Order of the Minister of Health no. 131
on approval of Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use

ISSUED BY: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, Part I no. 108 of 11 February 2016.

On seeing Approval Report no. A.C.P. 997/2016 of the Directorate for Policies on Medicinal Product and Medical Devices of the Ministry of Health and notification no. 59.619E of the National Agency for Medicines and Medical Devices, registered with the Minister of Health under no. 75.695/2014,

Taking into account provisions of Articles 800-803, of Articles 809 and 810, as well as of Article 857 of Law no. 95/2006 on healthcare reform, republished as amended,

Having regard to provisions of Article 12(9) of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

Based on Article 7 (4) of 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:

Article 1. – The Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use are hereby approved, as provided in the Annex which is integral part of this order.

Article 2. – On request, without additional inspection and within no longer than 2 years, before the date of this order entry into force, the National Agency for Medicines and Medical Devices shall grant wholesalers inspected pursuant to provisions of the Guideline for Good Distribution Practice in wholesale of medicinal products, approved through Order of the Minister of Health no. 761/2015, the Good Distribution Practice certificate and the Wholesale Distribution Authorisation in line with the updated format, based on the inspection conducted in the previously mentioned period.

Article 3. – On the date of this order entry into force, order of the Minister of Health no. 1.964/2008 on approval of Rules for setup, organisation and operation

of wholesale sites for medicinal products for human use, published in the Official Gazette of Romania, Part I, no. 855 of 19 December 2008.

Article 4. - This Order shall be published in the Official Gazette of Romania, Part I

p. Minister of Health,
Victor Dan Eugen Strâmbu,
Secretary of State

Bucharest, 04 February 2016
No. 131.

Ministry of Health - MH – Rules of 04 February 2016

ANNEX
to the Rules

Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use of 04.02.2016

In force as of February 2016
published in the Official Gazette of Romania, Part I no. 108 of 11 February 2016.

CHAPTER I
Definitions

Article 1. – For the purpose of these Rules, the terms and concepts used herein shall mean as follows:

a) *broker* - legal person established in the European Economic Area (EEA), involved in activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;

b) *wholesaler of medicinal products for human use* - legal person established in the EEA, conducting, in line with legal provisions, of activities consisting of procuring, holding, supplying or exporting medicinal products, as defined in Title XVIII "The Medicinal Product" of Law no. 95/2006 on healthcare reform, republished as amended, apart from supplying medicinal products to the public;

c) *responsible person* - person referred to in Article 802 b) of Law no. 95/2006, republished as amended, whose qualification requirements are described in the Guidelines on Good Distribution Practice of medicinal products for human use Guideline, approved through Order of the Minister of Health no. 761/2015;

d) *falsified medicinal product* - any medicinal product with a false representation of:

(i) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(ii) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(iii) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights;

e) *distribution site* – site for medicinal product wholesaler conduct of one or several activities provided under b);

f) *traceability* - the ability to verify the history, location, or application of a medicinal product by means of documented recorded identification;

g) *healthcare products* – products other than medicinal products that may be held and supplied to the public in pharmacies;
h) *critical deficiencies*:
- A deficiency which may result in or lead to a significant risk during medicinal product distribution, potentially harmful to the public;
- a combination of several "major" deficiencies, none of which on their own may be "critical", but which may together represent a critical deficiency and should be explained and reported as such;
i) *major deficiencies*:
- deficiencies that may affect medicinal product quality during distribution, however not critically; or
- a combination of several "other deficiencies", none of which on their own may be" major", but which may together represent a major deficiency and should be explained and reported as such;
j) *other deficiencies* – deficiencies which cannot be classified as either critical or major, but which indicate a deviation from good distribution practices.
A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as a major or critical;
k) *transportation hub* – location on the transport route where unloading/loading/transit storage (under 24 hrs.) may be performed;
l) *inspection of wholesale distribution authorisation* – inspection conducted for grant of wholesale distribution authorisation or modification thereof;
m) *routine inspection for assessment of compliance with good distribution practices (GDP)* – monitoring inspection conducted repeatedly to ensure GDP compliance by the authorised wholesaler, their premises and equipment.

CHAPTER II

Authorisation for wholesale of medicinal products for human use

Article 2. - (1) According to Article 800(1) of Law no. 95/2006, republished as amended, for wholesale distribution of medicinal products inside Romania, the applicants must own a wholesale distribution authorisation granted by the National Agency for Medicines and Medical Devices (NAMMD).

(2) Wholesale distribution authorisation is mandatory for each wholesale operator in the wholesale distribution chain, including free zones and free warehouses conducting such human medicines-related activities as:

a) procurement and delivery transactions;

b) holding (storing) and handling;

c) export.

Article 3. - (1) On Romanian territory, medicinal product wholesalers shall distribute medicinal products only that have been authorised for marketing pursuant to Law no. 95/2006, republished as amended, or by centralised procedure.

(2) By way of exception from provisions under (1), wholesalers may distribute medicinal products not authorised for marketing as provided in Articles 703(1) and (2) of Law no. 95/2006, republished as amended, based on authorisation for supply of medicinal products for special needs, granted by the NAMMD.

(3) Medicinal product wholesalers may hold and distribute other healthcare products as well, in compliance with legislation specific to their respective scope of work, which shall be stored in distinct areas.

(4) Wholesalers may supply medicinal products to such persons only that, in their turn, hold a wholesale distribution authorisation or are authorised for supply of medicines to the Romanian public.

Article 4. - (1) The wholesale distribution authorisation are authorised is granted on request of the legal representative of the applicant wholesaler; in the case of medicinal product manufacturers and importers, according to Article 800(4) of Law no. 95/2006, republished as amended, wholesale distribution is included into the manufacturing/import authorisation for the medicinal products included in the respective authorisation.

(2) A single medicinal product wholesaler may only hold a single or several wholesale site(s), each authorised pursuant to these Rules.

