MINISTRY OF HEALTH

O R D E R
on amendment of the Annex to Order of the Minister of Public Health no. 894/2006 on approval of Regulations regarding export of medicinal products for human use

On seeing the Approval report no. Cs.A. 12.386 of 24 November 2010 of the Medicinal Product Policy Directorate, taking into account:

- provisions of Title XVII - "The medicinal product" of Law no. 95/2006 on healthcare reform, as amended;
- Government Decision 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 operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. I. – The Annex to Order of the Minister of Public Health no. 894/2006 on approval of Regulations regarding export of medicinal products for human use, published in the Official Gazette of Romania, Part I, no. 656 of 28 July 2006, is amended and replaced with the Annex 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. 1.447.

ANNEX
(Annex to Order no. 894/2006)

REGULATIONS
on export of medicinal products for human use

Art. 1. – In accordance with Art. 846 (1) of Title XVII "The medicinal product" of Law 95/2006 on healthcare reform, as amended, the National Agency for Medicines and Medical Devices, on request of the manufacturer, importer, exporter, wholesale distributor or authorities of an importing country, certifies that a medicinal product manufacturer/importer/wholesale distributor holds a valid manufacturing authorisation, through approval of the export declaration set up by the applicant in accordance with Annex I.

Art. 2. – On request of the manufacturer, the National Agency for Medicines and Medical Devices issues the certificate of the medicinal product in the format recommended by the World Health Organisation, set up according to Annexes IIa) and IIb).

Art. 3. - Annexes I, IIa) and IIb) are integral parts of these Regulations.

ANNEX I
to Regulations

The declaration bears the letter head of the exporting unit

DECLARAŢIE DE EXPORT

EXPORT STATEMENT

(Articles 748 and 823 (4) of Law no. 95/2006 on healthcare reform, Title XVII, "The medicinal product", as amended)

destinată
intended for
……..

Subsemnatul, ..., persoană calificată/persoană responsabilă cu calitatea*) la societatea ....., care deţine Autorizaţia de fabricaţie/import/autorizaţia de distribuţie angro nr. ....., emisă în data de ..... (anexată prezentei), declar următoarele:
I the undersigned ....., Qualified Person/Responsible Person of the Pharmaceutical company ....., holding the Manufacturing/Import Authorisation/Wholesaling Distribution Authorisation no. ..... dated ..... (see attached authorisation) certify the following:

Numele medicamentului, concentraţia, forma farmaceutică, ambalajul:
Name of the medicinal product, dosage strength, pharmaceutical form, packaging:

Compoziţia:
Formula:

Statutul medicamentului în ţara importatoare:
Status of the medicinal product in the importing country:

înregistrat:
registered:
alt caz (se va preciza):

other (to be specified):

Statutul medicamentului în alte ţări:
Status of the medicinal product in other countries:

Locul de fabricaţie:
Manufacturing pharmaceutical site:

deţinător al Certificatului BPF anexat prezentei (nume şi adresă):
holder of the attached certificate of GMP (name and address):
alt caz (se va preciza):
other (to be specified):

Declar motivele pentru care autorizaţia de punere pe piaţă nu este disponibilă în România:
I state the reasons why the marketing authorisation is not available in Romania:
Declar că informaţiile chimice, farmaceutice, biologice (în special metodele de fabricaţie şi de control) şi cele clinice permit garantarea calităţii medicamentului şi evaluarea riscurilor legate de utilizarea acestuia.
I declare that the chemical, pharmaceutical, biological information (especially the methods of manufacturing and control) and the clinical data allow to guarantee the quality of the product and to assess the risks linked to its use.
Declar că orice modificare privind declaraţia de export va face obiectul unei declaraţii de export suplimentare care se va depune la Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale.
I declare that any modification regarding the export statement will be submitted to an additional export statement at the National Medicines and Medical Devices Agency.
Persoana calificată/Persoana responsabilă*The Qualified Person/The Responsible Person*

Data
Date

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*) Pharmacists shall provide proof of their membership to the College of Pharmacists in Romania.

