MINISTRY OF HEALTH

2351

Pursuant to Article 130, paragraph 2 of the Medicinal Products Act (Official Gazette 76/13 and 90/14), the Minister of Health hereby issues the following

ORDINANCE

ON GRANTING AUTHORISATION FOR THE PARALLEL IMPORT OF MEDICINAL PRODUCTS

Article 1

This Ordinance lays down the manner, terms, documents and data required for issuance, amendment and revocation of the authorisation for the parallel import of medicinal products into the Republic of Croatia.

Article 2

(1) The procedure for granting the authorisation for parallel import is initiated with a written application submitted to the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) pursuant to the provisions of the Medicinal Products Act (hereinafter: the Act) and this Ordinance.

(2) The applicant is obliged to submit the application for issuance of the authorisation for the parallel import of medicinal products in the Republic of Croatia in the original, in Croatian.

(3) The application from paragraph 1 of this Article shall be submitted separately for each pharmaceutical form and strength of the medicinal product.

(4) The application for the issuance of authorisation for parallel import may be submitted by a wholesaler holding a permit for the wholesale of medicinal products issued by the Agency or competent body of another European Union Member State, and which is not in business relations with the marketing authorisation holder for the medicinal product that is the subject of the application.

Article 3

(1) In addition to the application from Article 2 of this Ordinance, the applicant is obliged to submit the filled out form for the issuance of the authorisation for parallel import in Croatian, which is printed in the Appendix of this Ordinance, and which forms its integral part.

(2) The applicant is obliged to submit the form from paragraph 1 of this Article in the original, signed by the responsible person of the applicant.

Article 4

(1) In addition to the application for the issuance of authorisation for parallel import from Article 2 of this Ordinance, the applicant is required to submit the following documentation, i.e. data and documents:

– name and address of the applicant,

– class and date of the permit for wholesale trade of medicinal products issued by the Agency, or if the wholesale permit was issued by another European Union Member State, evidence of the submitted notification to the Agency of the intent to commence performing this activity in the territory of the Republic of Croatia, or copy of the valid production permit, if applicable,

– written statement that the applicant holds a signed agreement with the medicinal product supplier on notification in the case of a recall of a series of a medicinal product in the country of export, in the original or certified copy,

– written statement confirming that the applicant has an established procedure for the procedure of recalling medicinal products, with the appointment of the person responsible for implementing and coordinating the prescribed procedure, in the original or certified copy,

– written statement obliging the applicant that pursuant to the provisions of Article 131, paragraph 1 of the Act, the applicant will notify the Agency and marketing authorisation holder of the medicinal product in the Republic of Croatia, no later than 15 days before the import of the medicinal product for which the request is submitted, in the original or certified copy,

– written statement that it is not in business relations with the marketing authorisation holder of the medicinal product for which the application for issuance of authorisation for parallel import was submitted, it the original or certified copy,

– written substantiation outlining the grounds based on which it is confirmed that the medicinal product for which the application for the issuance of authorisation for the parallel import is submitted is in essence similar to a medicinal product having marketing authorisation in the Republic of Croatia, in the original or certified copy,

– written substantiation on the need to repackage the medicinal product for which the application for parallel import is requested, if applicable, in the original or certified copy,

– evidence that the marketing authorisation holder of the medicinal product for which the application for the issuance of authorisation for parallel import was submitted has received the notification on the intention to repackage the medicinal product that has been delivered to it, and the proposal for the new external packaging for the medicinal product that clearly states who performed the repackaging,

– proof of payment of the costs of the procedure for the issuance of authorisation for parallel import,

– proof of payment of the administrative fee.

(2) If the medicinal product for which the authorisation for parallel import has been sought is repackaged, the applicant is obliged to submit, in addition to the data and documents from paragraph 1 of this Article, the following data and documents:

– name and address of the legal or natural person to perform the repackaging of the medicinal product,

– number and date of the production permit, if the repackaging is performed by a natural or legal person seated in the Republic of Croatia, or a copy of the production permit and valid confirmation of the implementation of Good Manufacturing Practice, if the repackaging is performed by a natural or legal person seated in another European Union Member State,

– contract which establishes the mutual relations if the applicant and the person responsible for the repackaging of the medicinal product are not the same legal or natural person.

(3) The Agency shall release additional instructions on its website pertaining to the labelling of parallel imported medicinal products.

