Pursuant to the second paragraph of Article 78 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos. 31/06 and 45/08) the Minister of Health in agreement with the Ministry of Agriculture, Forestry and Food issues the

REGULATIONS
on parallel import licence and parallel distribution of medicines

I. GENERAL PROVISIONS

Article 1

These Regulations shall regulate:
– the contents of applications, the procedure and conditions for obtaining and extending the parallel import licence for medicinal products for human use and veterinary medicinal products (hereinafter: medicinal products);
- reasons for cessation of validity of parallel import licence for medicinal products;
- the obligations of the holder of parallel import licence for medicinal products;
- the conditions for implementing parallel distribution of medicinal products in the Republic of Slovenia.

Article 2

In addition to the definitions and terms defined in Articles 5 and 6 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos. 31/06 and 45/08; hereinafter: Act), the terms used in these Regulations shall have the following meanings:
1. A parallel imported medicinal product is a medicinal product for which parallel import licence was obtained based on the fact that such medicinal product has already obtained a marketing authorisation in the exporting Member State or in the European Economic Area (hereinafter: EU or EEA) and that for the needs of parallel importation based on the assessment of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: Agency) such medicinal product can be deemed sufficiently similar to a medicinal product for which marketing authorisation was obtained in the Republic of Slovenia.
2. The country of export is the EU Member State or country in the EEA in which the parallel imported medicinal product obtained a marketing authorisation and from which such medicinal product enters the territory of the Republic of Slovenia

Article 3

A parallel imported medicinal product can only be marketed in the territory of the Republic of Slovenia if it has obtained a parallel import licence.

Article 4

The marketing of parallel imported medicinal products in the territory of the Republic of Slovenia may be performed by wholesalers of medicinal products who are holders of authorisations for wholesale trade in medicinal products issued by the Agency or legal entities or natural persons with their registered office in other EU Member States who have obtained adequate authorisation to perform the activity of wholesale trade in medicinal

products in the EU Member State in question and who have notified the Agency of the performance of such activities in the Republic of Slovenia.

Article 5

The authority competent for issuing the parallel import licence for medicinal products shall be the Agency.

Article 6

The application for the issue, variation or extension of a parallel import licence for medicinal product may be submitted by wholesalers of medicinal products who:
- hold an authorisation issued by the Agency for wholesale trade in medicinal products or have obtained suitable authorisation for such activity in another EU Member State and who have notified the Agency of such activity in the Republic of Slovenia;
- were not authorised by the holder of the marketing authorisation for the medicinal product to market the medicinal product for which the application has been filed and are not affiliated with them.

Article 7

(1) The application from the previous Article must contain a complete application form and the prescribed data and documentation must be organised in the sequence denoted on the application form.
(2) The forms for the issue, variation and extension of parallel import licence for medicinal products (Form 342-01, Form 344-01 and Form 343-01) are located in the Annex which is a constituent part of these Regulations and are also published on the website of the Agency.

Article 8

(1) The forms for the issue, variation and extension of parallel import licence for medicinal products must be filled out in the Slovenian language.
(2) The evidence data that the application must contain may be either in the Slovenian or English languages and may be copies of the required documents except for documents that the Regulations require to be submitted in original or as certified copies.

Article 9

If the Agency determines that the application is incomplete, it shall within 30 days of the receipt of the application request the applicant to supplement it.

II. ISSUING OF THE PARALLEL IMPORT LICENCE FOR A MEDICINAL PRODUCT

Article 10

(1) The Agency may issue a parallel import licence for a medicinal product if based on the required data and evidence, during the procedure the Agency determines sufficient similarity between the medicinal product that has obtained a marketing authorisation in the country of export and for which the parallel import licence is being requested and a medicinal product with valid marketing authorisation in the Republic of Slovenia, and concludes that for the needs of parallel importation these products can be deemed as sufficiently similar.

(2) The Agency must assess sufficient similarity between the medicinal products from the preceding paragraph based on the following criteria:
- the medicinal products must have the same active ingredients;
- the medicinal products must have the same therapeutic effects;
- that eventual differences between the medicinal products do not present a risk to the health of humans and animals according to the Agency's assessment.

When assessing sufficient similarity between the medicinal products based on the criteria from the preceding paragraph, the Agency shall take into consideration regulations and opinions of experts, if necessary.

(4) When assessing essential similarity between the medicinal products, the Agency shall examine whether the medicinal products are manufactured by the same manufacturer or different manufacturers, according to the same licence or production specification.

Article 11

(1) A complete application for obtaining a parallel import licence for a medicinal product must contain the following information:
- data regarding the applicant;
- data and evidence regarding the medicinal product.

(2) The applicant must pay an application fee and an administrative fee for the application for parallel import licence for medicinal product.