ANNEX IIa)
to Regulations

(Letterhead of the National Agency for Medicines and Medical Devices)

CERTIFICATE OF A MEDICINAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization.

No. of Certificate: ....
Exporting (certifying) country: ROMANIA
Importing (requesting) country: .....
1. Name, dosage form and strength of the product:
.....
1.1. Active ingredient (s) and amount (s) per unit dose:

1.2. Is this product authorised to be placed on the market for use in the exporting country?
(Please check the right answer.)

Yes No

1.3. Is this product actually on the market in the exporting country?
(Please check the right answer.)

Yes No
If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B.

2.A.1. Marketing Authorisation number and issuing date:

2.A.2. Marketing Authorisation Holder (name and address)
Name: .....
Address: .....
2.A.3. Status of the Marketing Authorisation Holder:

a b c

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is:

2.A.4. Is a summary basis for approval appended?
(Please check the right answer.)

Yes No

2.A.5. Is the attached, officially approved product information complete and consonent with the marketing authorisation?

(Please check the right answer.)

Yes No

The applicant assumes the whole responsibility for the accuracy of the translation of the text from Romanian into English.

2.A.6. Applicant for certificate, if different from the Marketing Authorisation Holder (name and address):

.....
2.B.1. Applicant for certificate (name and address):
.....

2.B.2. Status of applicant:
(Please check the right category.)

a b c

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:

2.B.3. Why is marketing authorisation lacking?
(Please check the right answer.)

Not Required Not Requested Under Consideration Refused

2.B.4. Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
(Please check the right answer.)

Yes No Not provided

3.1. Periodicity of routine inspections (years): .....

3.2. Has the manufacture of this type of dosage form been inspected?

(Please check the right answer.)

Yes No

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?
(Please check the right answer.)

Yes No Not provided

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?

(Please check the right answer.)

Yes No

Address of certifying authority, the National Agency for Medicines and Medical Devices from Romania

Telephone Number:
Fax Number:
Name of authorised person:
Signature:
Stamp and date:
Complete composition:

ANNEX IIb)
to Regulations

(Letterhead of the National Agency for Medicines and Medical Devices)

CERTIFICATE OF A MEDICINAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization

No. of Certificate: ....
Exporting (certifying) country: ROMANIA
Importing (requesting) country: .....

1. Name, dosage form and strength of the product:
.....
1.1. Active ingredient (s) and amount (s) per unit dose:

1.2. Is this product authorised to be placed on the market for use in the exporting country?
Yes No

1.3. Is this product actually on the market in the exporting country?
Yes No

If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B.

2.A.1. Marketing Authorisation number:
Date of Marketing Authorisation:

2.A.2. Marketing Authorisation Holder (name and address):
Name:
Address:

2.A.3. Status of the Marketing Authorisation Holder:
a b c

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is:

2.A.4. Is a summary basis for approval appended?
Yes No

2.A.5. Is the attached, officially approved product information complete and consonent with the marketing authorisation?
Yes Not Provided

The applicant assumes the whole responsibility for the accuracy of the translation of the text from Romanian into English.
2.A.6. Applicant for certificate, if different from Marketing Authorisation Holder (name and address):

2.B.1. Applicant for certificate (name and address):

2.B.2. Status of applicant:
a b c

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:

2.B.3. Why is marketing authorisation lacking?
Not Required Not Requested Under Consideration Refused

2.B.4. Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes No Not Applicable

3.1. Periodicity of routine inspections (years): .....
3.2. Has the manufacture of this type of dosage form been inspected?
Yes No

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?
Yes No Not Applicable

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
Yes No

Address of certifying authority NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES from ROMANIA

Telephone Number:
Fax Number:
Name of authorised person:
Signature:
Stamp and date:
Complete composition
.....