(3) Wholesale distribution authorisations are granted based on favourable inspection report prepared by NAMMD inspectors.

(4) Wholesale distribution authorisations may also be granted conditioned by compliance with obligations imposed on authorisation, to be met on the deadlines established in the preventive and corrective measures plan prepared for resolution of deficiencies by the inspectee after conduct of the inspection.

(5) For grant of the wholesale distribution authorisation applicants submit an application to the NAMMD requesting schedule of an inspection, in accordance with the form stipulated in Annex I and the form filled in as shown in Annex no. 2, accompanied by the following documents:

a) administrative documents:

a1) certified copy of the statutes of the company;

a2) certified copy of the closure/resolution for company authorisation and registration;

a3) certified copy of the registration certificate granted and issued by the Registry of Commerce, annexes included;

a4) fact-finding certificate issued 30 days prior to application submission;

a5) certified copy of the of proof of location ownership, wholesale sites included;

a6) for distributors who do not have their own holding areas, certified copy of the contract for collaboration with an authorised medicinal product wholesaler

b) technical documents:

b1) master file established for each manufacturing site, in line with Annex no. 3; form no. 2 is to be filled in individually for each distribution site;

b2) plan of the premise(s), their description;

b3) labour contract or proof of liberal conduct of profession, full-time with 8 working hours for the responsible person in each distribution site and the membership certificate in professional colleges granted under the law;

b4) labour contract or proof of liberal conduct of profession and the membership certificate for the College of Pharmacists in Romania granted under the law, for pharmacists employed;

b5) labour contract or proof of liberal conduct of profession the membership certificate for the College of Physicians in Romania granted under the law, for physicians employed;

b6) labour contract and the membership certificate for the Order of Nurses, Midwives and Medical Assistants in Romania, for pharmacy assistants;

b7) commitment concerning monthly submission to the NAMMD of the status of trade operations, parallel import included or, respectively, medicinal product distribution outside Romania to other EEA countries conducted with medicinal products for human use in their own portfolio.

Article 5. – The Responsible person referred to in Article 802 b) of Law no. 95/2006, republished as amended, shall meet the following requirements:

a) be a pharmacist/physician with at least one year work experience in operations of medicinal product handling, storage and distribution or transactions related to medicinal product procurement or sales;

b) be cognizant of Law no. 95/2006, republished as amended, concerning provisions of the Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015, as well as any other regulatory provisions related to distribution work.

Article 6. - Ten days as of registration of the application, the National Agency for Medicines and Medical Devices notifies the applicant on status of documents submitted for conduct of the inspections:

a) For documentation compliant with provisions of Article 4(5), the applicant is informed on acceptance of the respective application for inspection as well as on inspection fee, as approved through Order of the Minister of Health, payable within 10 days as of receipt of the NAMMD notification; the inspection is conducted 10 days as of fee payment confirmation, on an agreed date;

b) For incomplete documentation, the applicant is notified as to further information to be submitted to the National Agency for Medicines and Medical Devices; in such cases, timeframes provided in Article 801 of Law no. 95/2006, republished as amended, are suspended until submission of complete documentation.

Article 7. - The inspection is conducted in line with an inspection plan established by an inspector/inspectors nominated by the NAMMD; the respective plan is notified to the applicant site prior to the date set for inspection.

Article 8. - (1) The inspection for authorisation of wholesale distribution assesses compliance with Guidelines on Good Distribution Practice of Medicinal

Products for Human Use, approved through Order of the Minister of Health no. 761/2015.

(2) Medicinal product wholesalers conducting either division-packaging operations or (re)packaging, (re)labelling operations for medicinal products, investigational medicinal products included, shall hold a manufacturing authorisation for the respective medicines, such operations being constitutive part of the manufacturing process.

Article 9. - (1) No later than 20 days as of the inspection date, the NAMMD provides to the applicant the list of deficiencies/inspection report, as appropriate.

(2) For the list of deficiencies, the applicant is required to submit the proposed corrective and preventive action plan within 15 days.

(3) In case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan.

(4) Where inspection reports are unfavourable (concluding on GDP non-compliance), in the shortest time possible, the NAMMD issues a GDP Non-compliance Statement in the European format approved by the European Commission; in such cases, after resolution of deficiencies found, the inspectee may apply for a new inspection.

(5) Where inspection reports are favourable (concluding on GDP non-compliance), the National Agency for Medicines and Medical Devices grants the manufacturing authorisation within 90 days as of the registration date of the full documentation submitted by the applicant.

(6) Follow-up of resolution of potential deficiencies found, other than critical, is performed after issue of the wholesale distribution authorisation, based on documentation submitted by the applicant or by means of a new inspection.

Article 10. - (1) The wholesale distribution authorisation is issued in the format approved by the European Commission, in two original copies, one of which is handed to the applicant, while the other remains with the National Agency for Medicines and Medical Devices.

(2) Wholesale distribution authorisations issued by the NAMMD shall remain valid indeterminately.

(3) NAMMD inspectors conduct routine inspections for assessment of GDP compliance to authorised wholesale distribution sites according to the Annual Inspection Plan prepared pursuant to risk assessment results for each wholesale distributor; frequency of follow-up inspections is noted in the inspection report and shall not exceed 5 years.

(4) Routine inspections for assessment of GDP compliance may also be conducted without prior notification, any time there is reason to suspect wholesaler GDP non-compliance.

Article 11. - For announced inspection for assessment of GDP compliance, provided under Article 10(3), 90 days prior to the date of the next inspection specified in the previous inspection report, the wholesale distribution

authorisation holder shall submit an application for inspection scheduling (as per Annex no. 1), accompanied by the Master File (according to Annex no. 3), the updated version of administrative documents mentioned in Article 4(5), in case of changes, and the status of corrective and preventive measures implemented after the previous inspection.

