MINISTRY OF PUBLIC HEALTH

ORDER

on approval of the Norms on the set up, organisation and functioning of wholesale distribution units of medicinal products for human use

Taking into account the dispositions of Title XVII – "The medicinal product" of Law No. 95/2006 on healthcare reform, approved with changes and completions,

on seeing approval report of the Pharmaceutical Directorate of the Ministry of Public Health,

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

the Minister of Public Health hereby issues the following order:

Art. 1. - The Norms on the set up, organisation and functioning of wholesale distribution units of medicinal products for human use, mentioned in the Annex which is integral part of this Order.

Art. 2. - (1) On the date of the coming into force of this Order, Minister of Public Health Order No. 893/2006 on approval of the Norms on the authorisation of the wholesale distribution of medicinal products, published in the Official Gazette of Romania, Part I, No. 665 of 28 July 2006, as amended.

(2) The dossiers submitted to the Ministry of Public Health No. 893/2006, as amended, going through the authorisation procedure, shall be finalised by this institution.

Art. 3. - The present order is carried out by the National Medicines Agency and is to be published in the Official Gazette of Romania, Part I.

Minister of Public Health,

Gheorghe Eugen Nicolăescu

Bucharest, 2 December 2008.
No. 1.964.

ANNEX

NORMS
on the set up, organisation and functioning of wholesale distribution units of medicinal products for human use

CHAPTER I
Definitions

Art. 1. – In accordance with the legislation in force, the terms and notions used have the following meanings:

a) *wholesale distributor of medicinal products* – juridical person established in the European Economic Area (EEA), who carries out, in accordance with the legal dispositions, acquirement activities, delivery or export of medicinal products for human use, the way they are defined in Title XVII "The medicinal product" of Law No. 95/2006 on healthcare reform, as amended, cu except for their release to the public;

b) *senior pharmacist of a wholesale distribution unit of medicinal products* – the pharmacist responsible for the sum of technical and administrative activities carried out by this unit, who represents it toward the professional authorities – The Ministry of Public Health and other institutions subordinated to or coordinated by it.

c) *counterfeit medicinal product* – the medicinal product having a false image of its representation - name, composition, strength or other elements -, of its history, source - manufacturer, manufacturing country, country of origin, marketing authorisation holder -, done in a deliberate, fraudulent manner;

d) *person responsible for the medicinal product quality* – person in the organisational structure of the wholesale distributor, meeting the requirements mentioned under Art. 5, further called "delegated person";

e) *wholesale distribution unit* – the area where a wholesale distributor of medicinal products carries out one or several activities mentioned under a) and which may be:

- *central wholesale distribution unit* – the wholesale distribution unit of medicinal products where the wholesale distributor coordinates from the logistic and administrative point of view those activities for which he is authorised, including those belonging to the wholesale working points.

- *wholesale distribution working point* – wholesale distribution unit of medicinal products, carrying out locally the wholesale distribution activities for which it is authorised;

f) *traceability* – the ability to restore the history, localisation and use of a medicinal product on the market, with the help of a record;

g) *healthcare products* – products other than medicinal products, mentioned on the Product List, other than medicinal products, which may be owned and released via pharmacies, approved through a Minister of Public Health Order;

h) *critical deficiencies*:

- deficiencies which may engender or lead to the occurrence of an important risk during the distribution process of a medicinal product, which could be harmful for the population; or

- a combination of deficiencies classified as "major", none of them being "critical", but which put up together may lead to a critical deficiency, which should be ex; a sum of deficiencies classified as "major", none of them actually being "critical"

i) *major deficiencies*:

- deficiencies which can affect the product's quality, but not critically; or

- a combination of deficiencies classified as "other deficiencies", from which none can be classified as "major", but which out up together may lead to a major deficiency which should be explained and reported accordingly;

j) *other deficiencies* – deficiencies which cannot be classified as critical or major, but which indicate a transgression from the good wholesale distribution practice. A deficiency may be classified as "other deficiencies" either because it is considered "minor", or because there are no sufficient information to classify it as critical or major.

CHAPTER II
Wholesale distribution of medicinal products

Art. 2. - (1) In accordance with Art. 788 (1) of Law no. 95/2006, as amended, the applicants should own a wholesale distribution authorisation issued by the EEA in order to be able to distribute wholesale medicinal product.

(2) In Romania, the wholesale distribution authorisation is issued by the National Medicines Agency (NMA), in accordance with provisions of Title XVII – "The medicinal product" of Law No. 95/2006, as amended.

(3) The wholesale distribution authorisation is necessary for each wholesale operator within the distribution chain, including intermediate agents and merchants, who carry out activities with medicinal products for human use, such as:

- sales transactions and procurement;
- wholesale distribution;
- storage and manipulation, including delivery;
- export.

Art. 3. - (1) The wholesale distributors of medicinal products only distribute medicinal products for human use which are authorised for marketing, in accordance with the law.

(2) Through exception from the provisions of (1), wholesale distributors may distribute medicinal products lacking marketing authorisation in those situations mentioned under Art. 699 (1) and (2) of Law No. 95/2006, as amended, based on the express approval of the Ministry of Public Health (*MPH*).

