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National Agency of Medicines and Medical Devices

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ORDERS OF THE MINISTER OF HEALTH

DECISIONS OF THE NMA SCIENTIFIC COUNCIL

MINISTRY OF HEALTH

ORDER

for supplementations of the Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances, approved through Minister of Health Order No. 312/2009

On seeing the common report for approval No. Cs. A. 13.119/15.12.2010 of the Medicinal Product Policy Directorate,

Taking into account:

- the provisions of Law No. 95/2006 on healthcare reform, as amended,
- Government Decision No. 734/2010 on organisation and functioning of the National Agency for Medicines and Medical Devices,

based on Government Decision No. 144/2010 on organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. I. – The Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances, approved through Minister of Health Order No. 312/2009, published in the Official Gazette of Romania, Part I, No. 198 and 198 bis of 30 March 2009, is amended as follows:

1. Under Art. 26 (1), a new paragraph is introduced after h), namely i), which reads as follows:

"i) for medicinal products centrally authorised in the European Union – based on the import authorisation and on the European Commission decision."

2. Under Art. 26 (2), a new paragraph is introduced after k), namely l), which reads as follows:

"l) for nationally authorised medicinal products in Romania – based on the wholesale distribution authorisation and the marketing authorisation released by the National Agency for Medicines and Medical Devices."

Art. II. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,

Cseke Attila

Bucharest, 14 January 2011.
No. 29.

DECISION
No. 16/27.11.2009

on amendment of the Regulations regarding marketing authorisation and supervision of medicinal products for human use, approved through SCD No. 11/31.03.2006

The Scientific Council of the National Medicines Agency
set up based on Order of the minister of health No. 1027/22.05.2008, reunited on summons of the National Medicines Agency President in the ordinary meeting of 27.11.2009 in accordance with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended, agrees on the following

DECISION

Art. 1. – The amendment of the Regulations regarding marketing authorisation and supervision of medicinal products for human use is approved, according to the Annexes which are integral parts of this decision.

Art. 2. – The present decision is to be approved through order of the minister of health and shall be published in the Official Gazette of Romania, Part I.

Art. 3. – On the date of the entry into force of this decision, NMA Scientific Council Decision No. 11/31.03.2006 is amended, approved through Minister of Public Health Order No. 895/20.07.2006.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,
Acad. Prof. Dr. Victor Voicu

MINISTRY OF HEALTH

ORDER
on amendment of the Annex to the Minister of Public Health Order No. 895/2006 on approval of the Regulations regarding marketing authorisation and supervision of medicinal products for human use

On seeing the approval report of the Direction on drug policy Cs. A. No. 12.388 of 24 November 2010,

Taking into account:

- the provisions of Title XVII „The Medicinal Products" of Law No. 95/2006 on healthcare reform, as amended;

- Government Decision No. 734/2010 related to the set up and functioning of the National Agency for Medicines and Medical Devices,

based on Government Decision No. 144/2010 on the organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. I. – The Annex to the Minister of Public Health Order No. 895/2006 on approval of the Regulations regarding marketing authorisation and supervision of medicinal products for human use, published in the Official Gazette of Romania, Part I, No. 660 of 1 August 2006, is amended and replaced with the Annex, which is integral part of this Order.

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

Minister of health,

Cseke Attila

Bucharest, 24 November 2010.
No. 1.448.

ANNEX
(Annex to Order No. 895/2006)

REGULATIONS
regarding marketing authorisation and supervision of medicinal products for human use

CHAPTER I
Overview

Art. 1. - (1) Present regulations have been set up in application of Chapter III "Placing on the Market" and Chapter X "Pharmacovigilance" of Title XVII "The Medicinal Product" of Law 95/2006 on Healthcare reform, as amended.

(2) These regulations are applicable in case of applications submitted through national procedure.

(3) Likewise, these applications are applicable to medicinal products for human use authorised through the mutual recognition and the decentralized procedure, taking into account the specific information related to the procedures detailed in Chapter IV.