Article 12. - Changes subsequent to grant of the wholesale distribution authorisation, including inclusion/elimination of a transportation hub, are notified to the National Agency for Medicines and Medical Devices in advance, at the same time with an application for new authorisation/annexes; depending on the nature of the change, the, wholesale distribution authorisation/annex is granted based on an updated dossier submitted (for administrative changes) or a new favourable inspection report (for technical changes).

Article 13. - For wholesale distribution of medicinal products containing psychoactive or psychotropic substances, provisions of Law no. 339/2005 shall apply on the legal regime of psychoactive or psychotropic plants, substances and preparations, as amended.

Article 14. - Loss of the wholesale distribution authorisation leads to its cancellation and a copy may be issued based on the following documents:

a) application submitted in the format mentioned in Annex no. 4;

b) proof of published notification of the loss in a widely circulated daily;

c) copies of documents originally submitted in view of the initial authorisation;

d) a statutory declaration mentioning that no changes have been implemented to data initially allowing grant of wholesale distribution authorisation.

Article 15. - (1) Should non-compliance with GDP be found on any inspection with, the NAMMD shall in the shortest time possible proceed to issue the GDP Non-compliance Statement in the European format approved by the European Commission; in such cases, after resolution of deficiencies found, the inspectee may apply for a new inspection.

(2) In line with provisions of Article 800(7) of Law no. 95/2006, republished as amended, should one or several conditions for conditional authorisation be found, or in cases of issuance of a GDP non-compliance statement, the National Agency for Medicines and Medical Devices shall suspend, in part or in whole, all non-complaint activities/operations until remedy of deficiencies found or revoke the wholesale distribution authorisation in case deficiencies found are beyond remedy; NAMMD shall notify the other Member States and the European Commission thereof.

(3) Suspension of the wholesale distribution authorisation may also be decided upon under the following circumstances:

a) the finding of contraventions established in Article 875(1) g), h) and n) of Law no. 95/2006, republished as amended;

b) on reasoned written request by the authorisation holder, for no longer than 6 months. Activities may only be resumed after submission to the NAMMD of a notification of recommencement of activities, accompanied by a mentioning that

no changes have been implemented to data initially allowing grant of wholesale distribution authorisation. Should the holder submit no such request for cancellation of suspension within 6 months, the authorisation shall be revoked permanently.

(4) In cases of suspension/revocation, the wholesale distribution authorisation shall be handed over to the NAMMD 3 days as of NAMMD decision for suspension/revocation or at the same time with submission of the holder's application for suspension/revocation; the authorisation shall be accompanied information on the medicinal product stocks in place and the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period. In case of partial suspension of the wholesale distribution authorisation, involving certain activities/operations only, the NAMMD shall issue a new wholesale distribution authorisation only containing activities it is valid for.

(5) The NAMMD may revoke the wholesale distribution authorisation for medicinal products either as a result of GDP non-compliance or on holder's request, based on written application; the authorisation shall be accompanied information on the medicinal product stocks in place and the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period.

(6) For suspensions of authorisation triggered by GDP non-compliance, activities may only be resumed based on a favourable inspection report.

Article 16. - (1) Holders of wholesale distribution authorisations for medicinal products may appeal the decision for suspension/revocation within 48 working hours since receipt of the decision.

(2) NAMMD review of the appeal is mandatory within 48 working hours; pending resolution of the appeal, submission of the application for appeal shall not suspend the NAMMD decision on suspension/revocation of the wholesale distribution authorisation for medicinal products.

Article 17. - (1) Authorisation for medicinal product wholesale activities includes the distributor's public service obligation provided under Article 699 pct. 19 and Article 804(2) of Law no. 95/2006, republished as amended, as well as obligations stipulated in Article 800(10) and Article 803 of Law no. 95/2006, republished as amended.

(2) The geographic area specified in Article 699 pct. 19 of Law no. 95/2006, republished as amended, refers to Romania.

Article 18. - Pharmacists and physicians working at the wholesale distribution site shall meet requirements established for conduct of their profession pursuant to Law no. 95/2006, republished as amended.

Article 19. - (1) Pharmacists, physicians and other staff may only conduct their profession at a medicinal product wholesale distribution site as proper employees

and/or independently, as appropriate, in compliance with legal provisions in force and based on a position description providing a detailed description of their tasks and duties according to their respective qualification in the field.

(2) When absent, the responsible person may be replaced by a different person of the same qualification and meeting the same requirements only.

(3) The position as responsible person may be held in one distribution site only..

Article 20. - (1) In order to meet their functions, responsible persons shall:

a) be directly subordinated to the representative of the top management of the wholesale distribution authorisation holder for medicinal products;

b) hold the authority as defined in the organisational chart;

c) have well-defined responsibilities;

d) have access to all areas, spaces and documents (contract with third-parties included) sand records related to activities conducted by the wholesalers;

e) provide for conduct of authorised activities in compliance with good distribution practice, the accuracy and quality of records, in line with standard procedures established for each type of activity;

f) prepare and maintain records of responsibility delegation;

g) have knowledge of medicinal products distributed (e.g., medicinal product classes, their marketing authorisation status, storage conditions, other specific conditions to be complied with on the market for their distribution, as appropriate) or any other non-medicinal product distributes (and related activities), able to influence medicinal product quality;

h) have knowledge of principles for quality management;

i) ensure implementation and maintenance of a quality management system;

j) hold quality and provenance documents for each medicinal product batch as well as records required to ensure traceability of distribution to the retailer.

Article 21. – Wholesalers of medicines must hold all documents, information and records of transactions with suppliers, subcontractors and other operators in the distribution chain, including written contracts required to ensure traceability of the distribution chain, of the internal transfer between its wholesale sites and distribution of each product to the retailer.