(3) Through exception from the provisions of (1), wholesale distributors may also distribute medicinal products for clinical investigation to the clinical units, which the NMA has approved in view of carrying out a clinical trial.

(4) The wholesale distributors may own and distribute other products as well, such as: pharmaceutical substances, cosmetics, supplements, medical devices, plants and herbal products, while being compliant with the legislation specific to the respective field, which shall be stored in different areas.

Art. 4. - (1) The wholesale distribution authorisation is issued by request of the legal representative of the applicant wholesale distributor; for manufacturers and importers of medicinal products, wholesale distribution should be included in the manufacturing authorisation and import authorisation, for medicinal products included in the respective authorisation, in accordance with Art. 788 (4) of Law No. 95/2006, as amended.

(2) A wholesale distributor of medicinal products may own a single wholesale distribution unit or, as required, a central unit and one or several wholesale working points, each being authorised in accordance with the present norms.

(3) The wholesale distribution authorisation is issued on the basis of the favourable inspection report issued by the NMA inspectors; the report is considered favourable if critical deficiencies are not found.

(4) The wholesale distribution authorisation may be conditionally issued by certain obligations on the occasion of the authorisation, which are supposed to be met within the given terms, which should not surpass one year as of the inspection's date.

(5) In view of obtaining a wholesale distribution authorisation, the applicant forwards to the NMA, either directly, via the post office or rapid courier, an application for the planning of the inspection, in accordance with the pattern in Annex 1, as well as the standard form in Annex 2, accompanied by:

a) Administrative documentation:

- the constitutive documents of the commercial company;
- for the judge delegated for the authorisation and registration of the commercial company or, on a case-by-case basis, a final court decision;
- copy of the registration certificate submitted to the National Trade Register Office with its annexes and, if required, the certificates of registration of related claims;
- title attesting the ownership of the premises belonging to the commercial societies, including wholesale distribution working points;
- cooperative contract with a storehouse of medicinal products authorised for wholesale distribution, in case of wholesale distributors who do not own storage premises;

b) technical documentation:

- forms No. 1 and 2 of the standard dossier, in the format mentioned in Annex 3; form 2 shall be completed for each wholesale distribution working point;
- template of the premises and their description;
- labour contract or proof of liberal labour conduct, for a full norm consisting of 8 hours of work, for the head pharmacist of each wholesale distribution unit, and the membership certificate of the Romanian College of Pharmacists (RCP), issued in accordance with the law;
- labour contract or proof of liberal labour conduct and the RCP membership certificate, issued in accordance with the law, in case of employed pharmacists;
- the labour contract and free practice authorisation for pharmacy assistants;
- the labour contract/contract for provision of services, for the delegated person ;
- The commitment concerning the quarterly transmission to the NMA of the list of distributed medicinal products (commercial name, international non-proprietary name, amount) in electronic format and/or in written form.

Art. 5. - The delegated person referred to under Art. 790 c) of law no. 95/2006, as amended, should meet the following requirements:

a) being a pharmacist; or

- owning a certificate attesting the qualified person status, issued by the NMA; or
- being an MD, chemist or biologist and having at least one year of practical experience in activities relating to handling, storage, distribution or transaction of medicinal products concerning the acquirement or marketing of medicinal products;

b) Having general knowledge concerning Law No. 95/2006, as amended, and the Guideline on Good Distribution Practice of Wholesale medicinal products, approved through Minister of Public Health Order.

Art. 6. - The NMA responds to the applicant concerning the documentation sent in view of inspection:

a) If the documentation is compliant with provisions of Art. 4 (5), the applicant is informed about the acceptance of his application in view of inspection and about the inspection fee, approved through Minister of Public Health Order, which should be paid in 10 days as of the date of the notification's receipt; the inspection takes place within 10 days as of the confirmation of the fee's receipt, on a date established agreed with the applicant;

b) If the documentation is not complete, the applicant is informed about the data which should be forwarded to the NMA; in this case, the enforcement of the term mentioned under Art. 789 of Law No. 95/2006, as amended, is suspended until the full documentation is provided.

Art. 7. - The inspection is carried out in accordance with an inspection plan issued by an inspector appointed by the NMA, which is forwarded to the applicant unit prior to the date settled for inspection.

Art. 8. - (1) The inspection in view of the wholesale distribution authorisation aims to be compliant with the Guideline on the Good Wholesale Distribution Practice of medicinal products, approved through Minister of Public Health Order.

(2) Wholesale distributors of medicinal products carrying out division-packaging operations, either (re)packaging, relabeling of medicinal products, investigational medicinal products included, should own a manufacturing authorisation for the concerned operations, which is a part of the manufacturing process.

Art. 9. - (1) The inspection ends with an inspection report, which is forwarded to the applicant in maximum 20 days as of the inspection date.

(2) In case of a favourable inspection report, the wholesale distribution authorisation is issued by the NMA in maximum 90 days as of the date of the application's receipt and the complete documentation.

(3) The follow-up of the solving of the potential complaints observed (major, other complaints) is done following the release of the wholesale distribution authorisation, based on the documentation forwarded by the applicant or based on another inspection.

(4) In case of an unfavourable inspection report, it may be contested in maximum 7 days as of the receipt, while the NMA equally answers in term of maximum 7 days as of the complaint's file.