Art. 2. - Following Romania's accession to the European Union, no medicinal product may be placed on the market unless a marketing authorisation has been issued by the National Agency for Medicines and Medical Devices in accordance with these Regulations provisions or an authorisation has been granted according to the centralised procedure.

Art. 3. - The marketing authorisation is granted by the National Agency for Medicines and Medical Devices to medicinal products for human use that meet quality, safety and efficacy requirements provided in Article 702 of Law 95/2006, as amended.

Art. 4. - The National Agency for Medicines and Medical Devices authorises for placement on the market medicinal products for human use as defined in Article 695 1, 3, 4, 5, 9, 30 and 31 of Law 95/2006, as amended.

Art. 5. - Marketing authorisations can only be granted to an applicant established in Romania (a company formed in accordance with the Romanian law, having its registered office, central administration or principal site of business within Romania) or any other European Union Member State (a company formed in accordance with the law of a Member State and having its registered office, central administration or principal place of business within the European Community).

Art. 6. – The National Agency for Medicines and Medical Devices decides on dossier admissibility as well as on granting, modification, suspension or withdrawal of a marketing authorisation for a medicinal product for human use, in line with present Regulations provisions.

Art. 7. - Depending on needs, the National Agency for Medicines and Medical Devices may require external experts for evaluation of the chemical-pharmaceutical and biological, pharmacotoxicological or clinical dossier, in view of marketing authorisation.

CHAPTER II
Submission of applications for marketing authorisation

Art. 8. - (1) To commence marketing authorisation procedures for a medicinal product for human use, the Applicant must submit to the National Agency for Medicines and Medical Devices an application in the form shown in Annex 1.

(2) The application for marketing authorisation shall be submitted together with documents and information mentioned under Article 702 (4) and (5) of Law 95/2006 and as outlined in the Annex to Order of the Minister of Public Health No. 906/2006 for approval of analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products, as amended (transposing Directive 2003/63/EC of 25 June 2003, amending Directive 2001/83/EC of the European Parliament and Council of 6 November 2001, on the Community code relating to medicinal products for human use).

(3) In the case of a radionuclide generator, the application for marketing authorisation shall also contain information and details mentioned in Article 703 of Law 95/2006, as amended.

Art. 9. - In line with cu provisions of Title XVII "The Medicinal Product" of Law 95/2006, as amended, the following types of applications for marketing authorisation may be submitted:

a) Application for marketing authorisation based on its own complete documentation including administrative particulars and information on quality, safety and efficacy ("independent" application = "stand-alone" application).

Documents in support of this type of application for marketing authorisation are as mentioned in Article 8 (2) and (3);

b) Applications for marketing authorisation not requiring self–conducted toxicological, pharmacological and clinical studies.

The applicant shall not be required to provide the results of self–conducted pre-clinical and clinical trials if he can demonstrate that:

1. The medicinal product is a generic of a reference medicinal product as outlined in Article 704 (1) and (2) of Law 95/2006, as amended (application for generic medicinal products);

2. The medicinal product contains one or several active substances with well-established medical use, according to Article 705 of Law 95/2006,as amended ("bibliographic" application for medicinal products with well-established medical use);

3. The marketing authorisation holder of a reference medicinal product allows the manufacturer use to be made of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications, according to Article 707 of Law 95/2006, as amended (informed consent application);

c) Applications for marketing authorisation requiring provision of preclinical tests and clinical trial results according to the status of the medicinal product:

1. The medicinal product does not belong to the category of generic medicinal products according to Article 704 (2) b) of Law 95/2006, as amended ("combined" application);

2. Biological medicinal product similar to a reference biological medicinal product not meeting conditions in the definition of generic medicinal products, according to Article 704 (4) of Law 95/2006, as amended (application for Similar biological medicinal product);

3. Medicinal products care containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, according to Article 706 of Law 95/2006, as amended (application for a fixed combination);

4. Traditional herbal medicinal products according to Article 714 of Law 95/2006, as amended (application for traditional herbal medicinal products);

5. Homeopathic medicinal products according to Article 710 of Law 95/2006, as amended; (application for homeopathic medicinal products – the applicant submits to the National Agency for Medicines and Medical Devices an application in the form provided in Annex 2).

