THE MINISTER OF PUBLIC HEALTH

ORDER
on approval of Regulations regarding export of medicinal products for human use

Taking into account provisions of Title XVII, The medicinal product of Law no. 95/2006 on healthcare reform and of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law no. 594/2002, with further changes and completions,

on seeing Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 2.274 din 20 July 2006,

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

the minister of public health hereby issues the following order:

Article 1. - Approval of Regulations regarding export of medicinal products for human use, provided in the Annex which is integral part of this order.

Article 2. - The present order shall come into force 28 July 2006, at which date all contrary provisions shall be repealed.

Article 3. - The present order is to be published in the Official Gazette of Romania, Part I.

The minister of public health,
Gheorghe Eugen Nicolăescu

Bucharest, 20 July 2006.
No. 894.

ANNEX

REGLEMENTĂRI
on export of medicinal products for human use

Article 1.- On request of the manufacturer, Exporter or Authorities of an importing country, the National Medicines Agency, certifies that a medicinal product manufacturer holds a valid manufacturing authorisation, through approval of the export declaration set up by the Applicant according to Annex No. I and II to these Regulations.

Article 2.- On request of a authorised manufacturer of medicinal products and/or raw materials used in medicinal product manufacturing, the National Medicines Agency may grant the good manufacturing practice compliance certificate, set up according to Annex No. III to these Regulations.

Article 3.- On request of a medicinal product manufacturer, the National Medicines Agency grants the medicinal product certificate, set up in compliance with the format recommended by the World Health Organisation, according to Annex No. IV to these Regulations.

Article 4.- Annexes No. I, II, III and IV are integral part of these Regulations

ANNEX No. 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)

destinată
intended for
.....

Subsemnatul ....., Persoana calificată*) la societatea ....., care deţine Autorizaţia de fabricaţie/import nr. ..... emisă în data de ..... (anexată prezentei), declar următoarele:

I the undersigned ....., Qualified Person Responsible of the Pharmaceutical company ....., holding the manufacturing licence no. ..... dated ..... (see attached licence) 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):

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

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 declaratia de export va face obiectul unei declaraţii de export suplimentare care se va depune la Agenţia Naţională a Medicamentului.
I declare that any modification regarding the export statement will be submitted to an additional export statement at the National Medicines Agency.

Persoana calificată
The Qualified Person

Data
Date

ANNEX No. II
to Regulations

The declaration bears the letterhead of the exporting unit

DECLARAŢIE DE EXPORT SUPLIMENTARĂ
ADDITIONAL EXPORT STATEMENT
(Articles 748 and 823 (4) of Law no. 95/2006 on healthcare reform, Title XVII, The medicinal product)

LA DECLARAŢIA DE EXPORT VIZATĂ ÎN DATA DE
TO THE EXPORT STATEMENT DATED
destinată
intended for
.....

Subsemnatul ....., Persoana calificată*) la societatea ....., care deţine Autorizaţia de fabricaţie/import nr. ..... emisă în data de ..... (anexată prezentei), declar următoarele:

I the undersigned ....., Qualified Person Responsible of the Pharmaceutical company....., holding the manufacturing licence no. ..... dated ..... (see attached licence) certify the following:

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

Următoarele rubrici au fost modificate de la Declaraţia mea de export vizată de Agenţia Naţională a Medicamentului:
The following items of the export statement have been changed since my export statement signed by the National Medicines Agency on as follows:

Declar că celelalte rubrici ale declaraţiei de export rămân neschimbate.
I certify that the other items of the export statement are unchanged.

Persoana calificată
The Qualified Person
Data
Date

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

ANNEX No. III a)
to Regulations

(LETTERHEAD OF NATIONAL MEDICINES AGENCY)

Certificate No:____/____/__

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Article 823(5) of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product or Article 55, 56, 57 of Minister of Public Health Order*) for approval of Regulations relating to the implementation of Good clinical practice in the conduct of clinical trials on medicinal products of human use

The competent authority NATIONAL MEDICINES AGENCY OF ROMANIA confirms the following:
The manufacturer .....
Site address .....
……
…

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ..... in accordance with Article 40 of Directive 2001/83/EC/Article 44 of Directive 2001/82/EC/Article 13 of Directive 2001/20/EC*) transposed in the following national legislation: Law No. 95/2006 regarding the reform in the field of health, Title XVII, Medicinal product/Minister of Public Health Order* for approval of Regulations relating the implementation of Good clinical practice in the conduct of clinical trials on medicinal products of human use*

*or**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Article 111(4) of Directive 2001/83/EC transposed in the following national legislation: Law No. 95/2006 regarding the reform in the field of health, Title XVII, Medicinal product

*and/or**

Is an active substance manufacturer that has been inspected in accordance with Article 111(1) of Directive 2001/83/EC transposed in the following national legislation: Law No. 95/2006 regarding the reform in the field of health, Title XVII, Medicinal product

*or**

Other (please specify): ……

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ...../...../..... [date], it is considered that it complies with the Good Manufacturing Practice requirements[1] referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1]/The principles of GMP for active substances[1].*

[1]These requirements fulfil the GMP recommendations of WHO.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

Part 2

□ Human Medicinal Products* □ Human Investigational Medicinal Products* for phase I, II, III clinical trials*
1. MANUFACTURING OPERATIONS* - authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary; - quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items; - if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.