(5) The submitted complaint related to an unfavourable inspection report is assessed by a commission issued by a Decision of the NMA president.

(6) In case of an unfavourable inspection report, following the solving of the complaints observed by the inspectors, the inspected unit might require the organisation of a new inspection.

Art. 10. - (1) The wholesale distribution authorisation is issued in the format mentioned in Annex 4, in 2 original copies, from which one is handed to the applicant unit, while the other remains at the NMA – Pharmaceutical Inspection Department.

(2) The wholesale distribution authorisation for medicinal products issued by the NMA is available during an undefined period.

(3) The NMA inspectors shall carry out periodic follow-up inspections in the authorised wholesale distribution units, in accordance with the annual inspection plan, issued in accordance with the results of the risk assessment in case of each wholesale distributor.

Art. 11. - (1) The authorisations for the wholesale distribution activity issued by the MPH in accordance with Minister of Public Health Order No. 893/2006 on the approval of the Norms on the authorisation for the wholesale distribution of medicinal products, with further changes, loses its availability one year as of the coming into force of the present norms.

(2) For the wholesale distributors of medicinal products who, on the coming into force of the present norms, hold a wholesale distribution authorisation of medicinal products issued by the MPH, the wholesale distribution authorisation shall be issued in the new format, one year as of the coming into force of these norms, based on a favourable inspection report issued by the NMA inspectors.

(3) Starting with the date of the coming into force of these norms and no later than 90 days as of the expiry of the term mentioned under (1), the wholesale distributors submit to the NMA the documents mentioned under Art. 4 (5).

Art. 12. - Any change subsequent to the release of the wholesale distribution authorisation is first notified to the NMA, while applying for a new authorisation/annex; depending on the type of change (administrative and/or technical), the wholesale distribution authorisation/annex is released on the basis of the forwarded updated documentation or via a new favourable inspection report.

Art. 13. - In view of the wholesale distribution of medicinal products and psychotropic and narcotics, provisions of Law No. 359/2005 on the juridical regime of plants, substances, narcotics and psychotropic preparations are enforced.

Art. 14. - The loss of the wholesale distribution authorisation implies the cancelling of the authorisation, and the issue of a new wholesale distribution authorisation is done on the basis of the following documents:

- an application in the format mentioned in Annex 5;
- the proof of publishing the loss in a popular newspaper;
- copies of the documents submitted to the initial authorisation file;
- statutory declaration attesting that no new changes intervened apart from the information that allowed the initial wholesale distribution authorisation.

Art. 15. - (1) In accordance with provisions of Art. 788 (7) of Law No. 95/2006, as amended, if the non-compliance with one or several conditions which have influenced the authorisation process is observed, the NMA cancels or withdraws the wholesale distribution authorisation and hereby informs the EU Member States and the European Commission.

(2) The cancelling of the wholesale distribution authorisation may also be decided under the following circumstances:

a) in case the contraventions mentioned under Art. 836 (1) g) and h) of Law No. 95/2006, as amended, are observed;

b) At the justified demand of the MAH, submitted in written form, for a period of maximum 6 months; if the MAH does not require the cancelling of the suspension during these 6 months, the authorisation shall be withdrawn for good.

(3) In case of the suspension/withdrawal of the wholesale distribution authorisation, these are submitted to the NMA in maximum 3 days as of the NMA suspension/withdrawal decision or at the same time with the submission of the application for suspension done by the MAH.

(4) The withdrawal of a wholesale distribution authorisation for medicinal products may be done by the NMA and upon request of the MAH, based on a written application, accompanied by information relating to the existent supplies of medicinal products and their clearance.

(5) If the unit willingly ceases its activity, the authorisation is submitted to the NMA in 30 days as of the date of the notification attesting the cessation of the activity.

(6) In case of the authorisation's suspension, the activity may be restarted only on the basis of a favourable inspection report.

Art. 16. - (1) The holder of the wholesale distribution authorisation for medicinal products may contest the suspension/withdrawal decision in 7 days as of the decision's receipt.

(2) The NMA has to analyse the complaint in 7 days; until the solving of the complaint, its submission does not cancel NMA's decision concerning the suspension/withdrawal of the wholesale marketing authorisation for medicinal products for human use.

Art. 17. - Wholesale distribution units are forced to be compliant with the provisions of the Guideline on the Good Wholesale Distribution Practice for medicinal products for human use, approved through a Minister of Public Health Order.

Art. 18. - (1) The authorisation for the wholesale distribution of medicinal products includes the distributor's public service obligation described under Art. 695 of Law No. 95/2006, as amended, as well as the obligations mentioned under Art. 788 (10) and Art. 791 of Law No. 95/2006, as amended.

(2) The geographical space mentioned under Art. 695 of Law No. 95/2006, as amended, is represented by the Romanian territory.

Art. 19. - The pharmacists and physicians employed by the wholesale distributor must meet the requirements of Law No. 95/2006, as amended, concerning the performance of the respective profession.

Art. 20. - (1) The employees may perform their profession in a wholesale distribution unit of medicinal products in salary/independent scheme, as required, while comply within to the provisions of the Labour Code and based on a job description accurately describing their attributions in accordance with their training and experience in the respective field.