Article 22. – In order to prevent and fight counterfeiting of medicines, the wholesale authorisation holder has the following obligations:

a) establish a functional mechanism to ensure that it can act effectively in cases of suspected tampering;

b) report without delay to the competent authorities (e.g., the NAMMD, investigation bodies, customs authorities, as appropriate) all information in their possession concerning a possible falsification of medicines;

c) cooperate with all parties involved, i.e. healthcare authorities, customs authorities, investigation bodies, the prosecutor's office, healthcare professionals etc., to detect falsified medicines, investigate cases and indictment of persons responsible for the manufacture or distribution of falsified medicines.

CHAPTER III
Good Distribution Practice Certificate

Article 23. - (1) Pursuant to Article 857(13) of Law no. 95/2006, republished as amended, in case of inspections concerning authorisation of medicinal product wholesalers or for any inspection for assessment of GDP compliance, in line with regulatory provisions, the National Agency for Medicines and Medical Devices grants the Good Distribution Certificate within 90 days as of the inspection date, on condition the inspection report confirms compliance with Good Distribution Practice Rules.

(2) The Good Distribution Certificate shall be valid for no longer than 5 years as of the date of inspection.

(3) Within 6 months prior to the expiry date stipulated under (2), applicants shall submit an application to the NAMMD requesting schedule of an inspection in accordance with the form stipulated in Annex I, accompanied by the Master File provided for in Annex no. 3, the updated version of administrative documents mentioned in Article 4 (5) (in case of changes) and the status of corrective and preventive measures implemented after the previous inspection.

Article 24. – Twenty days as of registration of the application, the National Agency for Medicines and Medical Devices shall notify the applicant on status of documents submitted for conduct of the inspections, as follows:

a) For full and compliant documentation, with provisions of Article 4 (3), the applicant is notified on acceptance of the respective application for inspection as well as on inspection fee; except otherwise justified, the inspection is conducted 30 days as of fee payment confirmation, on an agreed date;

b) For incomplete documentation, the applicant is notified as to further information to be submitted to the National Agency for Medicines and Medical Devices.

Article 25. - The inspection is conducted in line with an inspection plan established by an inspector/inspectors nominated by the NAMMD; the respective plan is notified to the applicant site prior to the date of inspection.

Article 26. - The inspection for grant of the Good Distribution Certificate assesses compliance with Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015.

Article 27. - The inspection results in a list of deficiencies or an inspection report, as appropriate, to be provided to the applicant within 30 days as of the date of inspection.

a) for the list of deficiencies, within 15 days, the applicant is required to submit the proposed corrective and preventive action plan;

b) in case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan;

c) In case of unfavourable inspection reports (concluding on GDP non-compliance), the NAMMD issues a GDP Non-compliance Statement in the European format approved by the European Commission, revokes the Good Distribution Certificate and operates the relevant changes in the wholesale distribution authorisation, as appropriate; in such circumstances, after resolution of deficiencies found, the inspectee may apply for a new inspection;

d) In case of favourable inspection reports, the National Agency for Medicines and Medical Devices grants the manufacturing authorisation within 90 days as of the date of inspection.

Article 28. - The Good Distribution Certificate is issued bilingually, in the format approved by the European Commission, in two original copies, one of which is handed to the applicant unit, while the other remains with the National Agency for Medicines and Medical Devices.

Article 29. - Loss of the Good Distribution Certificate results in cancellation thereof; grant of a duplicate manufacturing authorisation is done based on the following documents:

a) application as per the form mentioned in Annex 4;

b) proof of publication of the loss in a widely circulated daily;

c) statutory declaration that no changes have been made to information allowing for initial grant of wholesale authorisation.

Article 30. - (1) Should one or several conditions for grant of the Good Distribution Certificate be found, except for the situation stipulated under 27 a), that had not been met, the National Agency for Medicines and Medical Devices shall suspend the manufacturing authorisation granted, in part or in whole, until remedy of deficiencies found or revoke the manufacturing authorisation in case deficiencies found are beyond remedy.

(2) Should the company cease its activity, Good Distribution Certificates owned shall be returned to the National Agency for Medicines and Medical Devices for cancellation and withdrawal from the EudraGMP European database.

Article 31. - (1) Wholesalers already authorised at the date of these rules entry into force shall obtain Good Distribution Certificates within 2 years.

(2) At the same time with the Good Distribution Certificate, the NAMMD issues a new wholesale authorisation according to the updated format.

CHAPTER IV

Provisions on brokers of medicinal products for human use

Article 32. - In line with Article 810(2) of Law no. 95/2006, republished as amended, brokers of medicinal products for human use shall be registered with the NAMMD.

Article 33. - (1) For registration with the NAMMD, prior to the date anticipated for start of activities, brokers shall submit to the NAMMD the form stipulated in Annex no. 5.

(2) Brokers who, on the date of these Rules entry into force, were already conducting brokering activities shall submit the application form to the NAMMD no later than 30 days as of this date.

Article 34. - The form for application for registration shall be submitted at least 30 days prior to start of activities and shall be accompanied by the following documents:

a) administrative documents:

a1) certified copy of statutes of the company (statutory act, statutes, company contract, as appropriate);

a2) certified copy of closure/resolution for company authorisation and registration;

a3) a certified copy of the registration certificate granted and issued by the Registry of Commerce, annexes included;

a4) fact-finding certificate issued 30 days prior to application submission;

a5) payment form for fee payment in two copies, filled in according to Annex no. 6;

b) technical documents:

b1) procedure on contingency plan ensuring full implementation of any medicinal product recall/withdrawal from the market;

b2) procedure on records of all brokering transactions according to Article 803 f) of Law no. 95/2006, republished as amended;

b3) procedure on resolution of complaints;

b4) procedure on notification of the NAMMD marketing authorisation holders on medicinal products found/suspected to be falsified;

b5) procedure on verification of wholesale authorisation held by the wholesaler supplying medicinal products, of the manufacturing authorisation of manufacturers/importers supplying medicinal products, of customers' wholesale/ retail distribution authorisation.