Art. 10. - (1) Together with the dossier mentioned under Article 8 (2), the applicant also has to submit detailed expert reports in line with Article 709 of Law 95/2006, as amended, and Module 2 "Summaries" of the Annex to Minister of Public Health Order No. 906/2006, as amended.

(2) According to their professional qualification and experience, experts shall:

a) Provide detailed reports including their observations on the chemical, pharmaceutical and biological documentation (Module 3), nonclinical documentation (Module 4) and clinical documentation (Module 5), provided in the Annex to the Minister of Public Health Order No. 906/2006, as amended, with objective outline of qualitative and quantitative results;

b) Provide observations in line with provisions of Module 2 "Summaries" of the Annex to Minister of Public Health Order No. 906/2006, as amended;

c) When needed, specify reasons for the use of bibliographic data mentioned under Article 9 (1) b), 2.

Art. 11. - (1) For medicinal products containing chemical entities, the marketing authorisation application should be accompanied by the mock-ups of the packages; samples of finished products, exposed in the packages which are to be marketed or in their mock-ups (or in packages authorised in the country of origin and exposed in an internationally spoken language) may be requested throughout the assessment procedure, as well as the starting materials, waste products or other components, if required.

(2) For biological medicinal product, the application for marketing authorisation shall be accompanied by the necessary number of samples in line with the quality specification for full analysis as well as the summary of batch protocol.

(3) In accordance with provisions of Article 724 b) of Law 95/2006, as amended, the evaluator or the Marketing Authorisation Commission may request check of the control methods used by the manufacturer and outlined in quality specifications. If need be in such cases, the applicant shall provide the following for laboratory testing: samples of the finished medicinal product presented in the package it is to be marketed or in mock-up packages, in quantities allowing for verification of the methodology described in the chemical, pharmaceutical and biological particulars accompanying the application, its starting material/s, its intermediate products or other constituent materials; should the medicinal product be presented in several package sizes, laboratory testing shall be performed on the smallest pack size of the medicinal product.

(4) During the assessment procedure of the dossier, the National Agency for Medicines and Medical Devices may request the performance of an inspection at the manufacturing site(s), another inspection at the site(s) of performance of preclinical and/or clinical tests and/or another one at the site of the MAH or his/her representative, in view of checking compliance with the requirements and compliance of the pharmacovigilance system by the inspectors of the Pharmaceutical Inspection Department of the National Agency for Medicines and Medical Devices.

Art. 12. - An individual application for marketing authorisation shall be submitted for each different pharmaceutical form and strength of a medicinal product, presented under the same name.

Art. 13. - (1) The dossier in view of marketing/renewal authorisation should be forwarded via e-mail or presented in electronic format (CD/DVD), modules I - V, and in written form, signed in original, the authorisation application and the letter attached to the authorisation dossier (single copy only).

(2) In case of submitting the dossier in an electronic format, the applicant should submit an affidavit concerning the compliance of the existing data in electronic format with the original documentation.

Art. 14. - Documentation shall be presented strictly according to the Annex to Minister of Public Health Order No. 906/2006, as amended – in the format of the Common Technical Document.

Art. 15. - The documentation may be submitted in Romanian, English or French.

Art. 16. - (1) The marketing authorisation fee provided under Article 854 of Law 95/2006, as amended, as well as authorisation Tariffs established through decision of the Administration Council of the National Medicines Agency, approved through Order of the Ministry of Public Health and published in the Official Gazette of Romania, Part I, are to be paid in line with payment norms of the National Agency for Medicines and Medical Devices.

(2) When check of control methods has been necessary, the tariffs for laboratory testing established through decision of the Administration Council of the National Agency for Medicines and Medical Devices, approved through Minister of Health Order and published in the Official Gazette of Romania, Part I, are to be paid after completion of laboratory testing in question.