(2) The head-pharmacist and the delegated person may only be replaced, when missing, by a person having the same training and meeting the same requirements.

(3) The function of head-pharmacist cannot be fulfilled but for within the context of a single wholesale distribution unit (central unit/wholesale distribution working point).

(4) The head-pharmacist may also fulfil the attributions of the delegated person if the volume of the activities undertaken allows it.

Art. 21. - (1) In order to obtain the function of head-pharmacist, a pharmacist should know the respective legislation, namely: Title XVII – "The medicinal product" pf Law No. 95/2006, as amended, the Guideline on the Good Wholesale Distribution Practice for medicinal products, approved through a Minister of Public Health Order, and other legal provisions in his working field.

(2) The proof for being compliant with provisions of (1) is done via a statutory declaration of the appointed head pharmacist, which is attached to he documentation submitted to the NMA in view of inspection.

Art. 22. - (1) In view of carrying out the responsibilities which go to the head-pharmacist, he should:

a) be directly subordinated to the representative of the operations management carried out by the wholesale distribution MAH;

b) have the authority defined in the organisational chart;

c) have clearly defined responsibilities;

d) have access to all premises, areas and documents (including contracts with third parties) and records concerning the activities carried out by the wholesale distributor.

(2) Throughout his/her activity, the head-pharmacist should consider:

a) performing activities authorised in accordance with the good distribution practice, accuracy and quality of the records, in accordance with the standard operating procedures meant for each activity type;

b) The set up and storage of the evidence related to the delegation of responsibilities.

Art. 23. - (1) In view of carrying out his/her responsibilities, the delegated person should:

a) to have the authority mentioned in the organisational chart in order to ensure the implementation and maintenance of a quality system;

b) to have clearly defined responsibilities;

c) to have knowledge of the distributed medicinal products (e.g. medicinal product classes, their status toward the marketing authorisation, storage conditions, other specific conditions which should be met on the market where they are being distributed, if required) or of any other distributed non-medicinal product (and related activities) which may influence the products' quality;

d) to have knowledge of the quality management principles (policies concerning the quality, computerized systems, procedures, records).

(2) Throughout his/her activity, the responsible should consider:

a) the enforcement, maintenance and improvement of the quality system;

b) following the provisions of the Guideline on Good Distribution Practice for wholesale medicinal products, approved through Minister of Public Health Order;

c) the ownership of quality documents and documents attesting each medicinal product batch's provenience, as well as the records required in view of ensuring the traceability of the distribution path to the retail distributor.

Art. 24. - The wholesale distributor of medicinal products should have a standard operating procedure related to the interaction between the head-pharmacist and the top-level management representative, in order to allow the performance of all attributions belonging to the head pharmacist appointed through law.

Art. 25. - (1) The wholesale distributor of medicinal products should own all documents, information and records of the transactions carried out together with the providers, subcontractors and other operators involved in the supply chain (including written contracts), needed in view of ensuring the traceability of the distribution path, of the internal transfer between its wholesale working points and of the distribution of each medicinal product up to the retail distributor.

(2) The wholesale distributor shall quarterly submit to the NMA the list of distributed medicinal products (trade name, international non-proprietary name, quantity) in electronic format and/or in written form.

Art. 26. - In view of preventing and stopping the counterfeit of medicinal products, a holder of a wholesale distribution authorisation of medicinal products has the following responsibilities:

a) to establish a functional mechanism in order to ensure that it may efficiently take action in case of the suspicion concerning a potential counterfeit;

b) to report to the competent authorities (NMA, police, custom-house, as required) authorities as soon as possible;

c) To cooperate with all stakeholders (healthcare authorities, customs authorities, police, court, healthcare professionals, etc.) in view of detecting counterfeit medicinal products, the investigation of cases and charging of those responsible for the manufacturing/distribution of counterfeit medicinal products.

CHAPTER III
Final and transitory dispositions

Art. 27. - Annexes 1 - 5 are integral part of these Norms.

ANNEX No. 1
to the Norms

To
THE NATIONAL MEDICINES AGENCY
The Pharmaceutical Inspection Department

I, the undersigned ....., position …..…..…..……,
(first name, last name)
legal representative of ……....., located at ....., address....., telephone/fax ....., registered with the National Commercial Register Office ……....., fiscal code ....., hereby require planning of an inspection at the wholesale distribution site at ....., in view of wholesale distribution authorisation.

Please find attached to the present application the documentation required under Art. 4 (5) of the Norms on the set up, organisation and functioning of wholesale distribution units of medicinal products for human use, approved through Minister of Public Health Order No. 1964/2008*).

Signature and stamp,
.....

---

*) Both the application and documentation may be forwarded to the NMA headquarters either directly, or via the post office or express courier, to the NMA address: Aviator Sănătescu 48, sector 1, Bucharest, 011478.

ANNEX No. 2
to the Norms

Application form for the authorisation in view of the wholesale distribution of medicinal products for human use
(Please fill in all relevant sections with capital letters, legibly, in black ink)

Section 1. Application form: Administrative data

1.1. Details of the applicant

Authorisation number
(if previously authorised):

Name of the applicant:

Name of the representative*):

Address:

Postal code: Telephone

Mobile phone: Fax:

E-mail

---

*) The original document attesting the representative status shall be attached.

