MINISTRY OF PUBLIC HEALTH

ORDER
for approval of Regulations regarding the National Medicines Agency attestation of the qualified person of the Manufacturing/Importation Marketing Authorisation Holder

Taking into account provisions of Title XVII - The medicinal product of Law No. 95/2006 on healthcare reform, as amended, and of the Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended ,

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

on seeing the Approval Report of the Pharmaceutical Directorate No. EN 4708/2006,

the Minister of public health hereby issues the following order:

Article 1. – Regulations relating to the National Medicines Agency attestation of the qualified person of the Manufacturing/Importation Authorisation Holder, in accordance with the Annex which is integral part of this order, are approved.

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 - On this order coming into force, any other contrary dispositions shall be repealed.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, 2 October 2006.
No. 1200.

ANNEX

REGULATIONS
relating to the National Medicines Agency attestation of the qualified person of the Manufacturing/Importation Marketing Authorisation Holder

Article 1. – (1) In accordance with provisions of Article 757 (1) of Title XVII, The medicinal product of Law 95/2006 on healthcare reform, as amended, the Manufacturing/Importation Authorisation Holder shall permanently and continuously have at his disposal the services of at least one qualified person.

(2) The qualified person must meet the qualification and experience set out in Article 758 (2) - (8) of Law No. 95/2006, as amended.

Article 2. – Evidence that the qualified person meets the qualification and experience demands mentioned in Article 1 (2) consists of the certificate granted by the National Medicines Agency attesting to qualified person status.

Article 3. – Concerning grant of this document, the applicant submits to the National Medicines Agency an application in compliance with the form provided in Annex 1, accompanied by authenticated copies of documents mentioned in Article 758 (2) of Law No. 95/2006, as amended, such as:

a) formal qualifications awarded on completion of a university course of study university degree in theoretical and practical university studies extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, chemistry, medicine, biology; diploma or an equivalent document certifying graduation of practical and theoretical studies extending over a period of at least 3 and a half years in the pharmaceutical field, accompanied by proof of a theoretical and practical training period of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public; diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent in Romania, extending over a period of at least 3 years, which includes theoretical and practical studies bearing upon at least the following basic subjects: experimental physics, general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry (including the medicinal product analysis), general and applied (medical) biochemistry, physiology, microbiology, pharmacology, pharmaceutical technology, toxicology, pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin);

b) school transcript for each year of study, certifying graduation in the main fields as mentioned in Article 758 (5) of Law No. 95/2006, as amended;

c) employment record or an equivalent document as proof of at least 2 years practical experience in an authorised medicinal products manufacturing unit, in quantitative analysis of medicinal products and active substance quantitative analysis, as well as other tests and verifications needed for insurance of medicinal product quality; practical experience duration may be one year in case of at least 5 year university studies and 6 months in case of at least 6 year university studies;

d) any other documents relating to an ongoing professional education in the field of Good Manufacturing Practice rules, manufacturing and check-up of medicinal products.

Article 4. – (1) In case the documentation submitted by the applicant is compliant with Article 3 requirements, in 5 days as of application registration date, the applicant shall be informed on its actual approval, as well as of National Medicines Agency fees for application submission (according to the form in Annex 2).

(2) In case the documentation submitted by the applicant does not meet the Article 3 requirements, in 5 days as of application submission, he shall be informed of the rejection, the documents attached to the application being returned.

(3) 5 days as of confirmation of encashment of the tariff due to grant of the certificate, the National Medicines Agency issues the qualified person certificate, as shown in the form in Annex 3, in two original copies, one to be handed to the applicant, and the other to be retained by the NMA Pharmaceutical Inspection Department.

Article 5. – Any subsequent modification of data grounding grant of the qualified person certificate shall be notified to the National Medicines Agency on submission of accompanying support documentation.

Article 6. – Within two months at most as of Law No. 95/2006 coming into force, Good Manufacturing Practice Certificate Holders have the duty of submitting to the National Medicines Agency the application accompanied by documents requested under Article 3, allowing for grant of the qualified person certificate.

Article 7. – Loss of the qualified person certificate incurs annulment thereof and grant of a new certificate is done based on the following documents:

a) Application submitted according to the format as shown in Annex 4;

b) Proof of loss publication in a widely circulated daily newspaper;

c) Affidavit that no changes have been made to data allowing for initial certification.

Article 8. – In accordance with Article 760 (1) – (3) of Law No. 95/2006, as amended, the NMA rules suspension of the certificate granted to a qualified person on grounds of non-fulfilment of duties, on start of the administrative or disciplinary procedures against it due to the non-fulfilment of duties.

Article 9. – The NMA sets up and periodically updates the data base relating to the attestation of qualified persons.

Article 10. – Annexes 1-4 are integral part of the present regulations.

ANNEX 1
on Regulations

To
NATIONAL MEDICINES AGENCY
Pharmaceutical inspection department

I, the undersigned.....,
(name and surname)
employee of the unit …......, hereby apply for grant of a certificate which attests my qualified person status.

I hereby attach to the present application the requested dossier in accord with Article 3 of Order of the Minister of public health No.1200/2006 for approval of Regulations on the National Medicines Agency attestation of the qualified person of the Manufacturing/Importation Authorisation Holder, namely: .....

Signature, stamp

ANNEX 2
on Regulations

MINISTRY OF PUBLIC HEALTH
NATIONAL MEDICINES AGENCY
011478 Bucharest, 48,
Aviator Sănătescu street, sector 1
Phone: 317.11.02; Fax: 316.34.97

To,

……

We hereby inform you that, following study of the documents submitted to the National Medicines Agency, your application in view of release of a certificate attesting the qualified person status has been approved.

Please pay within 10 working days the tariff due for grant of this document, summing up ……., in compliance with order of Minister of public health No. 1200/2006 on the approval of Regulations related to the NMA certification of the qualified person of the Manufacturing/Importation Authorisation Holder.

The document shall be submitted within 5 days as of confirmation of the encashment of the fee.

President, ...

Head of the Pharmaceutical Inspection Department, ...

ANNEX 3
on Regulations

MINISTRY OF PUBLIC HEALTH
NATIONAL MEDICINES AGENCY
011478 Bucharest, 48,
Aviator Sănătescu street, sector 1
Phone: 317.11.02; Fax: 316.34.97

CERTIFICATE
which attests the qualified person status

The present certificate attests that Mr./Mrs. ....., position ....., meets the conditions of Title XVII - The medicinal product of Law No. 95/2006 on healthcare reform, as amended, on the following of the qualified person status in Manufacturing/Importation units of medicinal products for human use.

Emission date .....

President,
.....
Signature, stamp

ANNEX 4
on regulations

To
THE NATIONAL MEDICINES AGENCY
Pharmaceutical inspection department

I, the undersigned .....……..…….....,
representative of .....,
established in....., address ……., telephone number/fax number ……., registered in the Register of Commerce under No. ….....……, fiscal code ….....…, in accord with Article 7 from the Order of the Minister of public health No. 1200/2006 for approval of Regulations concerning the National Medicines Agency attestation of the qualified person of the Manufacturing/Importation Authorisation Holder, hereby apply for grant of a new certificate which attests the qualified person status.

I hereby attach to the present application the proof of notification on qualified person certificate in the daily paper ……..... .

.....
Signature, stamp