Article 5

(1) In addition to the data and documents from Article 4 of this Ordinance, the applicant is obliged to submit the following documentation, i.e. data and documents:

a) on the medicinal product for which the application for issuance of authorisation for parallel import was submitted:

1. name of the medicinal product in the country of export,

2. proposal of the new name under which the medicinal product will be marketed, with the substantiation of the need to change the name, if applicable,

3. pharmaceutical form, strength and size of packaging,

4. number of the valid marketing authorisation for the medicinal product in the European Union Member State from which it is exported,

5. name and address of the marketing authorisation holder for the medicinal product in the country of export,

6. name and address of the manufacturer responsible for releasing the medicinal product to the market and indications of the place of manufacture of the medicinal product,

7. copy of the Summary of Product Characteristics of the medicinal product and package leaflet approved in the country of export, and a certified translation into Croatian,

8. mock-up of the external and internal packaging of the medicinal product in the country of export,

9. proposal of the summary of product characteristics of the medicinal product, based on the summary of product characteristics of the medicinal product having marketing authorisation in the Republic of Croatia,

10. proposal of the package leaflet of the medicinal product,

11. proposal of the labelling of the medicinal product, including the mock-up of the external and internal packaging of the medicinal product,

12. statement of the responsible person for trade that repackaging will not affect the quality of the medicinal product, if the medicinal product is repackaged, in the original or certified copy,

13. statement that the proposal of the summary of product characteristics and the package leaflet of the medicinal product for which the authorisation for parallel import has been sought is identical to the summary of product characteristics and the package leaflet of the medicinal product having marketing authorisation in the Republic of Croatia, or an outline of the differences and their substantiation, if differences exist, in the original or certified copy,

14. written list and substantiation of the differences of the external and internal packaging between the medicinal product having marketing authorisation and the medicinal product for which the authorisation for parallel import is request, if differences exist,

15. qualitative and quantitative composition of excipients contained in the medicinal product,

16. if the applicant is not able to submit a quantitative composition of excipients, the Agency shall request data on the complete composition of the medicinal product from the competent body of the European Union Member State where the medicinal product has marketing authorisation;

b) about the medicinal product having marketing authorisation in the Republic of Croatia and with which similarities are established with the medicinal product for which the application for issuance of the authorisation for parallel import was submitted:

1. name of the medicinal product,

2. pharmaceutical form, strength and size of packaging,

3. marketing authorisation number of the medicinal product in the Republic of Croatia,

4. name and address of the marketing authorisation holder for the medicinal product in the Republic of Croatia,

5. name and address of the manufacturer responsible for releasing the medicinal product to the market, and indication of the place of manufacture of the medicinal product,

6. copy of the approved summary of product characteristics and package leaflet of the medicinal product, and copy of the external and internal packaging of the medicinal product.

(2) The applicant may submit the documentation from Articles 4 and 5 of this Ordinance in Croatian or English, except the documentation which this Ordinance lays down must be submitted in Croatian.

(3) The Agency may release additional instructions on its website on the content of the documentation on medicinal products and the manner of submission of the application.

(4) The documentation from Articles 4 and 5 of this Ordinance are submitted as copies, unless this Ordinance stipulates the original, or copy certified by a notary public.

(5) Exceptionally, the Agency may request the applicant provide insight into the original documentation on the medicinal product.

Article 6

(1) In the procedure for issuance of authorisation for parallel import, the Agency determines whether the medicinal product for which the authorisation for parallel import is requested and which has valid marketing authorisation in the country of export, is essentially similar to the medicinal product holding valid marketing authorisation in the Republic of Croatia.

(2) The Agency will determine the similarity from paragraph 1 of this Article between the medicinal product for which the authorisation for parallel import is sought and which has valid marketing authorisation in the country of export, and the medicinal product with valid marketing authorisation in the Republic of Croatia, if the medicinal products have the same quantitative and qualitative composition of active compounds, same pharmaceutical form and same efficacy and safety of use.

(3) Differences in the composition of excipients between the medicinal product for which the authorisation for parallel import is sought and the medicinal product with valid marketing authorisation in the Republic of Croatia may not be such that it represents a risk to human health, according to the expert assessment of the Agency.

(4) Differences in the composition of excipients from paragraph 3 of this Article are permitted only for oral pharmaceutical forms.

(5) In determining similarities between medicinal products from paragraph 1 of this Article, the Agency shall verify whether the medicinal products are produced by the same manufacturer or by different manufacturers producing the medicinal product pursuant to the same license.

(6) If, due to the quantitative and qualitative differences in the composition of excipients or different manufacturers of the medicinal product from Article 1, the Agency is not able to determine whether the medicinal products are essentially similar, it may request the applicant submit evidence of the appropriate bioavailability tests.

(7) If the applicant is not able to submit the evidence from paragraph 6 of this Article, the Agency shall request evidence of the appropriate bioavailability tests from the competent state body of the European Union Member State in which the medicinal product has marketing authorisation.