1.2. Information on the contact person (if different from above)

Contact person:

Name of the representative company:

Address:

Postal code: Telephone:

Mobile phone: Fax:

E-mail:

1.3 Information on invoicing address (if different from the MAH's address)

Contact person :

Company:

Address:

Postal code: Telephone:

Mobile phone: Fax:

E-mail:

Section 2. Information on the wholesale distribution site

2.1**. Information on the wholesale distribution site**

Sections 2 and 3 should be filled in for each wholesale distribution site to be mentioned in the authorisation.

Name of the distribution site:

Address:

Postal code:

Contact name:

Telephone: Fax:

Mobile phone:

E-mail:

2.2. **Types of activities**

□ Storage and handling

□ Procurement/marketing only (no storage)

□ Delivery

□ Export

□ Other*)

Name of the distribution site:

Postal code:

2.3. **Category of products handled at the distribution site**

Please indicate what categories of products are being handled at the respective site by checking the appropriate box.

□ Medicinal products without medical prescription

□ Medicinal products on medical prescription

□ Biological medicinal products

□ Traditional herbal medicinal products

□ Investigational medicinal products

□ Radiopharmaceutical medicinal products

□ Other*)

2.4. **Classes of medicinal products**

Sterile forms

Liquid dosage forms (large volume)	□ yes □ no
Liquid dosage forms (small volume) (e.g. eye drops)	□ yes □ no
Semisolid dosage forms (i.e. sterile creams and ointments)	□ yes □ no

---

*) If "Other", please specify:

Other sterile products	☐ yes ☐ no

If "Other", please specify:

Nonsterile forms

Liquid dosage forms (i.e. solutions, syrups, suspensions)	☐ yes ☐ no
Semisolid dosage forms (i.e. nonsterile creams and ointments)	☐ yes ☐ no
Solid dosage forms (i.e. tablets, capsules, suppositories and powders)	☐ yes ☐ no
Other nonsterile products	☐ yes ☐ no

If “Other”, please specify:

Medicinal gases	☐ yes ☐ no

2.5. **Activities specific for the distribution site**

Please answer the questions below in order to indicate the types of activities you intend to perform at the distribution site

Do you bring medicinal products without a marketing authorisation in the European Economic Area?	☐ yes ☐ no
Are parallel imported products handled here?	☐ yes ☐ no

Name of the distribution site:

Postal code:

2.6. **Other information**

The following information is necessary for the inspectorate, but shall not be included in the authorisation.

Are special products handled at the distribution site ? (e.g. narcotics) □ yes □ no

Do you provide medicinal products requiring freezing storage or storage at low temperature? □ yes □ no

Are the sites ready for inspection? □ yes □ no

Do you intend to function on the basis of a quality insurance system? □ yes □ no

Are you aware of the provisions of the Guideline on Good Distribution Practice, relating to the necessary documentation and quality control? □ yes □ no

Are there standard operation procedures (SOPs) available, as mentioned in the Guideline on Good Distribution Practice? □ yes □ no
Please attach a copy of these in written/electronic format.

Are the contracts you own available for inspection? □ yes □ no

Distribution methods

Post office □ yes □ no

Courier services □ yes □ no

Own transport services □ yes □ no

Taken over by the client □ yes □ no

Do you ensure measures for medicinal products requiring special transport conditions at low temperature?	☐ yes ☐ no

Other	☐ yes ☐ no

If "Other", please specify:

2.7. **Equipment/Facilities of the distribution site**

On a separate sheet, make a brief description (about 500 words) of the facilities available for the storage and distribution of medicinal products.

Section 3. Nominees

Please indicate below the personnel categories working at the distribution site.

Personnel	Number
Head pharmacist	
Responsible person (RP)	

For each personnel category listed above, please fill in one of the following pages.

Name of the distribution site: Postal code:

3.1. **Head pharmacist**

A relevant CV should be attached for the head-pharmacist; nomination of the head-pharmacist should be signed by the nominee and by the applicant.

Last name:

First name:

Office address:

Postal code: Telephone:

Fax: Mobile phone:

E-mail

Qualifications (relevant in view of authorisation):

Experience (brief description of the relevant occupations and responsibilities in view of authorisation):

Professional associations:

I hereby confirm that the previous details are correct and true in accordance with my knowledge and opinions. I agree to be nominated head-pharmacist.

Signature (of the nominee): .....

Date: .....

Full name: .....

Signature (of the applicant): .....

Date: .....

Name of the distribution site: Postal code:

3.2. **Responsible person**

A relevant CV should be attached for the proposed responsible person; the nomination of the responsible person should be signed by the nominee and the applicant.

Last name:

First name:

Office address:

Postal code:		Telephone:	
Fax:		Mobile phone:	
E-mail			

Are you a pharmacist?	□ yes □ no
Are you eligible to be a qualified person?	□ yes □ no

If the answer to any of the questions above is no, then you must be a physician, chemist or biologist and have at least one year practical experience in one of the activities below (please check, as required):

a) Handling, storage and distribution of medicinal products □

b) Transaction related to the marketing or procurement of medicinal products □

Qualifications (relevant in view of authorisation)

Experience (short description of the relevant occupations and responsibilities in view of authorisation):

Professional associations:

I hereby confirm that the previous details are correct and true in accordance with my knowledge and opinions. I agree to be nominated responsible person.