1.1	**Sterile Products**
	1.1.1. Aseptically prepared (list of dosage forms) 1.1.1.1. Large volume liquids 1.1.1.2. Lyophilisates 1.1.1.3. Semi-solids 1.1.1.4. Small volume liquids 1.1.1.5. Solids and implants 1.1.1.6. Other aseptically prepared products <free text>
	1.1.2. Terminally sterilised (list of dosage forms) 1.1.2.1. Large volume liquids

	1.1.2.2. Semi-solids 1.1.2.3. Small volume liquids 1.1.2.4. Solids and implants 1.1.2.5. Other terminally sterilised prepared products <free text>
	1.1.3. Batch certification only
1.2	**Non-sterile products**
	1.2.1. Non-sterile products (list of dosage forms) 1.2.1.1. Capsules, hard shell 1.2.1.2. Capsules, soft shell 1.2.1.3. Chewing gums 1.2.1.4. Impregnated matrices 1.2.1.5. Liquids for external use 1.2.1.6. Liquids for internal use 1.2.1.7. Medicinal gases 1.2.1.8. Other solid dosage forms 1.2.1.9. Pressurised preparations 1.2.1.10. Radionuclide generators 1.2.1.11. Semi-solids 1.2.1.12. Suppositories 1.2.1.13. Tablets 1.2.1.14. Transdermal patches 1.2.1.15. Other non-sterile medicinal product <free text>
	1.2.2. Batch certification only
1.3	**Biological medicinal products**
	1.3.1. Biological medicinal products 1.3.1.1. Blood products 1.3.1.2. Immunological products 1.3.1.3. Cell therapy products 1.3.1.4. Gene therapy products 1.3.1.5. Biotechnology products 1.3.1.6. Human or animal extracted products 1.3.1.7. Other biological medicinal products <free text>
	1.3.2. Batch certification only (list of product types) 1.3.2.1. Blood products 1.3.2.2. Immunological products 1.3.2.3. Cell therapy products 1.3.2.4. Gene therapy products 1.3.2.5. Biotechnology products 1.3.2.6. Human or animal extracted products 1.3.2.7. Other biological medicinal products <free text>
1.4	**Other products or manufacturing activity** (any other relevant manufacturing activity/product type that is not covered above e.g.

	sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing etc.).
	1.4.1. Manufacture of: 1.4.1.1. Herbal products 1.4.1.2. Homoeopathic products 1.4.1.3. Biological active starting materials 1.4.1.4. Other <free text> *1.4.2.* Sterilisation *of active substances/excipients/finished product*: 1.4.2.1. Filtration 1.4.2.2. Dry heat 1.4.2.3. Moist heat 1.4.2.4. Chemical 1.4.2.5. Gamma irradiation 1.4.2.6. Electron beam *1.4.3. Others <free text>*
1.5	**Packaging only**
	1.5.1. Primary packing 1.5.1.1. Capsules, hard shell 1.5.1.2. Capsules, soft shell 1.5.1.3. Chewing gums 1.5.1.4. Impregnated matrices 1.5.1.5. Liquids for external use 1.5.1.6. Liquids for internal use 1.5.1.7. Medicinal gases 1.5.1.8. Other solid dosage forms 1.5.1.9. Pressurised preparations 1.5.1.10. Radionuclide generators 1.5.1.11. Semi-solids 1.5.1.12. Suppositories 1.5.1.13. Tablets 1.5.1.14. Transdermal patches 1.5.1.15. Other non-sterile medicinal products <free text>
	1.5.2. Secondary packing
1.6	**Quality control testing**
	1.6.1. Microbiological: sterility 1.6.2. Microbiological: non-sterility 1.6.3. Chemical/Physical 1.6.4. Biological
2. IMPORTATION OF MEDICINAL PRODUCTS*) . - importation activities without manufacturing activity	

. - importation activities include storage and distribution unless informed to the contrary	
2.1	**Quality control testing of imported medicinal products**
	2.1.1. Microbiological: sterility 2.1.2. Microbiological: non-sterility 2.1.3. Chemical/Physical 2.1.4. Biological
2.2	**Batch certification of imported medicinal products**
	2.2.1. Sterile Products 2.2.1.1. Aseptically prepared 2.2.1.2. Terminally sterilised *2.2.2. Non-sterile products*
	2.2.3. Biological medicinal products 2.2.3.1. Blood products 2.2.3.2. Immunological products 2.2.3.3. Cell therapy products 2.2.3.4. Gene therapy products 2.2.3.5. Biotechnology products 2.2.3.6. Human or animal extracted products 2.2.3.7. Other biological medicinal products <free text >
	2.2.4. *Other importation activities* (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products etc.) 2.2.4.1. Radiopharmaceuticals 2.2.4.2. Medicinal gases 2.2.4.3. Herbal products 2.2.4.4. Homoeopathic products 2.2.4.5. Biological active starting materials 2.2.4.6. Other <free text>

Manufacture of active substance. Names of substances subject to inspection*:
.....
.....
Any restrictions or clarifying remarks related to the scope of this certificate*:
.....
.....
.....

...../...../..... [*date*] Name and signature of the authorised person of the National Medicines Agency from Romania[2]
.....
..

[*name, title, national authority, phone & fax numbers*]

(*): delete that which does not apply.

[2] The signature, date and contact details should appear on each page of the certificate.

ANNEX No. IV b)
to Regulations

(LETTERHEAD OF NATIONAL MEDICINES AGENCY)

CERTIFICATE OF A PHARMACEUTICAL 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 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 according 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 MEDICINES AGENCY from ROMANIA

Telephone Number:

Fax Number:

Name of authorised person:

Signature:

Stamp and date:

Complete composition