MINISTRY OF PUBLIC HEALTH

ORDER

on approval of the procedure for the parallel import authorisation for medicinal products for human use

On seeing the Approval Report of the General Pharmaceutical Directorate No. E.N. 12.411 of 2 December 2008,

Taking into account:

- provisions of Title XVII – The medicinal product of Law No. 95/2006 on healthcare reform, as amended;

- Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved through changes and completions through Law No. 594/2002, as amended,

Based on Government Decision No. 862/2006 on the organisation and functioning of the Ministry of Public Health, as amended,

The Minister of Public Health hereby issues the following order:

Art. 1. – The release procedure for the parallel import authorisation for medicinal products for human use, included in the Annex which is integral part of this Order.

Art. 2. – This Order is published in the Official Gazette of Romania, Part I.

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This Order has been adopted in accordance with the notification procedure mentioned in Directive 98/34/EC of the European Parliament and Council concerning the procedure for the exchange of information in the field of technical standards and regulations, published in the Official Journal of the European Communities L 204 of 21 July 1998, modified by Directive 98/48/EC of the European Parliament and Council, published in the Official Journal of the European Communities L 217 of 5 August 1998.

Minister of Public Health,

Gheorghe Eugen Nicolăescu

Bucharest, 2 December 2008.
No. 1.962.

ANNEX

PROCEDURE
for the release of parallel import authorisations*[1)] for medicinal products for human use

CHAPTER I
Definitions

Art. 1. - In the context of the present procedure, the following terms are defined as follows:

a) *parallel import* - The operation through which a medicinal product for which a marketing authorisation has been released by the National Medicines Agency (NMA) is introduced in Romania via other distribution channels than those agreed by the MAH of the respective medicinal product; there are minor differences between the parallel imported medicinal product and the one who has been authorised on the Romanian market, provided that there is no difference between the therapeutic effect and the directly distributed medicinal product;

b) *country of export* – an EU/EEA country from which the parallel imported product is introduced into Romania and where the respective marketing authorisation is in force; it is not necessary that the imported batch had physically existed in the concerned country, but it must have been released in a EU/EEA country;

c) *directly distributed original product* – medicinal product marketed in Romania via the distribution channel(s) agreed by the MAH and which enables the parallel import.

CHAPTER II
Introduction

Art. 2. - The NMA manages the parallel import of medicinal products authorised at national level, through national procedure or mutual recognition/decentralised procedure*[2)].

Art 3. – The NMA handles the parallel import of medicinal products for human use in accordance with Art. 28 and 30 of the EC Treaty, Communication Commission on the parallel import of medicinal products for proprietary medicinal products for which marketing authorisations have already been granted, the jurisprudence of the European Court of Justice and of the present procedure.

Art. 4. - (1) Medicinal products introduced in Romania through parallel import cannot be distributed or sold before NMA releases the parallel import authorisation.

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*[1)] Although the term "import" has lost most of its relevance due to the development of the internal market, and the actual terminology refers to "intra-community trade", due to practical reasons, the term "import" is mainly used in the European Area, the same thing being mentioned in the Communication Commission concerning imports of medicinal products for which marketing authorisations have already been granted (COM/2003/0839 final).

*[2)] Parallel distribution of medicinal products authorised at national level through the centralised procedure (in accordance with Regulations No. 2.309/1993/EC and, namely, No. 726/2004/EC) is handled by the European Medicines Agency (EMA). (2) Centrally authorised medicinal products are exceptions to provisions of (1)).

CHAPTER III

Conditions for parallel import

Art. 5. - (1) In accordance with European regulations in force, the following requirements should be met in order to allow the NMA to issue a parallel import authorisation:

a) there should be a marketing authorisation issued by the NMA for the directly distributed original product;

b) the parallel imported medicinal product should be imported from an exporting country, as defined under Art. 1 b);

c) The imported medicinal product should be subject to a marketing authorisation in force in the exporting country, as defined under Art. 1 b);

d) the parallel imported medicinal product is quite similar to the directly distributed original product, although there are some differences concerning their excipients.