Signature (of the nominee): .....

Date: .....

Full name: .....

Signature (of the applicant): .....

Date: .....

Full name: .....

Name of the distribution site:		Postal code:	

Section 4. Comments

Please specify any other type of information which may provide support to your application. Moreover, you may provide details on any address and nominee changes etc.

Section 5. Declaration

I hereby apply for the granting of the wholesale distribution authorisation to the nominated holder in this application form, for the activities referred to in the application.

5.1. The activities shall be in accordance with the information in the application or forwarded in respect to this application.

5.2. In accordance with my opinions and knowledge, the details in the application are correct and complete.

Signature (of the applicant): .....

Data: .....

Full name: .....

Quality as signatory: .....

ANNEX No. 3
to the Norms

STANDARD DOSSIER
of the wholesale distribution unit

This form is issued so as to, via completion by the applicant, provide information about procurement, possession, delivery and/or export carried out at the distribution site to be inspected. If some of the aforementioned operations are not carried out at the distribution site, the dossier shall be filled in only regarding those operations, e.g. storage.

FORM 1: INFORMATION CONCERNING THE COMPANY

1. *GENERAL INFORMATION*

1.1. Brief information concerning the company

1.1.1. Name of the company, the way it is recorded by the legal authority.
1.1.2. Postal address.
1.1.3. Telephone (24/24) and fax numbers and permanent e-mail address in order to contact the head-pharmacist or his substitute in case of a batch recall may be contacted.
1.1.4. Number and date of the most recent wholesale distribution authorisation.
1.1.5. Other authorisations held. Please specify for each authorisation the number, date and name of the issuing authority.

2. *RELEVANT ACTIVITIES FOR THE COMPETENT AUTHORITY*

Fill in the appropriate blanks:

Distributed products	Percentage of distributed commercial units		Classification of the distribution according to the status of receipt (%)		
	Romania	Other countries	Pharmacies	Distributors	Others*)
Medicinal products for human use					
Other products*)					

*) If “Other products” or "Other", please specify.

3. *DISTRIBUTION SITES OF THE COMPANY*

Please fill in the table below:

Name of the distribution site	Address	Telephone/Fax	Authorised activities

FORM NO. 2: INFORMATION ON THE DISTRIBUTION SITE

Notice: A "Form No. 2" shall be filled in for each distribution site.

CHAPTER 1: GENERAL INFORMATION

1.1. Brief information concerning the distribution site

1.1.1. Name of the distribution site, address and postal address (if different from the address of the distribution site)

1.1.2. Telephone and fax number of the contact person

1.1.3. Permanent contact telephone number

1.2. Authorised distribution operations

1.2.1. Please specify whether the distribution site has been authorised by the National Medicines Agency (NMA) or other authorities (in the latter case, name the authority and purpose of the authorisation, indicate if the same or different from the one described in the application).

1.2.2. Please specify the number and availability of the authorisation issued by the competent authority. Any type of conditions and/or restrictions should be stated.

1.3. Any other operation issued at the distribution site

Both the pharmaceutical/non-pharmaceutical activities should be described.

1.4. Type of products handled at the distribution site and information on the toxic and hazardous products handled, while maintaining the handling mode and cautions taken.

1.4.1. Please specify the type of handled medicinal products, mentioning whether they are handled on the basis of a contractual agreement with a contract provider (i.e. radiopharmaceuticals).

1.4.2. Please note any type of handled toxic, hazardous, strongly sensitizing substances, i.e. antibiotics, hormones, cytostatics. Please specify whether any special precautions are taken concerning such products.

1.5. Brief description of the distribution site (size, location and immediate surroundings and other activities performed)

(No more than 250 words on a A4 sheet)

1.5.1. Please provide a map of the site and surroundings. Mark the site, describe the surroundings and activities performed nearby.

1.5.2. Size of the distribution site, types of buildings and their age

1.5.3. Other activities performed at the distribution site

1.6. Number of employees involved in the administration, storage, distribution and transport

Note: Please include both part-time and full-time employees.

1.6.1. Administration

1.6.2. Storage

1.6.3. Distribution

1.6.4. Transport

1.6.5. Technical support services

1.6.6. Number of employees

1.7. Contracted activities, operations carried out under contract (if yes, see Chapter 8 for further details)

For each contract beneficiary (including transportation companies, if required), please specify:

1.7.1. Name, address, telephone and fax number of the contract beneficiary

1.7.2. Brief description of the activity performed (in less than 100 words or one half of a A4 sheet)

1.8. Brief description of the company's quality management system

(No more than 750 words of 3 A4 sheets)

1.8.1. Please describe the company's quality policy.

1.8.2. Describe the quality management elements, i.e. the organisational structure responsibilities, procedures, processes.

1.8.3. Describe the audit programme (self-inspections or audits issued by external bodies).

1.8.4. Describe the way results are analysed in view of attesting that the quality system is adequate relating to its objectives, i.e. quality and integrity of the product (also see Chapter 8).

1.8.5. Mention whether standards such as ISO 9000 are used by the company.

CHAPTER 2: STAFF

2.1. The organisational chart should include the key persons

The organisational chart for key functions, as approved. Mention only the heads and supervisors.