Article 7

(1) After granting authorisation for the parallel import of a medicinal product, the holder of the authorisation for parallel import for the medicinal product is obliged to follow all changes pertaining to the marketing authorisation in the country of export and the marketing authorisation in the Republic of Croatia, and:

– without delay, to notify the Agency of the approved change(s) to the marketing authorisation in the country of export, if the approved change(s) does not affect a change in the data in the authorisation for parallel import or in the summary of product characteristics, package leaflet, and labelling of the medicinal product,

– submit a request for approval of the change(s) to the authorisation for parallel import of the medicinal product if the change(s) to the marketing authorisation in the country of export affects a change to the data in the authorisation for parallel import and/or a change to the data in the summary of product characteristics, package leaflet and labelling of the medicinal product for which the authorisation for parallel import was granted.

– submit a request for the approval of change(s) to the authorisation for parallel import of the medicinal product if the approved change(s) to the marketing authorisation in the Republic of Croatia affects a change to the data in the authorisation for parallel import and/or a change to data in the summary of product characteristics, package leaflet and labelling of the medicinal product for which the authorisation for parallel import was granted.

(2) In the case from paragraph 1, subparagraphs 2 and 3 of this Article, the holder of the authorisation for parallel import is obliged to submit the new proposal of the summary of product characteristics and/or package leaflet and/or labelling of the medicinal product in Croatia, indicating the change(s) in comparison to earlier authorisation(s) and the proposal of the same in writing.

(3) The holder of the authorisation for parallel import of the medicinal product may not implement the change(s) from paragraph 1 of this Article prior to the approval of the change(s) by the Agency.

(4) The holder of the authorisation for parallel import of the medicinal product is obliged to keep written records of monitoring the changes from paragraph 1 of this Article, and submit the same to the Agency upon request.

Article 8

(1) The procedure for approval of the change(s) is initiated via a written request submitted by the holder of the authorisation for parallel import to the Agency, pursuant to the provisions of the Act.

(2) The applicant is obliged to submit the request for approval of the change(s) in the original, in Croatian.

(3) The written request from paragraph 1 of this Article is submitted separately for each pharmaceutical form and strength of the medicinal product.

(4) With the request for the approval of change(s) to the authorisation for parallel import of a medicinal product, the applicant is obliged to submit the following data and documents:

1. name and address of the holder of the authorisation for parallel import,

2. class and reg. no. of the authorisation for parallel import of the medicinal product,

3. data on the change(s) with the substantiation of whether the change(s) affect the quality, safety of use and efficacy of the medicinal product,

4. proof of payment of the costs of the procedure for the approval of the change(s) to the authorisation for parallel import of the medicinal product,

5. proof of payment of the administrative fee.

Article 9

The Agency will revoke the authorisation for the parallel import of a medicinal product if it ascertains:

– that the marketing authorisation of the medicinal product in the Republic of Croatia has been revoked for the reason that it causes a threat to human health,

– that the holder of the authorisation for parallel import of the medicinal product did not act in accordance with Article 7 of this Ordinance,

– at the request of the holder for the authorisation for parallel import,

– if pursuant to the subsequently submitted documentation of the marketing authorisation holder for the medicinal product in the Republic of Croatia, to which the applicant referred in the application for granting the authorisation of parallel import, establishes that there are significant differences in terms of the quality, safety of use and efficacy between the medicinal product for which the authorisation for parallel import was granted, and the medicinal product having marketing authorisation in the Republic of Croatia.

– if the marketing authorisation of the medicinal product is revoked in the country of export.

Article 10

(1) The holder of the authorisation for the parallel import of the medicinal product is obliged to keep records of the origin, quantities and lot numbers of parallel imported medicinal products, and submit such information to the Agency, upon request.

(2) In the case of a recall of a lot number of the medicinal product in the country of export, the holder of the authorisation for parallel import of the medicinal product is obliged to take all necessary measures in line with the good practice requirements in the trade of wholesale medicinal products, and pursuant to its own written procedure, to identify all those to whom the lot of the recalled medicinal product was delivered and to notify them of the recall.

Article 11

The parallel trade of medicinal products in the Republic of Croatia may be performed by natural or legal persons from Article 2, paragraph 4 of this Ordinance who have notified the European Medicines Agencies thereof and received the authorisation of the European Medicines Agency on the parallel trade of the medicinal product.

Article 12

(1) Legal or natural persons from Article 11 of this Ordinance are obliged to notify the Agency in writing of their intention of performing parallel trade of the medicinal product in the territory of the Republic of Croatia, no later than 15 days prior to the import of the medicinal product into the Republic of Croatia.

(2) In addition to the notification from paragraph 1 of this Article, the applicant is also obliged to submit the authorisation for the parallel trade of the medicinal product issued by the European Medicines Agency, and the mock-up of the external and internal packaging and copy of the package leaflet in Croatian.

Article 13

This Ordinance enters into force as of the eighth day from the date of its publication in the Official Gazette.

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Zagreb, 1 October 2014

Minister

Primarius Siniša Varga, DDM, m. p.

APPENDIX