(2) When the holder in the country of export of the marketing authorisation of the parallel imported medicinal product is the same, belongs to the same group of companies as a MAH for the source product distributed in Romania or when there is a bond existing between the two holders, such as a licence contract or a similar juridical situation.

(3) The NMA decides on grant of the authorisation on the basis of extremely detailed information, including via the request of additional information from the competent authorities in the exporting country; in this case, the NMA suspends the procedure ("clock-stop") until the receipt of the information requested.

(4) The parallel imported medicinal product's name may differ from the name of the medicinal product authorised in Romania or in the exporting country, while being compliant with the legislation in force concerning the medicinal products' names.

CHAPTER IV
Submission of the application in view of the parallel import authorisation's release

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 NMA, thus submitting an application to the Documents admission and sampling bureau within the NMA Evaluation-Authorisation Department, in accordance with the model mentioned in Annex 1, the completed payment form and support documentation.

(2) The application and support documentation should be submitted in 2 copies.

(3) If the medicinal product is imported from several exporting countries, an application shall be submitted for each exporting country.

(4) The application should be submitted prior to the medicinal product's distribution on the market.

Art. 7. - (1) The Documents admission and sampling bureau checks up the existence of the necessary documentation, as well as the existence of finished product samples, if needed.

(2) If the documentation is compliant with provisions of the present procedure, the application is validated; if non-compliant, the application is declared invalid and the reason for invalidation is noted in the receipt register.

(3) The application's invalidation does not prevent the applicant to submit a new application to the NMA, following the correction of non-compliances which represented the reason for the invalidation.

CHAPTER V
Resolution of applications for release of parallel import authorisations

Art. 8. - (1) Following payment of the tariff for release of the parallel import authorisation and payment to the NMA account of the respective sum, in accordance with the Minister of Public Health Order in force concerning payment of tariffs for services provided by the NMA, the assessment procedure of the documentation in view of parallel import authorisation release is started.

(2) Within 30 days following the beginning of the procedure, the NMA analyses the submitted documentation and, if necessary, sends the potential objections or comments to the applicant.

(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.

(4) Unless there are complaints/comments or if these have been clarified, the NMA issues the marketing authorisation.

(5) In case there are no objections or comments, the NMA issues the parallel import authorisation within 45 days as of receipt of payment to the NMA account.

(6) In case of objections or comments, the 45-day period is prolonged with the period of suspension for completions or clarifications.

(7) The availability period of the parallel import authorisation is 5 years and it is renewed for a new 5-year period.

CHAPTER VI
Variations of the parallel import authorisations

Art. 9. - (1) The parallel importer has the duty to inform the NMA concerning any modifications of the parallel imported medicinal product, thus submitting, as required, depending on the situations mentioned hereby, a notification or an application for variation of the parallel import authorisation, in accordance with the form mentioned in Annex 2.

(2) In case of a modification of the parallel imported medicinal product aspect, not in consequence of a modification in product composition, and when the modification implies only the form of a tablet, a groove or a form of engraving on a tablet surface, the medicinal product may be marketed until the NMA legitimately decides otherwise and informs the parallel importer thereof.

(3) In case of a modification of the commercial company and/or address of the MAH/manufacturer, the parallel importer may continue to distribute the medicinal product until the NMA decides otherwise (and provides proof) and informs the parallel importer thereof.

(4) In case of other insignificant modifications, appreciated as such on his/her own account by the parallel importer, he/she may continue distributing the medicinal product until the NMA decides otherwise and informs the parallel importer thereof.

(5) In case of a modification concerning the composition, aspect, primary package of the parallel imported medicinal product or the status of the MAH in the exporting country, compared to the moment of the granting of the parallel import authorisation, the medicinal product cannot be marketed until the NMA grants an authorisation for this purpose, by approving a variation of the parallel import authorisation.