Article 35. - (1) Should the documentation submitted be found incomplete or non-compliant with provisions of Article 34, the applicant shall be notified on information to be further submitted to the NAMMD.

(2) Within 10 days as of acceptance of documentation and fee payment, the NAMMD shall enter broker's data in a public register to be made available on the NAMMD website. The NAMMD informs the broker in writing on the respective entry into the Public register of brokers of medicinal products for human use, according to the form provided in Annex no. 7.

Article 36. - (1) Further to start of operation, the NAMMD may at any time conduct announced or unannounced inspections, in line with provisions of Article 857 of Law no. 95/2006, republished as amended.

(2) Conduct of inspections at brokering sites for medicinal products is established based on risk evaluation.

3) Inspection at brokering sites pursues assessment of compliance with Guidelines on Good Distribution Practice of Medicinal Products for Human Use, approved through Order of the Minister of Health no. 761/2015.

(4) The inspection is conducted in line with NAMMD procedures for medicinal product wholesale operations.

Article 37. - (1) The inspection results in a list of deficiencies or an inspection report, as appropriate, to be provided to the applicant within 20 days as of the date of inspection.

(2) For the list of deficiencies, within 15 days, the applicant is required to submit the proposed corrective and preventive action plan.

(3) In case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan; where corrective and preventive plans are not submitted within 15 days, the deadline may be extended only once, with a similar duration.

(4) Where the corrective and preventive plan is inadequate or not submitted within 15 days, pursuant to provisions above, the NAMMD shall eliminate the respective broker from the Public register, to be re-entered only following inspection ending in favourable results.

(5) In case of unfavourable inspection reports (concluding on GDP non-compliance), after remedy of deficiencies found, the broker may apply for re-entry into the Public register, possible only following inspection ending in favourable results.

Article 38. - (1) Within 30 days, brokers shall notify the NAMMD on any changes to data published in the Public register of brokers of medicinal products for human use; no later than 10 days as of notification receipt, the NAMMD operates the respective changes accordingly.

(2) Within 30 days as of voluntary discontinuation of operations, brokers shall notify the NAMMD and submit information on the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period.

Article 39. – Annexes no. 1-7 are integral part of these rules.

ANNEX no. 1
to the Rules

To

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES
The Pharmaceutical Inspection Department

I, the undersigned, ... (Name and Surname), position ....., legal representative of …....., established in …….., address…….., telephone/fax number ……, registered with the National Trade Register under no. …….., Fiscal code no. ……, hereby apply for schedule of an inspection at the wholesale distribution site at (address)…… for the purpose of authorisation of wholesale distribution/certification of Good Manufacturing Practice.

Please find attached to the present application*) the documentation required under Order of Minister of Health no. 131/2016 on approval of Rules on authorisation of human medicinal product wholesalers Good Distribution Practice certification and registration of brokers of medicinal products for human use.

***)** The application and documentation may be submitted to the National Agency for Medicines and Medical Devices (NAMMD) either directly, or by post or by express delivery, at NAMMD address: Str. Aviator Sănătescu, no. 48 sector 1, Bucharest 011478.

Signature, stamp
. . . . . .

ANNEX no. 2
to the Rules

Application form for wholesale distribution authorisation for medicinal products for human use

(Please complete all relevant sections in this form in block capitals, legibly, using black ink)

Section 1
Application form: administrative data

1.1. Applicant's details

Authorisation number (if previously authorised):		☐
Name of the company:		☐
Name of the representative*):		☐
Address:		☐
Postal code:	☐ Telephone no.:	☐
Mobile no.:	☐ Fax no.:	☐
E-mail address:	☐	

***)** Please attach the original document attesting the quality as representative.

NOTICE: ALL INFORMATION SPECIFIED IN THE SECTION ABOVE IS MANDATORY

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

Contact name:	☐
Name of represented company:	☐
Address:	☐

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail address:

1.3. Information on invoicing address (if other than that of the authorisation holder)

Contact name:

Company:

Address:

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail address:

Section 2

Information regarding the wholesale site

2.1. Information regarding the wholesale site

Sections 2 and 3 have to be filled in for each individual distribution site required for inclusion in the authorisation

Name of the distribution site:

Address:

Postal code:

Contact name:

Telephone no.: Fax no.:

Mobile no.: ☐ ☐

E-mail address: ☐ ☐

2.2. Types of operations

□ Procurement
□ Holding
□ Delivery
□ Export
□ Other*): < please specify >
***)** If „Other", please specify:

Name of the distribution site: . . . . . Postal code: . . . . . .

2.3. Categories of products handled at the distribution site

Please check the appropriate box to product categories handled at the site

1.1 □ with authorisation for marketing in member states of the European Economic Area

1.2 □ without authorisation for marketing in member states of the European Economic Area and intended to be marketed in the European Economic Area**)

1.3. □ without authorisation for marketing in member states of the European Economic Area and intended for exportation

2. □ Products compliant with Article 806 of Law 95/2006 - Title XVIII[1]

2.1 □ Drugs and psychotropic products

2.2 □ Blood-derived medicinal products

2.3 □ Immunologicals

2.4 □ Radiopharmaceuticals (radionuclide kits included)

3. □ Medicinal gases

4. □ Products distributed within the "cold chain" (which require handling at low temperatures)

5. □ Other products: < please specify here >

1 Notwithstanding any other authorisation required in accordance with legislation in force.

****)** Article 699 of Law no. 95/2006 - Title VIII or Article 83 of Regulation (EC) no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

2.4. Medicinal product classes

Sterile forms

Dosage forms - large volume liquids	yes	no
Dosage forms - small volume liquids (e.g. eye drops)	yes	no
Dosage forms - semisolids (e.g. sterile creams and ointments)	yes	no
Other sterile products	yes	no

If „Other", please specify:

Non-sterile forms

Dosage forms - liquids (e.g. solutions, syrups, suspensions)	yes	no
Dosage forms - semi-solids (e.g. non-sterile creams and ointments)	yes	no
Dosage forms - solids (e.g. tablets, capsules, suppositories and powders)	yes	no
Other non-sterile products	yes	no

If „Other", please specify:

2.5. Activities specific to the distribution site

Please answer the questions below to indicate the types of activities you intend to conduct at the distribution site

Medicinal products not authorised for marketing are imported at this site from the European Economic	yes	no
Products from parallel imports are handled at this site	yes	no

Name of the distribution site: . . . . . Postal code: . . . . . .