Article 12

The data regarding the applicant from the preceding paragraph shall comprise:
1. name and registered office of the legal entity or natural person;
2. statement and signature of the responsible person;
3. indication of the number and date of the authorisation for the wholesale of medicinal products issued in the Republic of Slovenia, or certificate of notification of the activity to the Agency if the authorisation for performing such activity was not issued in the Republic of Slovenia;
(4) proof of delivery of the notification on parallel importation with which the applicant for the parallel import licence for medicinal product notified the manufacturer of the medicinal product on his intent to conduct parallel import;
5. statement of the applicant that he is not authorised to market the medicinal product by the market authorisation holder of the medicinal product issued in the country of export;
6. in the case of repackaging:
- name and address of the legal entity performing repackaging of the medicinal product;
- manufacturing authorisation related to packaging for the medicinal product which was issued in accordance with regulations regulating in detail the conditions that the manufacturer or producer of the medicinal product must fulfil and the procedure for its verification. If the manufacturer who repackages the medicinal product has its registered office in the Republic of Slovenia, only the number of the manufacturing authorisation related to packaging issued by the Agency should be denoted;
- contract with the applicant for obtaining parallel import licence for medicinal product if the applicant does not perform repackaging himself.

Article 13

(1) The information and evidence regarding the medicinal product from Article 11 hereunder are as follows:
A) Data and evidence regarding the medicinal product for which the application for obtaining a marketing authorisation for parallel importation of the medicinal product was submitted:
1. name of the medicinal product in the country of export;
2. pharmaceutical form, strength and packaging size;

3. number of the valid marketing authorisation of the medicinal product in the country of export;
4. data regarding the holder of the marketing authorisation of the medicinal product in the country of export (name, address);
5. data regarding the manufacturer and manufacturing site;
6. copy of the summary of the product characteristics approved in the country of export and certified expert translation thereof in the Slovenian language;
7. copy of the patient information leaflet approved in the country of export and certified expert translation thereof in the Slovenian language except if the medicinal products being compared were included in the mutual recognition or decentralised procedures;
8. proposed summary of product characteristics in the Slovenian language and statement that the summary of product characteristics for the medicinal product for which an application was submitted for obtaining parallel import licence is identical to the summary of product characteristics for a medicinal product with marketing authorisation the applicant is referencing or a precise denotation of the differences unless the medicinal products being compared are included in the mutual recognition or decentralised procedures;
9. proposed patient information leaflet in the Slovenian language and statement that the patient information leaflet for the medicinal product for which an application was filed for obtaining a parallel import licence is identical to the patient information leaflet for a medicinal product with marketing authorisation the applicant is referencing or a precise denotation of the differences;
10. outer packaging the medicinal product has in the country of export;
11. mock-up of the outer packaging and patient information leaflet in the Slovenian language and graphical presentation of the immediate packaging of the medicinal product for which an application was filed for obtaining parallel import licence, and
12. in the case of repackaging:
- mock-up of the new immediate and outer packaging in the Slovenian language and a statement regarding their effect on the product;
- name and address of the legal entity performing the repackaging of the medicinal product;
- manufacturing authorisation related to packaging for legal entities with their registered seat outside the Republic of Slovenia or the manufacturing authorisation number for legal persons with their seat in the Republic of Slovenia and the contract between the applicant and legal entity performing the repackaging if this does not regard the same legal entity;
- denotation of the modified indications on the outer packaging, if applicable.

B) Data regarding the medicinal product that has obtained marketing authorisation in the Republic of Slovenia and which is being compared with the medicinal product for which an application has been filed for obtaining parallel import licence:
1. name of the medicinal product;
2. pharmaceutical form, strength and packaging size;
3. number of the marketing authorisation;
4. data regarding the holder of the marketing authorisation of the medicinal product (name, address);
5. data regarding the manufacturer and manufacturing site;
6. summary of product characteristics;
7. patient information leaflet;
8. immediate and outer packaging, and
9. list of differences between the medicinal product for which an application for obtaining parallel import licence has been submitted and the medicinal product that has already obtained marketing authorisation in the Republic of Slovenia.

(2) A detailed expert explanation must be given for each difference separately (e.g. differences regarding summaries of product characteristics, patient information leaflets, packaging, composition of excipients, tablet colours, breakability) in which it is evident that the differences have no effect on the therapeutic efficacy and on the quality, safety and efficacy of the medicinal product.

Article 14

(1) The Agency shall make a decision regarding the application within 60 days of the receipt of the complete application.

(2) The parallel import licence for medicinal product shall be issued for a period of five years and can be extended.

Article 15

(1) The applicant shall pay a fee to cover the costs for the issuance, variation or extension of a parallel import licence for a medicinal product in accordance with the executive act regulating fees for procedural costs in the area of medicinal products.

(2) The applicant shall pay an administrative fee for the application and the issuance, variation or extension of the parallel import licence for a medicinal product.

III. VARIATIONS OF A PARALLEL IMPORT LICENCE FOR A MEDICINAL PRODUCT

Article 16

(1) During the validity of the parallel import licence for a medicinal product the licence holder is obliged to monitor changes to the medicinal product in the country of export that are publicly available and notify the Agency thereof on a regular basis.

(2) If such variations concern a modification to the summary of the product characteristics or patient information leaflet, the holder is obliged to notify the Agency through an application within 60 days of such variations going into effect in the country of export.

(3) If the variations concern the medicinal product's packaging, the marketing authorisation holder is obliged to give notification thereof through an application within 90 days prior to such changes going into effect.