CHAPTER VII
Withdrawal of the marketing authorisation of the directly distributed original medicinal product

Art. 10. - (1) When withdrawing the marketing authorisation of a directly distributed medicinal product, on public healthcare grounds, the NMA also withdraws the parallel import authorisation(s) meant for the same medicinal product.

(2) When withdrawing the marketing authorisation on commercial grounds, the NMA informs the holder of a parallel import authorisation about it and requires a written declaration within 30 days, in case the holder wishes to further hold the parallel import authorisation.

(3) If the holder of a parallel import authorisation does not declare within 30 days that he wishes to hold the authorisation, it is considered "justly recalled", when the 30-day term will have expired; in this case, the product may still circulate until the exhaustion of the stocks, no more than one year as of the withdrawal.

(4) If the holder of a parallel import authorisation declares within 30 days as of the declaration's registration that he wishes to hold the authorisation, he/she should submit to the NMA the following:

a) Data or arguments enhancing the fact that the simultaneous marketing of the parallel imported medicinal product and other similar products does not represent a public healthcare risk;

b) A leaflet into Romanian, as well as a translation into Romanian/English/ French of the leaflet from the country of export of the imported medicinal product, if it is written in another language than English or French.

(5) The NMA assesses the data and documents under (4) and decides in a 30-day term on the maintenance of the parallel import authorisation, while informing the MAH about this.

(6) If required, the NMA may require additional information from the competent authority in the country of export; in this case, the NMA informs the holder of the parallel import authorisation about the procedure's suspension ("clock-stop") until the receipt of the respective information.

(7) In case the NMA decides to withdraw the parallel import authorisation, following the assessment of the information and documentation mentioned under (4), the medicinal product may still circulate until the exhaustion of the stocks, but no more than one year as of the withdrawal.

CHAPTER VIII
Authorisations of the parallel importer

Art. 11. - (1) The applicant (parallel importer) should be the owner of a valid wholesale distribution authorisation for a medicinal product, in accordance with Art. 77 of Directive 2001/83/EC, as amended.

(2) If the parallel importer intends to bring modifications to the labelling process, outer packaging etc., he should also own a manufacturing authorisation apart from the distribution authorisation.

(3) The parallel importer should follow the Good Distribution Practice rules and, if needed, the Good Manufacturing Practice rules.

(4) The parallel importer is directly responsible for the juridical problems concerning the trademark of the parallel imported medicinal product.

CHAPTER IX
Obligations of the parallel importer

Art. 12. - (1) The parallel importer has the duty to monitor the side effects and notify the NMA about any side effect or deficiency of a medicinal product undergoing a parallel import.

(2) In case the marketing authorisation of the directly distributed original product has been recalled, the parallel importer has the duty to submit the updated periodic safety reports, in accordance with the provisions of Title XVII – The medicinal product of Law No. 95/2006 on healthcare reform, as amended.

Art. 13. – Annex 1 and 2 are integral parts of this Procedure.

ANNEX No. 1

APPLICATION
for the release by the National Medicines Agency of a parallel import authorisation

.....
1. The name under which the medicinal product is marketed in Romania: ….....
.....
2. Number of the parallel import authorisation*[1]):
…….....

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*[1]) Do not fill in. Granted by the NMA.

3. Name and address/site of the applicant:
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Name and address/site of the correspondent*[2]):
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*[2]) If different from the applicant.

4. I hereby request the release 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:

- I shall meet all legal requirements (national/community) applicable to the parallel import authorisation;
- No essential information has been willingly omitted in this application.

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

INFORMATION ON THE PARALLEL IMPORTED MEDICINAL PRODUCT

5. **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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(iii) Has the MAH been informed about the intention to import the medicinal product in Romania?

□ YES □ NO

If yes, please attach the notification evidence.

(iv) Authorisation number(s) granted in the exporting country

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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 which is 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 which is about to be parallel imported, in its original packaging.

(viii) Please mention all information you know concerning the medicinal product before it arrives to the aforementioned provider.

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Signature: Date:

Information about the medicinal product in Romania

6. Information about the marketing authorisation in force in Romania, which covers a medicinal product which the applicant considers identical/therapeutically similar to the product which is to be imported:

(i) Name of the medicinal product .....