2.6. Other information

The following are required for the inspectorate, which will not be included in the authorisation.

Products of animal are present at the distribution site.	yes	no

The premises are ready for inspection.	yes	no

It is your intention to operate based on a quality assurance system.	yes	no

You are familiar with provisions of the Guideline on Good Distribution Practice as regards documentation and quality control required.	yes	no

Standard Operating Procedures (SOPs) are available, as shown in the Guideline for Good Distribution Practice. Please attach a copy thereof in either paper or electronic format.	yes	no

The contracts you hold are available for inspection.	yes	no

Distribution method

Regular mail	yes	no

Delivery services	yes	no

Company transport service	yes	no

Direct customer collection	yes	no

Appropriate measures are in place for products requiring low temperatures transportation?	yes	no

Other	yes	no

If “Other”, please specify:

2.7. Distribution site equipment/facilities

On a separate sheet, please provide a brief description (ca. 500 words) of facilities available for medicinal product storage and distribution.

Section 3
Persons assigned

Please specify staff categories employed at the distribution site.

Staff	Number
Responsible person (RP)	
Alternate of the responsible person	

For each staff category listed above, please fill in one of the following sheets.

Name of the distribution site: . . . . . Postal code: . . . . . .

3.1. Responsible person

Please attach a relevant CV for the proposed Responsible Person; the assignation of the responsible person must be signed by both the nominee and the applicant.

Surname:

First name

Office address:

Postal code: Telephone no.:

Fax no.: Mobile no.:

E-mail

Qualifications (relevant for authorisation):

Experience (brief outline of positions and responsibilities relevant for authorisation purposes)

Association with professional bodies:

To the best of my knowledge and belief, the particulars above are correct, truthful and complete. I agree with my assignation as Responsible Person.

Signature (of the person assigned): . . . . . .
Date: . . . . . .
Full name: . . . . . .
Signature of the applicant: . . . . . .
Date: . . . . . .

Name of the distribution site: . . . . . Postal code: . . . . . .

3.2. Alternate of the responsible person

Please attach a relevant CV for the alternate of the proposed Responsible Person; assignation of the responsible person must be signed by both the nominee and the applicant.

Surname:			
First name			
Office address:			
Postal code:		Telephone no.:	
Fax no.:		Mobile no.:	
E-mail			

Are you a pharmacist?	yes no
Are you a physician?	yes no

Qualifications (relevant for authorisation)

Experience (brief outline of positions and responsibilities relevant for authorisation purposes)

Association with professional bodies:

To the best of my knowledge and belief, the particulars above are correct, truthful and complete. I agree with my assignation as Responsible Person**.**

Signature (of the person assigned): . . . . . .
Date: . . . . . .
Full name: . . . . . .
Signature of the applicant: . . . . . .
Date: . . . . . .
Name in full: . . . . . .

Name of the distribution site: . . . . . Postal code: . . . . . .

Section 4
Comments

Please provide any other information that may support your application. You can also detail any changes to addresses, persons assigned etc.

Section 5
Statement

I hereby apply for grant of a Wholesale Distribution Authorisation to the proposed holder named in this application form in respect of the activities to which the application refers.

5.1. The activities are to be in accordance with the information set out in the application or furnished in connection with it.

5.2. To the best of my knowledge and belief, the particulars I have given in this form are correct and complete.

Signature of the applicant: . . . . . .
Date: . . . . . .
Full name: . . . . . .
Quality of the signatory: . . . . . .

ANNEX no. 3
to the Rules

MASTER FILE
of the wholesale site

This form is designed so as, by completion by the applicant, to provide information on procurement, holding, delivery and/or export operations carried out at the distribution site to be inspected. If any of the above operations is not conducted at the distribution site, the master file shall only be filled in for operations actually conducted, e.g. storage only.

FORM no. 1: COMPANY INFORMATION

1. GENERAL INFORMATION
1.1. Brief overview of the company
1.1.1. Company name, as registered by the legal authority
1.1.2. Postal address.
1.1.3. Telephone and fax numbers (24/24) and permanent e-mail address to contact the Responsible Person or their alternate in case of batch withdrawal.
1.1.4. Number and date of the latest wholesale authorisation.
1.1.5. Other authorisations held. Please specify the number, date and name of issuing authority for each authorisation.
2. RELEVANT ACTIVITIES FOR THE COMPETENT AUTHORITY
Please tick where appropriate:

Products distributed	Percentage of commercial units distributed		Allocation of distribution depending on beneficiary type (%)	
	In Romania	In other countries	Pharmacies	Wholesalers
Medicinal products for human use				
Other products*)				

***)** If "Other products", please specify.

3. COMPANY DISTRIBUTION SITES
Please fill in the table below:

Name of the distribution site	Address	Telephone/Fax number	Authorised activities

FORM no. 2: INFORMATION CONCERNING THE DISTRIBUTION SITE

Note:
Please fill in a Form no. 2 for each distribution site.

CHAPTER 1
GENERAL INFORMATION

1.1. Brief overview on 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 Agency for Medicines and Medical Devices or by other authorities (in the latter case, please specify the authority and scope of authorisation, indicating whether it is the same or different from the one described in the application).