Article 17

(1) A complete application for variation to a parallel import licence for a medicinal product must contain the following information:

1. applicant data from Article 12 hereunder;
2. data regarding the variations from the preceding paragraph, accompanied by documentation on the variations and explanation regarding assessment of the quality, safety and efficacy or differences connected to the therapeutic efficacy of the medicinal product.

(2) The applicant must pay an application fee and an administrative fee for notification of amendment variation to the parallel import licence for the medicinal product.

Article 18

The Agency shall deal with the complete application from the previous paragraph and during the procedure assess the effect of notified variations to the medicinal product on sufficient similarity to the medicinal product that has obtained the marketing authorisation in the Republic of Slovenia based on the criteria from Article 10 hereunder and within a month of the day of receiving the complete application, make its decision on whether the parallel import licence for the medicinal product shall apply up to the expiration period from the second paragraph of Article 14 hereunder or whether the licence shall cease to be valid.

IV. EXTENSION OF THE PARALLEL IMPORT LICENCE FOR A MEDICINAL PRODUCT

Article 19

If the holder of a parallel import licence for a medicinal product decides to extend such licence, he shall no later than 90 days prior to its expiry, file an application with the Agency for an extension of the licence.

Article 20

(1) A complete application for the extension of a parallel import licence for a medicinal product shall contain the following information:
1. applicant data from Article 12 hereunder;
2) data and evidence regarding the medicinal product specified in Article 13 hereunder denoting any variations, evidence and a chronological list of variations since the obtaining of the parallel import licence for the medicinal product;.
3. statement that the conditions under which a valid parallel import licence for the medicinal product was issued have not changed.
(2) The applicant must pay an application fee and an administrative fee for extension of the parallel import licence for the medicinal product.

Article 21

2)The Agency shall treat the complete application for the extension of a parallel import licence of the medicinal product and during the procedure on the basis of the criteria of Article 10 hereunder, decide on the extension of such licence within one month of receiving the complete application.

V. CESSATION OF VALIDITY OF A PARALLEL IMPORT LICENCE FOR A MEDICINAL PRODUCT

Article 22

(1) The parallel import licence for a medicinal product shall cease to be valid upon the expiration of the period for which it was issued.
(2) The Agency shall revoke the parallel import licence for a medicinal product:
- if the validity of the marketing authorisation of the reference medicinal product has ceased and if such cessation concerns the quality, safety or efficacy of the medicinal product;
- in the event of changed conditions on whose basis the parallel import licence for the medicinal product was issued, if the holder of such licence failed to give notification of the changes in question in accordance with Article 17 hereunder;
- on the basis of an application by the holder of the parallel import licence for the medicinal product or
- on the basis of an examination of evidence submitted by the manufacturer or other legal entity or natural person denoting significant differences regarding quality, safety or therapeutic efficacy exist between the medicinal product that obtained a marketing authorisation in the country of export and the medicinal product that obtained a marketing authorisation in the Republic of Slovenia.

VI. OBLIGATIONS OF THE HOLDER OF PARALLEL IMPORT LICENCE FOR A MEDICINAL PRODUCT

Article 23

The holder of a parallel import licence for a medicinal product shall have the same obligations as the holder of the marketing authorisation of the medicinal product pursuant to law.

Article 24

The holder of a parallel import licence for a medicinal product must ensure a continuous and suitable supply of the medicinal product in question.

VII. QUALITY CONTROL

Article 25

The medicinal products for which a parallel import licence was issued shall be subject to quality control in accordance with regulations on the quality control of medicinal products.

VIII. CONDITIONS FOR IMPLEMENTING THE PARALLEL DISTRIBUTION OF MEDICINAL PRODUCTS

Article 26

The parallel distribution of medicinal products in the territory of the Republic of Slovenia is permissible if carried out by the legal entities or natural persons specified in Article 4 hereunder who have notified the European Medicines Agency (hereinafter: EMEA) of such intent and have not within 30 days of the receipt of the notification by the EMEA received a negative response.

Article 27

The legal entities or natural persons of the previous Article must prior to commencing the parallel distribution of the medicinal products in the territory of the Republic of Slovenia notify the Agency of such intent. The notification shall contain:
1. evidence from the EMEA that it received the notification on parallel distribution;
2. statement of the applicant that the EMEA has not issued a negative response within the 30 days of receiving the notification from the preceding point;
3. name of the medicinal product, pharmaceutical form, strength and packaging size;
4. data regarding the manufacturer and manufacturing site;
5. mock-up of the outer packaging and patient information leaflet in the Slovenian language and graphical presentation of the immediate packaging of the medicinal product that concerns the notification.

IX. FINAL PROVISIONS

Article 28

On the day these Regulations enter into force the Rules on the parallel import and parallel distribution of medicinal products (Official Gazette of the Republic of Slovenia, No. 73/05) shall cease to be valid.

Article 29

These Regulations shall enter into force fifteen days after their publication in the Official Gazette of the Republic of Slovenia.

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Borut Miklavčič
Minister of Health

I agree!
Dr. Milan Pogačnik
Minister of Agriculture, Forestry and Food