MINISTRY OF HEALTH

O R D E R
on ammendment and supplementation of the Procedure for the grant of parallel import authorisations for medicinal products for human use, approved through Order of the Minister of Public Health no. 1.962/2008

On seeing the Approval Report of the Medicinal product policy directorate no. Cs.A. 12.387 of 24 November 2010,

Taking into account:

- Provisions of Title XVII - "The medicinal product" of Law no. 95/2006 on healthcare reform, as amended;

- Government Ordinance no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices,

Based on Government Decision no. 144/2010 on the organisation and functioning of the Ministry of Public Health, as amended,

the **minister of health** hereby issues the following order:

Art. I - The Procedure for the grant of parallel import authorisations for medicinal products for human use, approved through Order of the Minister of Public Health no. 1.962/2008, published in the Official Gazette of Romania, Part I, no. 867 of 22 December 2008, is amended and supplemented as follows:

1. **Under Article 6, paragraph (1) is amended and reads as follows:**

"Art. 6. - (1) Persons desiring to perform parallel import activities from an exporting country as mentioned under Art. 1 b) should submit an application for a parallel import authorisation to the NAMMD, thus submitting an application to the Register– document distribution and release Bureau within the Information, Logistics and Electronic Management of Data Department, in accordance with the model mentioned in Annex 1, the completed payment form and support documentation."

2**. Under Article 7, paragraph (1) is amended and reads as follows:**

"Art. 7- (1) The Register– document distribution and release Bureau checks up the existence of the necessary documentation, as well as the existence of finished product samples, if needed."

3. The title of Chapter V is amended and reads as follows:

"CHAPTER V

Assessment of applications for grant of parallel import authorisations"

4. Under Article 8, paragraphs (1), (3), (5) and (7) are amended and read as follows:

"Art. 8 - (1) Following payment of the tariff for grant of the parallel import authorisation and payment to the NAMMD account of the respective sum, in accordance with the Order of the Minister of Health in force concerning payment of tariffs for services provided by the NAMMD and following validation of the application and support documentation, the NAMMD shall require a report containing all required information about the product, as authorised in the exporting Member State of the European Economic Area. After receipt of the required information, the assessment procedure of the documentation in view of parallel import authorisation grant is started.

.....

(3) In case of objections or comments, the procedure is suspended ("clock-stop") each time, until receipt of the needed documents or information in view of clarification. The applicant should reply within 30 days. A longer deadline is allowed only when there are arguments attesting that the procedure for check up of the leaflet user test has not yet been concluded. The NAMMD will communicate twice with the applicant in view of transmission of the information or of the required amendments. The third and last letter shall be forwarded to the applicant to inform him/her about the refusal of grant of the parallel import authorisation, determined by a couple of missing documents.

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(5) In case there are no objections or comments, the NAMMD issues the parallel import authorisation within 45 days as of assessment procedure onset.

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(7) The availability period of the parallel import authorisation is 5 years and it is renewed for a new 5-year period by submission of an application filled in according to the form in Annex 3."

5. Under Article 11, paragraph (4) is amended and reads as follows:

"(4) The parallel importer is directly responsible for the juridical problems concerning the trademark of the parallel imported medicinal product and for the other issues related to compliance with industrial property rights."

6. Article 13 is amended and reads as follows:

"Art. 13 - Annex 1, 2 and 3 are integral parts of this Procedure."

7. Annex 1 to the procedure is amended and replaced with Annex 1, which is integral part of this Order.

8. A new Annex is introducted after Annex 2 to the procedure, Annex 3, contained in Annex 2, which is integral part of this Order.

Art. II – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Cseke Attila

Bucharest, 24 November 2010.
No. 1.449.

ANNEX 1
(Annex 1 to the Procedure)

APPLICATION
for the grant by the National Agency for Medicines and Medical Devices of a parallel import authorisation

.....
1. The name under which the medicinal product is marketed in Romania:
.....
(presentation of the pharmaceutical form, strength, package size)
.....
2. Number of the parallel import authorisation [1]:
.....
.....
3. Name and address/Site of the applicant:
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.....
Name and address/Site of the correspondent [2]:
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.....
3.1. Number of the wholesale distribution authorisation:
.....
.....
3.2. Manufacturing authorisation (and, if needed, the contract signed with the wholesale distribution authorisation holder) of the relabeling/repackaging site:
attached copies

.....
.....
4. I hereby request grant of a 5-year parallel import authorisation for the medicinal product referred to in the information and documents in the present application or attached to it, attesting that:

4.1. I shall meet all legal requirements (national/Community) applicable to the parallel import authorisation;
4.2. No essential information has been knowingly omitted in this application.
4.3. I shall immediately provide the National Agency for Medicines and Medical Devices any new product-related information which would lead to amendment of the information/documents included in the parallel import authorisation;
4.4. I shall subsequently notify the Ministry of Health about the lower price of the medicinal product in Romania following use of the parallel import authorisation.
5. I declare that I am personally responsible for the legal issues related to the trademark of the parallel imported product and/or to other industrial property issues.

Date: ..... Signature: .....
Name of the signatory:
.....
Quality of the signatory:
.....
Telephone number: ..... Fax: .....
E-mail: .....

[1] Do not fill in. Granted by the NAMMD.
[2] If different from the applicant.

INFORMATION ON THE PARALLEL IMPORTED MEDICINAL PRODUCT

6. General information on the parallel imported medicinal product

(i) Exporting country (EEA member state)

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(ii) Name of the medicinal product in the exporting country

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(presentation of the pharmaceutical form, strength, package size)

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(iii) Please attach the evidence attesting that the Marketing Authorisation Holder has been informed about the intention to import the medicinal product in Romania.

