assessment report, Summary of Product Characteristics, labelling and product leaflet due to a possible serious public health risk, the provisions of Article 74j of this Ordinance shall apply.

Republic of Croatia as a participating country in the mutual recognition procedure

Article 74h

If at the time of submission of the application for marketing authorisation in the Republic of Croatia another European Union Member State has already granted marketing authorisation for the same medicinal product, and the applicant intends to request marketing authorisation for the said medicinal product in the Republic of Croatia, the applicant shall be obliged to submit to the Agency a request for initiation of the mutual recognition procedure in which the Republic of Croatia is a participating country. The applicant is obliged to submit to the Agency a statement that the submitted documentation on the medicinal product is identical to the documentation submitted to the reference country and other participating countries.

Within 90 days of the date of receipt of the valid application, the Agency shall accept the report by the reference country on the medicinal product assessment, together with the Summary of Product Characteristics, labelling and product leaflet, except in exceptional cases from Article 74j of this Ordinance.

The applicant is obliged within five calendar days from the date of completion of the international part of the procedure to deliver the appropriate Croatian translation on the product leaflet, taking the expert terminology used in the Republic of Croatia into consideration. Within 30 days of the date of completion of the international part of the mutual recognition procedure, the Agency shall grant the marketing authorisation for the medicinal product.

Republic of Croatia as a participating country in the decentralised procedure

Article 74i

The applicant is obliged to submit to the Agency a statement that the submitted documentation on the medicinal product is identical to the documentation submitted to the reference country and other participating countries.

Within 90 days of the date of receipt of the valid application, the Agency shall accept the report by the reference country on the medicinal product assessment, together with the Summary of Product Characteristics, labelling and product leaflet, except in exceptional cases from Article 74j of this Ordinance.

The applicant is obliged within five calendar days from the date of completion of the international part of the procedure to deliver the appropriate Croatian translation on the product leaflet, taking the expert terminology used in the Republic of Croatia into consideration. Within 30 days of the date of completion of the international part of the decentralised procedure, the Agency shall grant the marketing authorisation for the medicinal product.

Arbitration procedure CMD(h)

Article 74j

When the Agency does not accept the medicinal product assessment report, Summary of Product Characteristics, labelling and product leaflet from Article 74h or Article 74i of this Ordinance due to a possible serious public health risk, it shall provide detailed substantiation for the rejection and inform the reference country, other participating countries and the

applicant thereof. It shall also inform the CMD(h) of the reasons for the rejection immediately.

The Agency shall attempt, together with other participant countries in the CMD(h), to reach an agreement on the necessary measures concerning the request from paragraph 1 of this Article. The CMD(h) shall allow the possibility for the applicant to present its position, verbally or in writing. If the European Union Member States reach an agreement within 60 days of the notice on the reasons for the disagreement, the reference country shall note the same, complete the international part of the mutual recognition procedure or decentralised procedure and inform the applicant thereof. The procedure is completed with the granting of marketing authorisation for the medicinal product within 30 days of the date of completion of the international part of the procedure, and the applicant shall submit the appropriate Croatian translation of the product leaflet within five calendar days, taking the expert terminology used in the Republic of Croatia into account.

If the European Union Member States do not reach the agreement within the time period from paragraph 2 of this Article, the EMEA shall be so informed immediately, with instructions that arbitration proceedings from Article 74m of this Ordinance be prepared with a detailed report on the reasons for a lack of agreement by the European Union Member States and the reasons for their disagreement. A copy of the report shall be delivered to the applicant.

After receiving notification that the case has been handed over to the EMEA, the applicant shall submit a copy of the necessary documentation to the EMEA.

If the Agency, in the case from paragraph 3 of this Article, accepts the medicinal product assessment report of the reference country, together with the Summary of Product Characteristics, labelling and product leaflet, the Agency may, at request of the applicant, grant the marketing authorisation without waiting for the outcome of the procedure from Article 32 of Directive 2001/83/EC. In that case, the granted marketing authorisation shall not affect the outcome of that procedure.

Arbitration proceedings and harmonisation of varying decisions by European Union Member States

Article 74k

If the European Union Member States have already accepted different decisions with regard to the granting or revocation of marketing authorisation for medicinal products, the Republic of Croatia, i.e. the Agency, other European Union Member States, the European Commission or authorisation holder for the medicinal product may propose to the Committee for Medicinal Products for Human Use to initiate the procedure from Article 74m of this Ordinance, which allows for the harmonisation of decisions.