(ii) Marketing Authorisation Number .....

(iii) Name of the MAH

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7. Is the medicinal product which is to be parallel imported anyhow different from the product covered by the marketing authorisation mentioned under point 6?

YES/NO. If "yes", please detail.

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8. If the following information about the medicinal product which you plan on importing are not compliant with the marketing authorisation for the medicinal product mentioned 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

9. Details on relabelling/repackaging:

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Attach templates of the packagings and leaflets into Romanian, which are to be used for the repackaged medicinal product.

INFORMATION ON THE MEDICINAL PRODUCT

10. Active substances:	Quantity/Therapeutic unit or %	Therapeutic unit
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.....
Overdoses and specifications shall be written as in the marketing authorisation issued in the exporting country.

Signature: Date:

11. Other constituents:
……..
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The quantities, overdoses and specifications shall be written as in the marketing authorisation issued in the exporting country.

12. Pharmaceutical form (i.e. tablet, film-coated tablet etc.):
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13. Classification according to the manner of release:
……..
14. Describe the type of container, closure system and any other administration device
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15. Packaging size(s) Unit
..... …….....
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16. Availability
(i) Sealed
(ii) After opening/reconstitution: .....
17. Special storage precautions
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18. Name and address/site of the manufacturer to be mentioned in the patient leaflet
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19. Name, address/site and authorisation number of the parallel importer's authorisation[*3]):
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[*3]) Authorisation of the wholesale distribution of medicinal products for human use.

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

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21. Units responsible for the release of the repackaged batch of the medicinal product (and/of testing, if needed):
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22. Site of the storage place:
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23. Name, address/site and number of the authorisation belonging to the distributor(s) (if needed):
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Signature: Date:

ANNEX No. 2

APPLICATION
for the variation of a parallel import authorisation

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1. Name of the medicinal product ……..
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2. Number of the parallel import authorisation
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3. Name and address/site of the holder of the parallel import authorisation
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Name and address/site of the correspondent (if different from the holder of the parallel import authorisation):
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.....
4. Grounds for variation:
…….....
5. I hereby require the modification of the aforementioned authorisation, in accordance with the following proposals, and I certify that these modifications shall not harm the product's quality/safety/efficacy:
Date: ..... Signature:
Signatory:
.....
Quality of the signatory:
.....
Tel: ..... Fax: .....
Telephone number: E-mail: .....
6. Exclusively for NMA's use (do not fill in):
Recorded:
7. Object of the variation

1. O Modification of the marketing authorisation number in the exporting country
2. O Urgent amendment to the labelling or leaflet due to safety reasons, following the written request sent by the NMA.
3. O Other
4. O Modification of the name and/or address/site of the holder of the parallel import authorisation
5. O Modification of the name and/or address/site of the MAH of the imported product
6. O Modification of the manufacturer's name
7. O Modification of the details concerning the provider
8. O Supplying with a storage site
9. O Deletion of an import site, providing, manufacture, batch release, storage

10. O Deletion of some details concerning the medicinal product (packaging size, name of the medicinal product)
11. O Modification of the marketing authorisation number and/or of the name and/or address/site of the MAH for the directly distributed original product in Romania
12. O Manufacturing site of the parallel imported medicinal product.
13. O Repackaging/batch release/storage site
14. O Modification of the medicinal product's name
15. O Modification of the description/aspect of the pharmaceutical form
16. O Modification of the packaging
17. O Modification of the packaging size
18. O Modification of the excipients
19. O Maintenance of the availability or storage conditions
20. O Others
21. O Modification of the labelling only
22. O Modification of the leaflet information

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

8. Please describe all modifications undertaken. Attach samples of the labelling, leaflets or other relevant samples, as required.

Actual text: …….....
Proposed text: ..... 9.
Exclusively for NMA's use (do not fill in):
This application for variation for the parallel import authorisation is approved.

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

Assessor,
.....