2.2. Qualifications, experience and responsibilities of the key-staff

2.2.1. Brief description of the universal qualifications, specialisations for the activity performed and years of experience in the field of the persons nominated in the organisational chart

2.2.2. Job descriptions of the key staff

2.3. Training of the staff and relevant documents concerning the training program

Please provide brief details concerning the training program and include the continuous training and employment training, as follows:

2.3.1. Describe how the training necessities are identified and by whom.

2.3.2. Provide details concerning the specific training in view of the good distribution practice.

2.3.3. Describe the type of training, i.e. internal, external, the way practical training is carried out and what segment of the staff is concerned.

2.3.4. Explain the way training efficacy is assessed, i.e. via forms.

2.3.5. Explain the way retraining necessities are identified.

2.3.6. Specify whether you own records of training performed.

CHAPTER 3: SITES AND FACILITIES

3.1. Simple drafts of the site and description of the storage site

3.1.1. Transmit a draft of the site, checking all storage sites and other operational sites.

3.1.2. Please describe the measures taken in order to prevent unauthorised access.

3.1.3. Please forward a simple plan for each site (i.e. reception, storage, recalled products, expedition, for medicinal products having special storage requirements).

Note: The plans should be legible on a A4 sheet. If deemed necessary, they can be forwarded on a A3 sheet.

3.2. Brief description of the ventilation systems (maximum 500 words written on two A4 sheets). Further details should be given for the critical sites where special storage conditions are ensured.

Note: In order to reduce the text size, schematic drawing should be used.

3.2.1. Projection criteria, i.e. specifications concerning the air, temperature, humidity provided

3.3. Special sites for the handling of extremely toxic, hazardous and sensitizing materials

Please use the same plan as in point 3.1. above in order to describe the special sites for the handling of extremely toxic, hazardous and sensitizing materials.

3.4. Maintenance (description of the preventive maintenance programs and of the record system)

3.4.1. Describe the planned preventive maintenance program.

3.4.2. Who is responsible for the maintenance (contract beneficiaries included).

3.4.3. Are there written procedures and detailed contracts available in view of the contracted activities?

3.4.4. Are there adequate written procedures available and record forms in view of maintenance (including contract beneficiaries). Are there the type/frequency of the check-ups, the details of the activities, remedies and modifications registered in these documents?

3.4.5. Are the routine maintenance activities which could affect product's quality identified?

3.4.6. Are the reports forwarded to the users?

3.5. The existence of the written specifications and cleaning procedures of the sites?

3.5.1. Are there written procedures for cleaning and specifications for the cleansing agents and their strength for the cleaning method and frequency?

3.5.2. Which are the cleaning methods (and their frequency) for auto vehicles?

3.6. Policy on the storage of materials

3.6.1. How are the materials of different status (i.e. quarantine, recalled, approved etc.) segregated and controlled (i.e. computer, labels)?

3.6.2. How are materials stored, i.e. on blades?

3.6.3. Describe the storage conditions for narcotics and psychotropes, if required.

3.6.4. Describe the program meant for the prevention of the insects' access and other pests.

CHAPTER 4: STOCK HANDLING AND CONTROL

4.1. Record system of the distribution activities

4.1.1. Please describe the receipt, handling and storage of materials:

- types of check-ups done on materials

- does the delivery order comply with the First-In-First-Out principle (FIFO) and does it identify the batch number?

- which are the distribution methods towards the clients?

4.1.2. Distribution record

Do the records kept allow complete traceability from factory to client as regards the sale date, the client's details and delivered quantities?

4.1.3. Stock intervention procedure. Please include information concerning the way in which the listing and frequency are carried out.

4.2. Delivery and transport

4.2.1. Please describe the way in which security, storage conditions and quality projection conditions during transportation are ensured.

4.2.2. Describe the available auto vehicles:

a) number of vehicles and their capacity

b) are these dedicated vehicles?

c) Are the vehicles adapted in order to transport medicinal products or other special products (i.e. products requiring low temperatures, radioactive products)?

d) How are the transportation routes planned?

CHAPTER 5: DOCUMENTATION

5.1. Set up, revision and distribution of the needed documentation, including the storage of primary documents

5.1.1. Is there a description of the documentation system?

5.1.2. Who is responsible for the set up, revision and distribution of the medicinal product?

5.1.3. Where are primary documents kept?

5.1.4. Is there a standard format and instructions concerning the manner of the documents' set up?

5.1.5. How is the documentation assessed?

5.1.6. How long are the documents kept?

5.1.7. Please describe the recording methods in electronic format/microfilm.

5.2. Any other documents referring to the product's quality which are not mentioned elsewhere

Are the following documents available and used?