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

1.3. Any other type of operations conducted at the distribution site.

Both pharmaceutical and non-pharmaceutical activities should be described.

1.4. Type of products handled at the distribution site and information on the handled medicinal products containing toxic and dangerous substances, specifying the manner of handling and cautions taken.

1.4.1. Specify the type of medicinal products handled, specifying whether these are handled based on a contractual agreement with a contract provider (e.g. radiopharmaceuticals).

1.4.2. Note any toxic, dangerous, highly sensitizing substances handled, e.g. antibiotics, hormones, cytostatics. Specify whether special cautions are taken for such products.

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

(Please do not exceed 250 words on an A4 sheet)

1.5.1. Provide a map of the site and surrounding areas. Please label the site, describe the surrounding area and activities conducted in the neighbourhood.

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

1.5.3. Other activities performed at the distribution site.

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

Note:

Include both part-time and full-time employees

1.6.1. Administration

1.6.2. Storage

1.6.3. Distribution

1.6.4. Shipment

1.6.5. Technical support services

1.6.6. Total number of employees

1.7. Contract-based activities, contract-based operations (if any, see Chapter 8 for more details)

For each contract beneficiary (including shipment 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 conducted (in less than 100 words or half of an A4 sheet).

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

(Please do not exceed 750 words or 3 A4 sheets)

1.8.1. Description of the company's quality policy.

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

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

1.8.4. Please describe: how are outcomes analysed in order to demonstrate that the quality system is adequate in relation to its objectives, e.g. product quality and integrity (see also Chapter 7).

1.8.5. Please specify whether standards such as ISO 9000 are employed by the company.

CHAPTER 2
STAFF

2.1. Organisational chart including key-persons

The organisational chart for key-functions, as approved. Please mention the heads and supervisors only.

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

2.2.1. Brief description of higher education competences, specialisations for the activity performed and years of experience in the field of persons appointed in the organisational chart

2.2.2. Position descriptions of the key-staff

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

Provide brief details concerning the training programme and include training received upon hiring as well as ongoing training, as follows:

2.3.1. Describe the manner of how training requirements are identified and by whom.

2.3.2. Provide details concerning specific Good Distribution Practice training.

2.3.3. Please declare the manner of training, e.g. internal, external, type of practical training and staff involved.

2.3.4. Please explain the manner of assessment of the training efficacy, e.g. via questionnaires.

2.3.5. Explain how retraining needs are identified.

2.3.6. Specify whether you hold records of performed trainings.

CHAPTER 3
SITES AND FACILITIES

3.1. Simple plans of the site and description of the storage area.

3.1.1. Submit a plan of the site, indicating all storage areas and other operational areas.

3.1.2. Describe measures taken to prevent unauthorised access.

3.1.3. Submit a simple plan for each area, indicating the scale. Specify the destination for each area (e.g. reception, storage, recalled products, expedition, for medicinal products with special storage conditions).

Note:

The plans should be legible, on an A4 sheet. If deemed necessary, plans can be sent on an A3 sheet.

3.2. Brief description of the ventilation systems (maximum 500 words on two A4 sheets). Please provide more details for critical areas where special storage conditions are ensured.

Note:

Diagrams should be used in order to reduce the text.

3.2.1. Design criteria (e.g. specifications for the air provided, temperature, humidity).

3.3. Special areas for handling extremely toxic, dangerous and sensitising materials.

Use the same plan as the one under point 3.1 above in order to describe the special areas for handling extremely toxic, dangerous and sensitising materials.

3.4. Maintenance (description of preventive maintenance and registration system programmes).

3.4.1. Describe the planned preventive maintenance programme.

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

3.4.3. Are there written procedures and detailed contracts available on contracted activities?

3.4.4. Are there written procedures and adequate registration forms available for maintenance (contract beneficiaries included)? Do those documents specify the type/frequency of checks, details of the activity, rehabilitation and changes?

3.4.5. Are there routine maintenance activities identified, which could affect product quality?

3.4.6. Are reports sent to users?

3.5. Written specifications and procedures in place for area cleaning.

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

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

3.6. Policy for storage of materials.

3.6.1. How are materials with different status (e.g. quarantine, refused, approved etc.) separated and controlled (e.g. computer, labels)?

3.6.2. How are materials stored, e.g. on pallets?

3.6.3. Please describe the storage conditions for narcotic drugs and psychotropic substances, if required.

3.6.4. Describe the plan for insect and other pest prevention.

CHAPTER 4
STOCK HANDLING AND CONTROL

4.1. Registration systems for distribution activities

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

- types of checks performed with materials
- is the delivery order compliant with the "first in - first out" (FIFO) principle and does it identify the batch number?
- which are the methods of distribution to the customers?

4.1.2. Distribution records

Do records kept ensure full traceability from plant to customer as regards date of marketing, customer details and delivered amounts?

4.1.3. Stock inventory procedure. Please provide information on the manner of inventory performance and its frequency.

4.2. Delivery and shipment

4.2.1. Describe how security, storage and safety conditions are ensured in order to maintain material quality during shipment.

4.2.2. Describe your vehicles:

a) number of vehicles and their capacity

b) are these dedicated vehicles?

c) are these vehicles adapted for shipment of medicinal products or other special products (e.g. products requiring low temperatures, radioactive products)?

d) how are transportation routes planned?

CHAPTER 5
DOCUMENTATION

5.1. Preparation, revision and distribution of required documentation as well as maintenance of starting documents

5.1.1. Is there a description of the documentation system?

5.1.2. Who is responsible for preparation, revision and distribution of documents?

5.1.3. Where are starting documents stored?

5.1.4. Are there any instructions and standard formats for document set-up?

5.1.5. How is the documentation controlled?

5.1.6. How long are documents stored?

5.1.7. Please provide details on the manners of registration in electronic format or microfilm.

5.2. Any other documents related to product quality which are not mentioned elsewhere

Are the following documents available and used?