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(iv) Authorisation number(s) granted in the exporting country stating the issuance/expiry date

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(v) Name and address/Site of the MAH in the exporting country

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(vi) Name, address/Site and (if known) number of the authorisation granted by the EEA provider of the medicinal product

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(vii) Please make a full description of the medicinal product to be imported from the EEA member state (e.g. oral solid form, size, form, aspect, external features)

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.....
.....

Please attach a sample of the future parallel imported product to be imported in parallel, in its original packaging.

(viii) Please mention all information you are aware of concerning the medicinal product before arrival at the aforementioned provider.

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.....
.....

Date: ..... Signature: .....

INFORMATION ABOUT THE MEDICINAL PRODUCT IN ROMANIA

7. Information about the marketing authorisation in force in Romania, covering a medicinal product the applicant considers identical/therapeutically similar to the product to be imported:

(i) Name of the medicinal product

.....

(presentation of the pharmaceutical form, strength, package size)

(ii) Number of the parallel import authorisation granted by the NAMMD, issuing/expiry date included:

.....

(iii) Name of the Marketing Authorisation Holder .....

.....
.....

8. Is the medicinal product to be imported in parallel in any way different from the product covered by the marketing authorisation mentioned under point 7?

YES/NO.

If "yes", please detail.

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.....

9. The Summary of Product Characteristics and the leaflet – the version in force as approved by the national authority

If the following information about the medicinal product you plan on importing are not compliant with the marketing authorisation for the medicinal product in Romania, please attach complete details:

(i) Recommended clinical indications and administration route(s)

(ii) Recommended dose and scheme of administration

(iii) Contraindications, precautions and warnings

(iv) Pharmacodynamic information

(v) Pharmacokinetic information

10. Details on relabelling/repackaging:

10.1. Name of the person performing the relabelling/repackaging operation: .....

Address: .....

.....

Telephone number: .....Fax number: .....

Changes proposed by the parallel importer for the original packaging (for example, sticking a label on the primary and secondary packaging, issuing a new packaging mock-up etc.)

Please describe the changes brought to the original packaging: .....

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.....

.....

10.2. Changes proposed by the parallel importer for the packaging size and confirmation of authorisation of this packaging size in Romania

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10.3. Statement on Braille imprinting

10.4. Statement on not (directly or indirectly) influencing the features of the original product by relabelling/repackaging

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Please attach mock-ups of the packagings and leaflets (in Romanian) to be used for the repackaged medicinal product.

Date: ..... Signature: .....

INFORMATION ON THE MEDICINAL PRODUCT

11. Active substances:

Quantity/Therapeutic unit or % Therapeutic unit

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Overdoses and specifications are written in the same way as in the marketing authorisation granted in the exporting country.

12. Other constituents, including the composition of the capsule surface layer:

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Overdoses and specifications are written in the same way as in the marketing authorisation issued in the exporting country.

13. Pharmaceutical form (i.e. tablet, film-coated tablet etc.):

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14. Classification according to the manner of release:

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15. Describe the type of container, closure system and any other administration device

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16. Packaging size(s) Unit

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17. Availability

(i) Sealed

(ii) After opening/reconstitution: .....

18. Special storage precautions

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19. Name and address/Site of the manufacturer to be mentioned in the patient leaflet

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(i) Name and address of the manufacturing site(s) for the stages of the manufacturing process

(ii) Name and address of the batch release site

(iii) Manufacturing site of the active substance(s) ……

20. Name, address/site and authorisation number of the parallel importer's authorisation[3]:

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21. Name, address/Site and number of the authorisation held by the persons responsible for repackaging:

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22. Units responsible for the release of the repackaged batch of the medicinal product (and/of testing, if needed):

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23. Site of the storage place:

(i) Name of the contact person in case of issues related to quality and batch recall

(ii) Name of the contact person responsible for pharmacovigilance activity

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24. Name, address/site and number of the authorisation belonging to the distributor(s) (if needed):

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.....

Date: ..... Signature: .....

[3] Authorisation of the wholesale distribution of medicinal products for human use.

ANNEX 2

(Annex 2 to the Procedure)

APPLICATION
for renewal by the National Agency for Medicines and Medical Devices of a parallel import authorisation

1. The name under which the medicinal product is marketed in Romania:
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(presentation of the pharmaceutical form, strength, package size)
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2. Number of the parallel import authorisation granted by the NAMMD, issuance/expiry date included:
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.....
3. Name and address/Site of the parallel import authorisation holder:
.....
.....
Name and address/Site of the mail correspondent [1]:
.....
.....
.....
.....
3.1. Number of the wholesale distribution authorisation:
.....
.....
3.2. Manufacturing authorisation (and, if needed, the contract signed with the wholesale distribution authorisation holder) of the relabeling/repackaging site:
attached copies
.....
.....
4. Registernumber of the company at the Registerof Commerce
.....

[1] If different from the applicant.

5. I hereby request grant of a 5-year parallel import authorisation for the medicinal product referred to in the information and documents in the present application or attached to it, attesting that:
5.1. I shall meet all legal requirements (national/community) applicable to the parallel import authorisation;
5.2. No essential information has been knowingly omitted in this application.
5.3. All changes brought to the original parallel import authorisation have been described, forwarded and approved as variations by the National Agency for Medicines and Medical Devices;
5.4. I shall subsequently notify the Ministry of Health about the lower price of the medicinal product in Romania following use of the parallel import authorisation.

Date: ..... Signature: .....
Name of the signatory:
.....
Quality of the signatory:
.....
Telephone number: ..... Fax: .....
E-mail: .....

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