5.2.1. Training procedures

5.2.2. Specifications concerning the software:

a) connection to the system (internet, intranet) and authorisation to grant access

b) monitoring of all new posts and modifications ("audit trail") and frequency of check-ups

c) data saving procedures

5.2.3. Documentation control

5.2.4. Calibration of the instruments used

5.2.5. Please list and briefly explain the use of any other standard documentation normally used.

CHAPTER 6: COMPLAINTS AND PRODUCT RECALL

6.1. Measures taken when dealing with complaints and product recall

6.1.1. Complaints

6.1.1.1. Is there a written procedure concerning the complaints brought to medicinal products?

6.1.1.2. Who is responsible for the following:

a) record

b) classification

c) investigations of the complaints

6.1.1.3. Are there written reports issued?

6.1.1.4. Who performs the check-up of these records?

6.1.1.5. How long are the complaint records kept?

6.1.2. Product recall

6.1.2.1. Is there a written procedure describing the sequence of the actions which should be performed, including:

a) distribution list of the concerned product

b) announcement of the clients

c) reception/segregation/inspection of the returned goods

d) investigation/reporting of the cause

e) reporting of corrective actions

6.1.2.2. Who is responsible for the performance of recalls?

6.1.2.3. Who informs the competent authority (NMA) about the complaints and recalls?

6.1.2.4. Is the NMA involved in the recall decision?

6.1.2.5. May the recall be performed up to the level of en detail distributor?

6.1.3. Counterfeit products

6.1.3.1. Is there a procedure in view of the detection, report (to the NMA) and placement into quarantine of counterfeit medicinal products?

CHAPTER 7: SELF-INSPECTIONS

7.1. Brief description of the self-inspection system (see 1.8.4.)

7.1.1. Please describe the manner in which the activities having an impact upon the product quality are assessed via self-inspection.

7.1.2. Is there a documented procedure for the self-inspection system and follow-up actions?

7.1.3. Are self-inspection results documented, forwarded to the staff responsible for the inspected site or activities?

7.1.4. Do the persons responsible for the site/activity implement the proposed corrective actions in due time?

CHAPTER 8: UNDER CONTRACT ACTIVITIES

8.1. Description of the manner in which compliance with BPD/other adequate standards of the contract beneficiary.

8.1.1. Briefly describe the details of the technical contracts between the provider and the contract beneficiary and the manner in which the compliance with BPD/other adequate standards of the contract beneficiary is assessed. The selected standards should be assessed as regards their implementation. The types of activities performed by the contract beneficiary should be specified.

ANNEX No. 4
to the Norms

FORM
Wholesale distribution authorisation

1. Authorisation No. .....

2. MAH name …….....

3. Address(es) of the wholesale distribution site(s) .....

.....
(All authorised sites should be listed.)

4. MAH legally registered address ….....
5. Authorisation field – Annex No. 1.1 - 1.x
(Individual annexes should be submitted for each site.)
6. Legal bases of the authorisation …….
7. Name of the responsible person of the National Medicines Agency (the Romanian competent authority granting the wholesale distribution authorisation) .....
8. Signature .....

9. Date .....

10. Attached annexes: Annex No. 1.1 - 1.x

Annex No. 2.1 - 2.x

ANNEX No. 1.x
to Wholesale Distribution Authorisation no. ....

THE FIELD COVERED BY THE AUTHORISATION
(fill in the applicable sections)
Name and address of the distribution site
…….……..

□ Medicinal products for human use
AUTHORISED ACTIVITIES
□ Procurement/marketing activities
□ Holding (storage)/handling activities
□ Delivery activities
□ Export activities
CATEGORIES OF PRODUCTS TO BE HANDLED*)
□ Medicinal products on medical prescription
□ Medicinal products without medical prescription
□ Biological medicinal products
□ Traditional herbal medicinal products
□ Investigational medicinal products
□ Radiopharmaceuticals
□ Others:
MEDICINAL PRODUCT CATEGORIES*)
Sterile medicinal products
□ Liquid dosage forms – large volume
□ Liquid dosage forms – small volume (i.e. eye drops)
□ Semi-solid dosage forms (i.e. sterile creams and ointments)
□ Solid dosage forms (i.e. sterile powders)
□ Other sterile products:
Non-sterile medicinal products
□ Liquid dosage forms (i.e. solutions, syrups, suspensions)
□ Semi-solid dosage forms (i.e. non-sterile creams and ointments)
□ Solid dosage forms (i.e. tablets, capsules, suppositories and powders)
□ Other non-sterile products
□ Medicinal gases

*) in accordance with the application form in view of inspection submitted to the National Medicines Agency.

This authorisation reflects the status of the wholesale distribution site relating to compliance with legislation in force, observed during the inspection of ....., and is available for an undetermined period of time.

The information authenticity may be assessed by the issuing authority.

Name and function of the authorised person ….....

Signature .... Stamp and date ....

ANNEX No. 2.x
to Wholesale Distribution Authorisation no. ....

Name of head pharmacist .....
Name of the responsible person .....

Name and function of the authorised person
.....

Signature ..... Stamp and date .....

ANNEX No. 5
to Norms

To
THE NATIONAL MEDICINES AGENCY
The Pharmaceutical Inspection Department

I the undersigned (first name, last name) ....., position ....., legal representative of ....., residing at ....., address....., telephone/fax ....., registered with the National Trade Register Office ....., fiscal code ....., in accordance with Art. 14 of the Norms on the set up, organisation and functioning of wholesale distribution units of medicinal products for human use, approved through Minister of Public Health Order No. 1.964/2008, I hereby require release of a new wholesale marketing authorisation. We hereby attach the evidence for the loss of the wholesale distribution authorisation in..... .

Signature and stamp,
….....