(3) If the case may be, the authorisation tariff is regulated at the end of the evaluation procedure.

CHAPTER III
Marketing Authorisation Procedure

Art. 17. - Applicants submit to the Data and document management, the Registry – document distribution and release Bureau of the Information Logistics and Electronic Management of Data Department, the payment form, the authorisation dossier and materials mentioned in Chapter II, according to the type of medicinal product for which authorisation is requested.

Art. 18. – The Registry – document distribution and release Bureau checks whether all required documents are in place, arranged in the requested order and whether requested finished product samples have been submitted, if needed.

Art. 19. – Should documentation and materials submitted not comply with present regulations, the application for marketing authorisation is rejected and the reason thereof is entered in the admissions register.

Art. 20. - (1) After payment of the authorisation tax and tariff and confirmation by the Economic Department of payment as stipulated under Art. 16 (1), the Data and document management service forwards the authorisation application and dossier to the Administrative Verification and Product Index Bureau and to the National Procedure Administrative service of the National Procedure Department, in view of validation within 30 days.

(2) If the submitted dossier is available, it is distributed to the assessment services of the National Procedure Department, the European Procedure Department or, for biological products, to the Biological Product Evaluation and Control Department.

(3) If, throughout the validation stage of the dossier, it is discovered that it must be supplemented with several administrative and technical documents/information which have not been identified on the date of application submission, the list containing the requirements needed in view of the validation of the authorisation dossier shall be granted.

(4) The authorisation dossier forwarded to the National Agency for Medicines and Medical Devices is considered validated only after the receipt of all required documents and after their assessment.

(5) The applicant shall be informed that the application has been validated from an administrative viewpoint and thus enters the 210-day period stipulated in Art. 722 of Law No. 95/2006, as amended, in view of assessment of the documentation concerning the release of the marketing authorisation.

Art. 21. - The National Procedure Department, the European Procedure Department or, for biological products, the Biological Product Evaluation and Control Department examines whether the documentation submitted is compliant with provisions of Articles 702, 703, 704, 705, 706 and 707 of Law 95/2006, as amended, and whether all the conditions for granting a marketing authorisation are satisfied.

Art. 22. - Should the submitted dossier be incomplete, the time mentioned under Article 20 (5) is suspended before additional information is provided by the applicant as requested by the National Agency for Medicines and Medical Devices.

Art. 23. - The authorisation dossier evaluation process results in issuance of a final report with recommendation for authorisation or a final report with recommendation for rejection of authorisation.

Art. 24. - (1) If the assessor/marketing authorisation committee have requested the check-up of the control methodology within the authorisation procedure, in accordance with Art. 11 (3), the control departments of the National Agency for Medicines and Medical Devices initiate the analysis of the control methodology described in the dossier; if there's any lack or misunderstanding, a supplementation address is sent to the applicant containing all requirements of the Control Department referring to the methodology and number of samples, reference substances, impurities, waste needed in laboratory control 30 days from the date of repartition of the dossier to the control departments. The period stipulated in Art. 20 (5) is suspended until the assessor/marketing authorisation committee provides the outcomes and conclusions related to control methodology.

When laboratory testing is requested in the authorisation procedure according to Article 11 (3), control departments check the control methodology outlined in the documentation; in case of deficiencies and ambiguities, within 30 days as of distribution of documentation to control departments, the applicant is addressed a request for supplementation of particulars provided specifying all requirements from the control department related to methodology and the number of samples, reference substances, impurities, degradation products required for laboratory testing.

(2) Exception to this provision is the influenza vaccine under authorisation/renewal procedure, for which check of control methodology and samples shall be organised in such a way as to perform testing in maximum 60 days as of their submission.

Art. 25. - After issuance, complete evaluation reports together with results of laboratory testing if the case may be, are presented in meetings of the Marketing Authorisation Commission, which decides on grant of the marketing authorisation.