The Republic of Croatia, i.e. the Agency, and other European Union Member States, send an annual list to the CMD(h) of medicinal products that require preparation of a harmonised Summary of Product Characteristics in order to stimulate the alignment of marketing authorisation in the European Union.

Arbitration procedure and protection of the interests of the European Union

Article 74l

The body competent for medicinal products of the Republic of Croatia, i.e. the Agency, other European Union Member States, the European Commission, applicant or authorisation holder for the medicinal product may, in special cases when it is in the interest of the European Union, hand over the case to the Committee for Medicinal Products for Human Use for the implementation of the procedure from Article 74m of this Ordinance, prior to the acceptance of the decision relating to the application for granting marketing authorisation, temporary revocation or termination of the marketing authorisation, or any changes to the conditions for granting marketing authorisation, especially for the compilation of information from the area of pharmacovigilance.

The body competent for medicinal products of the Republic of Croatia, i.e. the Agency, other European Union Member States or the European Commission shall clearly define the issues handed over to the Committee for Medicinal Products for Human Use for consideration, and shall inform the marketing authorisation holder thereof.

The European Union Member States and authorisation holder for the medicinal product shall submit all available data relating to the case from paragraph 1 of this Article to the Committee for Medicinal Products for Human Use.

Progression of the arbitration procedure

Article 74m

The further progression of arbitration proceedings in the Committee for Medicinal Products for Human Use and the issuance of the opinion of the European Commission are prescribed in Articles 32 to 34 of Directive 2001/83/EC.

Measures for public health protection

Article 74n

When the Agency assesses it necessary to amend the marketing authorisation issued in compliance with the provisions of this Ordinance, or to temporarily withdraw or revoke the marketing authorisation for reasons of public health protection, the case is immediately handed over to the EMEA for the implementation of proceedings from Article 74m of this Ordinance. Regardless of the provisions of Article 74l of this Ordinance, in exceptional cases when prompt action is important for the protection of public health, the Agency may temporarily suspend the sale and use of the medicinal product in question in its territory until a final decision is made. The Agency shall inform the European Commission and other European Union Member States of the causes of such measures, no later than the next working day after implementation of the measures.”

Article 32

In Appendix IV, subtitle 6.6. Instructions for the use and handling and special measures for the removal of unused medicinal products and waste materials originating from medicinal products, items 8 and 9 are amended and read:

“8. Class of the decision on the marketing authorisation of the medicinal product;

9. Date of first marketing authorisation/date of renewal of the marketing authorisation.”

Article 33

APPENDIX 4 of the Ordinance is amended and reads:

“Class:

Reg no:

Date:

Acting on the request for approval of amendment(s) in the medicinal product documentation

Agency for Medicinal Products and Medical Devices pursuant to Articles 24 and 120 of the Medicinal Products Act (Official Gazette 71/07 and 45/09) hereby issues the

NOTIFICATION ON APPROVAL OF VARIATION(S) IN THE MEDICINAL PRODUCT DOCUMENTATION

Applicant:	
Date of application:	
Name of medicinal product:	
Name of active substance (INN):	
Pharmaceutical form:	
Dosage:	
Packaging(s):	

In the proceedings carried out pursuant to the submitted documentation, the following variations to the medicinal product documentation are hereby approved:

1. state the variation that is approved

2.

3.

Attachment:

Signature: signature

cc:

Article 34

The provisions of this Ordinance pertaining to non-eCTD and e-CTD forms of the medicinal product documentation shall apply appropriately to requests submitted pursuant to the provisions of the Ordinance on special conditions for placement on the market of the Republic of Croatia of medicinal products having marketing authorisation in the European Union Member States (Official Gazette 10/08).

Article 35

This Ordinance shall come into force on eighth day from the date of its publication in the Official Gazette, with the exception of Article 1 and 31 of this Ordinance, which shall come into force on the date of accession of the Republic of Croatia to the European Union.

Class: 011-02/09-02/141

Reg no: 534-07-09-1

Zagreb, 18 December 2009

Government Vice-president and Minister of Health
and Social Welfare
Darko Milinović, MD, MSc, v.r.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use