DECISION

No. 13/26.06.2009

on approval of amendment of Regulations on the exportation of medicinal products for human use, approved through SCD No. 16/2006

The Scientific Council of the National Medicines Agency, set up based on Order of the minister of public health No. 1027/22.05.2008, reunited on summons of the National Medicines Agency President in the ordinary meeting of 26.06.2009 in accordance with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and operation of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, adopts the following

DECISION

Art. 1. – The amendment of the Regulations relating to the exportation of medicinal products for human use is approved, in accordance with the Annex which is integral part of this Decision.

Art. 2. – This Decision is to be approved through Order of the Minister of Health and shall be published in the Official Gazette of Romania, Part I.

Art. 3. – On the date of this Decision coming into force, NMA Scientific Council No. 16/31.03.2006 is amended.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,

Acad. Prof. Dr. Victor Voicu

ANNEX
(Annex to Order No. 894/2006)

REGULATIONS
on the exportation of medicinal products for human use

Art. 1. – In accordance with Art. 846 (1) of Title XVII "The medicinal product" of Law No. 95/2006 on healthcare reform, as amended, the National Agency for Medicines and Medical Devices, on request by the manufacturer, importer, exporter, wholesale distributor or authorities in an importing country, shall certify tenure by a manufacturer/importer/wholesale distributor of medicinal products of a manufacturing/import authorisation or a valid wholesale distribution authorisation, by approval of the export statement submitted by the applicant in accordance with Annex No. I.

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

Art. 3. – Annexes No. I, IIa) and IIb) are integral part of these Regulations.

ANNEX I
to Regulations

The statement shall bear the header 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/Quality Responsible Person of the Pharmaceutical company ....., holder of Manufacturing/Import Authorisation/Wholesale Distribution Authorisation no. ..... dated ..... (see attached authorisation), hereby declare the following:

Numele medicamentului, concentraţia, forma farmaceutică, ambalajul:
Name of the medicinal product, 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 site:

deţinător al Certificatului BPF anexat prezentei (nume şi adresă):
holder of the attached GMP certificate (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 hereby state the reasons for marketing authorisation unavailability 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 (particularly the manufacturing and control methods) and the clinical data allow guaranteed quality of the product and assessment of risks related 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 Dispozitivelor Medicale.

I declare that any change regarding the export statement will be submitted to the National Medicines and Medical Devices Agency as an additional export statement.
Persoana calificată/Persoana responsabilă
Qualified Person/Responsible Person

Data
Date

---
*) Pharmacists should provide proof of membership in the Romanian College of Pharmacists.

ANNEX IIa)
to Regulations

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

MEDICINAL PRODUCT CERTIFICATE

This certificate is issued in accordance with the WHO recommended format.

Certificate No.: .....
Exporting country (country releasing the certificate): ROMANIA
Importing country (country requiring the certificate):
1. Name, pharmaceutical form and strength of the medicinal product:
.....
1.1. Active substance(s) and quantity(ies) per unit dose:

1.2. Is this product authorised for marketing in the exporting country?
(Check the appropriate answer.)

Yes No
1.3. Is this product represented on the market in the exporting country?
(Check the appropriate answer.)

Yes No

If the answer to 1.2 is "Yes", please proceed to section 2A and omit section 2B. If the answer to section 1.2 is "No", omit section 2A and proceed to section 2B.

2.A.1. Marketing authorisation number of the product and date of issue:
2.A.2. Marketing authorisation holder of the product (name and address):
Name: .....
Address: .....
2.A.3. Status of the marketing authorisation holder:

a b c

2.A.3.1. For b and c, the name and address of the manufacturer of the respective pharmaceutical form is
.....

2.A.4. Is there any summary attached which led to the approval?
(Check the appropriate answer)

Yes No
2.A.5. Is full, officially approved, marketing authorisation compliant information on the product available?
(Check the appropriate answer)

Yes No

The applicant assumes full responsibility for the accuracy of the text's translation from Romanian into English.

2.A.6. The certificate's applicant, if different from the marketing authorisation holder (name and address)
.....
2.B.1. The certificate's applicant (name and address)
.....

2.B.2. Applicant's status
(Check the appropriate answer)

a b c

2.B.2.1. For b and c, the name and address of the manufacturer of the given pharmaceutical form is

2.B.3. Why isn't there a marketing authorisation?
(Check the appropriate answer)

Not necessary Not required Undergoing assessment Rejected

2.B.4. Observations:

3. Does the authority issuing the certificates perform periodic inspections at the manufacturing site of the given pharmaceutical form?
(Check the appropriate answer)

Yes No

3.1. Periodicity of routine inspections (in years):

3.2. Was the manufacturing process of such pharmaceutical form inspected?
(Check the appropriate answer)

Yes No

3.3. Are facilities and operations compliant with GMP rules, as recommended by the Minister of Health Order?
(Check the appropriate answer)

Yes No Not required

4. Does the information sent by the applicant satisfy the authority releasing the certificate, as regards all product-related issues?
(Check the appropriate answer)

Yes No

Address of the authority issuing the certificate, The National Agency for Medicines and Medical Devices

Telephone number:
Fax number:
Authorised person:
Signature:
Stamp and date:
Complete formula (composition) of the pharmaceutical form:

ANNEX II b)
to Regulations

(LETTERHEAD OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES)

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organisation
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 licensed 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. Product licence holder (name and address):
Name:
Address:
2.A.3. Status of product licence 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 consonant with the licence?
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 licence 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 Organisation?
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
.....