MINISTRY OF PUBLIC HEALTH

ORDER

on approval of Norms concerning the approval of export declaration for medicinal products for human use

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 set up, organisation and functioning of the National Medicines Agency, approved as amended by Law No. 594/2002, as amended,

based on Government Decision No. 862/2006 on organisation and functioning of the Ministry of Public Health, with further changes,

on seeing the Approval Report of the Pharmaceutical Sector No. E.N.8504 of 29 December 2006,

the Minister of Public Health hereby issues the following order:

Article 1. – The Norms concerning the approval of export declaration of medicinal products for human use are approved, according to the Annex which is integral part of the present order.

Article 2. – On this order coming into force, any other contrary dispositions shall be repealed.

Article 3. – The present order shall be published in the Official Gazette of Romania, Part I.

Minister of Public Health

Gheorghe Eugen Nicolăescu

Bucharest, 29 December 2006.

No. 1809.

ANNEX

Norms
on the approval of export declaration for medicinal products for human use

Article 1. – In compliance with provisions of Article 1 from the Regulations on the exportation of medicinal products for human use, approved through order of the Minister of public health No. 894/20.07.2006, concerning the enforcement of Article 846 (1) of Law No. 95/2006 on healthcare reform, as amended, at request of the manufacturer, exporter or authorities of an importing country, the National Medicines Agency approves the export declaration for medicinal product for human use.

Article 2. - (1) For every exported medicinal product, an export declaration shall be filled in, as required, in compliance with No. I, Annex 2 respectively on regulations concerning the exportation of medicinal products for human use, approved through Order of the Minister of public health No. 894/2006.

(2) For every export operation of a medicinal product, the approval of an export declaration shall be requested from the National Medicines Agency.

(3) For approval of an export declaration, the applicant submits to the National Medicines Agency an application in accordance with the format in Annex 1, accompanied by 3 original samples of each export declaration and by the following documents/information:

a) certificate attesting the Qualified Person status, issued by the National Medicines Agency (copy);

b) in case the Qualified Person is a pharmacist, evidence of membership at The Romanian Pharmacists' College (copy);

c) manufacturing authorisation (copy);

d)importation authorisation (copy) issued by the Ministry of Public Health, available for 2 years after being issued, or importation authorisation (copy) issued by the National Medicines Agency, in compliance with Title XVII – The medicinal product of Law No. 95/2006, as amended;

e) batch(es) and quantity(es) exported, for each medicinal product which received an export declaration.

Article 3 - (1) 3 days following the grant of the documentation, the National Medicines Agency – Pharmaceutical inspection Department shall check the accuracy of the information and the manner in which those have been mentioned in the export declaration, as well as the existance of complete documentation submitted as adjuvant in the export declaration, in compliance with Article 2 (3).

(2) If the submitted documentation is in line with provisions of Article 2 (3), the applicant shall be informed (in compliance with the format in Annex 2) on the value of the fee calculated for each export declaration; moreover, the Pharmaceutical inspection Department informs (in compliance with the format in Annex 4) The Economic Department of the National Medicines Agency about the tariff which must be payed by the concerned applicant in view of the export approval.

(3) If the information given in the export declaration is not real, not properly completed or not accompanied by all documents mentioned under Article 2 (3), the applicant shall be informed (in compliance with the format in Annex 3) on the necessity of renewal of declaration and/or completion of the attached documentation.

Article 4. - (1) At the moment of the confirmation of the payment submitted by the Economic Department (in compliance with the format in Annex 5), the National Medicines Agency – Pharmaceutical inspection Department approves the 3 original samples of the export declaration, via signature of the head of the Pharmaceutical inspection Department, by applying "Approved".

(2) Two original samples of each approved export declaration shall be released for the applicant.

Article 5. - All information on the exportation of medicinal products for human use contained in the export declarations approved by the National Medicines Agency are registered in the database designed and administered by the National Medicines Agency – Pharmaceutical inspection Department.

Article 6. - Annexes No. 1-5 are integral part of the present norms.

ANNEX 1

on Norms

To

NATIONAL MEDICINES AGENCY

Pharmaceutical inspection Department

Unit ....., represented by ……,

(name, surname)

please approve the export declaration(s) hereby attached.

We hereby attach to the present application the export declarations set up in accordance with Annex 1/Annex 2 on regulations concerning the exportation of medicinal products for human use, approved through order of Minister of public health No. 894/2006, completed with required information and requested documents in accordance with Article 2 (3) of the Norms on approval of export declaration of medicinal products for human use, approved through Minister of public health order No. 1809/2006.

We attach below the batch(es) and amount(s) exported (measured in commercial unities), for each medicinal product referred to in the export declaration.

……
……
……

Signature, stamp

…….

ANNEX 2
on Norms

MINISTRY OF PUBLIC HEALTH
NATIONAL MEDICINES AGENCY

011478 Bucharest, 48, Aviator Sănătescu street,
sector 1

Tel. 317.11.02; Fax No.: 316.34.97

To,

……

We hereby inform you that, following study of the dossier submitted to the National Medicines Agency, your application for endorsement of the export declaration(s) has been approved.

We hereby solicit payment of endorsement of the export declaration(s) submitted to the National Medicines Agency, summing up ……., in accord with order of the Minister of public health No. 876/2006.

After having confirmed the encashment of the fee, you shall receive two original copies of each export declaration, approved by the National Medicines Agency – Pharmaceutical inspection Department.

President, **Head of the**

Pharmaceutical inspection Department,

....

ANNEX 3
on Norms

MINISTRY OF PUBLIC HEALTH
NATIONAL MEDICINES AGENCY

011478 Bucharest, 48, Aviator Sănătescu street,
sector 1

Tel. 317.11.02; Fax No.: 316.34.97

To,

……

We hereby inform you that, in view of the notice of the export declaration(s) submitted to the National Medicines Agency, it is mandatory to rewrite/fill in the following documents, attached to your application, then to forward them to:

.....
.....

The submitted documents shall grant the necessary information in view of the export declaration(s), you shall receive an affirmative answer and we shall inform you of the fee which must be paid at the Economic Department of the National Medicines Agency, in accord with Minister of Public Health Order No. 876/2006.

President, **Head of the**

Pharmaceutical inspection Department,

..... ……

ANNEX 4

to Norms

PHARMACEUTICAL INSPECTION DEPARTMENT

To

The Economic Department

We hereby inform you that, in view of approval of export declaration(s) for the following product(s): ……....., unit .....,

(name, address)

must pay the fee consisting of ....., in accord with Minister of Public Health Order No. 876/2006.

Head of the Pharmaceutical inspection Department,

.....

ANNEX 5

to Norms

ECONOMIC DEPARTMENT

To

The Pharmaceutical inspection Department

We hereby inform you that, in view of the notice of export declaration(s) for the following product(s):

.....

……

……,

submitted by .....,

we have received ……, under statement of account …….. .

The fee has been paid in full, according to your notification No. ……. .

Head of the Economic Department, **Elaborated by,**

…… ……