5.2.1. Training procedures

5.2.2. Specifications for software:

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

b) monitoring of all entries and amendments ("audit trail") and frequency of verifications

c) data saving procedures

5.2.3. Control of the documentation

5.2.4. Calibrating of used tools

5.2.5. List and briefly explain the use of any other standard documentation usually employed.

CHAPTER 6
COMPLAINTS AND PRODUCT RECALL

6.1. Measures for handling complaints and product recalls

6.1.1. Complaints

6.1.1.1. Is there a written procedure on product complaints?

6.1.1.2. Who is responsible for:

a) registration

b) classification

c) investigation of complaints

6.1.1.3. Are written reports drafted?

6.1.1.4. Who checks these reports?

6.1.1.5. How long are the records of complaints kept?

6.1.2. Product recall

6.1.2.1. Is there a written procedure describing the sequence of actions to be conducted, including:

a) the list of distribution of the concerned product

b) notification of customers

c) reception/separation/inspection of returned goods

d) investigation/reporting of the cause

e) the reporting of corrective actions

6.1.2.2. Who is responsible for recalls?

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

6.1.2.4. Is the NAMMD involved in making the decision for recall?

6.1.2.5. Can retail be performed up to the level of retail distributor?

6.1.3. Falsified products

6.1.3.1. Is there a procedure for detection, reporting (to the NAMMD) and quarantine of falsified products?

CHAPTER 7
SELF INSPECTIONS

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

7.1.1. Describe the manner of assessing the activities impacting product quality through self-inspection.

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

7.1.3. Are self-inspection results documented, brought to the attention of staff responsible for the inspected area/activities?

7.1.4. Do the responsible persons for the area/activity manage to timely implement the proposed corrective actions for deficiencies found?

CHAPTER 8
CONTRACT ACTIVITIES

8.1. Describe the manner of assessing compliance of the contract beneficiary with the GDP or other adequate standards

8.1.1. Briefly describe details of technical contracts between the supplier and the contract beneficiary and the manner of assessing compliance of the contract beneficiary with the GDP or other adequate standards. Selected standards should be assessed as regards their applicability. The types of activities conducted by the contract beneficiary must be specified.

ANNEX no. 4
to the Rules

To

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
The Pharmaceutical Inspection Department

I, the undersigned, ... (Name and Surname), position ……, legal representative of …....., established at……..……. (address)……., telephone/fax number ……., registered with the National Trade Register Office under no . . . . . , fiscal code no ……, in accordance with Order of the Minister of Health no. 131/2016 on approval of Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use, hereby apply for release of a duplicate wholesale distribution authorisation/Good Distribution Certificate. We hereby attach the notification of loss of the wholesale distribution authorisation/ Good Distribution Certificate in the daily . . . . . .

Signature,
stamp
. . . . . .

ANNEX no. 5
to the Rules

Form for request of registration of brokers of medicinal products for human use

(Please complete all relevant sections in this form in block capitals, legibly, using black ink)

1. Applicant's details:
Name of the company:
Registration no. with the National Trade Register:
Applicant's permanent legal address:
Telephone number:
Fax number:
E-mail address:
Contact person:
Address of the site where brokerage activities are performed:
Telephone number:
Fax number:
E-mail address:
Contact person:

2. Statement

I hereby apply for registration of the aforementioned broker.

2.1. I hereby confirm that medicinal products are subject to a marketing authorisation granted through the centralised procedure or by the National Agency for Medicines and Medical Devices in accordance with provisions of Law 95/2006 on healthcare reform, republished as amended.

2.2. I hereby confirm I have prepared an emergency plan to ensure effective implementation of any withdrawal from the market, requested by the National Agency for Medicines and Medical Devices or conducted in cooperation with the manufacturer or, as appropriate, with the wholesale distributor or with the Marketing Authorisation Holder for the product.

2.3. I hereby confirm to hold a system which allows storage of evidence either as purchase invoices, in electronic or any other format, providing for any brokerage transaction at least the following information: date, product name, name and country of origin of the manufacturer, manner of presentation, pharmaceutical form, concentration of active substances, packaging size, batch and sate of expiry, quality certificate and analysis bulletin, as appropriate, quantity received, supplied or subject to brokerage, name and address of the supplier/beneficiary, as appropriate, as well as the product batch.

2.4. I hereby confirm that the evidence mentioned in point 2.3 shall be kept for at least 5 years.

2.5. I hereby confirm that c0mpliance with requirements for brokers set up in the Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015.

2.6. I hereby confirm that I have implemented and hold a quality system specifying the responsibilities, processes and risk management measures related to activities performed.

2.7. I am aware of the requirement of the National Agency for Medicines and Medical Devices concerning immediate notification of the NAMMD and, as appropriate, of the Marketing Authorisation Holder concerning medicinal products presented, which I find/suspect to be falsified.

2.8. To the best of my knowledge, the particulars I have given in this form are correct and complete.

I shall notify any amendment of the information above to the National Agency for Medicines and Medical Devices.

Signature of the applicant:. . . . . .
Full name:. . . . . Date:. . . .
Quality of the signatory:

ANNEX no. 6
to the Rules

FORM FOR PAYMENT OF THE FEE FOR REGISTRATION IN THE REGISTRY OF BROKERS OF MEDICINAL PRODUCTS FOR HUMAN USE

Name of the broker

Address of the broker	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Name of the paying company	
Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	
Fiscal code:	
Number introduced at the Registry of commerce	
IBAN account:	
Bank:	

Service billed: registration in the Registry of brokers of medicinal products for human use

Person de contact

Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Fiscal code:

According to the signatories, the particulars given in this form are correct.
Date. . . . . .

Broker
Name, signature, stamp

ANNEX no. 7
to the Rules

Public Registry of brokers of medicinal products for human use

No.	Registration no.	Date of registration	Broker	Permanent legal address