Art. 26. – After the draw up of a favourable opinion of the Commission for marketing authorisation and confirmation granted by the Economic Department related to the payment of all due sums required by the authorisation procedure, in accordance with Art. 16 (1) and (2), the marketing authorisation and the 5 annexes are set up by the Registry – document distribution and release Bureau from the Information Logistics and Electronic Management of Data Department and by the Medical Information Bureau from the National Procedure Department.

Art. 27. - The marketing authorisation includes identification data of the medicinal product (registration name, composition, marketing authorisation holder or manufacturer, as the case may be, manufacturers responsible for finished medicinal product batch release, ATC classification, release, packaging, shelf life, storage conditions, marketing authorisation number) and is accompanied by 5 annexes: leaflet, summary of product characteristics, information on labelling, qualitative and quantitative composition, data on medicinal product manufacturing.

Art. 28. - (1) Medicinal products authorised for marketing in Romania are entered in the Register of medicinal products authorised in Romania.

(2) The marketing authorisation number must be inscribed on the outer packaging of the medicinal product; the number is made up of 3 groups of figures, standing for:

a) marketing authorisation number;

b) year of authorisation;

c) number corresponding to authorised types of packaging.

Art. 29. - In the case of influenza vaccine, documentation shall be yearly updated in line with the recommendations of the World Health Organisation on circulating strains in the respective season; documentation also includes presentation of clinical trials demonstrating medicinal product efficacy for the current season and is submitted at a date prior to submission of samples for testing.

Art. 30. – As stipulated in Art. 730 (10) of Law No. 95/2006 on healthcare reform, as amended, the dossier remains in the possession of the National Agency for Medicines and Medical Devices and is recorded by the Archive Service of the General Administration Department. In circumstances such as provided under Article 730 (10) of Law 95/2006 on healthcare reform, as amended, documentation is returned on applicant request.

CHAPTER IV
Marketing authorisation of medicinal products authorised through mutual recognition, or decentralised procedures

Art. 31. - (1) In case of marketing authorisation applications sent through mutual recognition/decentralised procedure, the specific provisions stipulated in section 5, Title XVII – The medicinal product of Law No. 95/2006, as amended, the NAMMD guidelines on the handling of marketing authorisation applications through mutual recognition and decentralised procedure, as well as the guidelines of the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human, CMD(h) are applied; these can be accessed online, on the website of the body called ,,Heads of Medicines Agencies": http://www.hma.eu.

(2) Information on the manner of display of the dossier and samples, of the number of copies of each CTD module (Common Technical Document) can be found in Chapter 7 of Volume 2A Notice to Applicants, published on the website of the European Commission - www.ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev 1.htm.

CHAPTER V
Refusal of application for marketing authorisation

Art. 32. - The National Agency for Medicines and Medical Devices may refuse an application for marketing authorisation of a medicinal product, in line with cu provisions of Article 732 of Law 95/2006, as amended.

Art. 33. - In the case of an unfavourable opinion of the marketing authorisation commission of the National Agency for Medicines and Medical Devices, the applicant is notified in writing on rejection of the application for marketing authorisation; refusal is accompanied by a report justifying the decision based on conclusions of evaluation reports.

Art. 34. - Within 30 days as of receipt of the refusal report, the applicant may send the National Agency for Medicines and Medical Devices an appeal that has to be accompanied by detailed justification in its support.

Art. 35. - Within 90 days as of receipt of the appeal and justifying documents, the National Agency for Medicines and Medical Devices must respond on its resolution of the appeal; the solution may be disputed and subjected to administrative law.

CHAPTER VI
Marketing authorisation renewal

Art. 36. - The marketing authorisation may be renewed on application by the marketing authorisation holder.

Art. 37. - (1) In line with Article 730 (2) of Law 95/2006, as amended, the application for marketing authorisation renewal is submitted to the National Medicines Agency 6 months prior to expiry of previous authorisation.

(2) The applicant submits to the National Agency for Medicines and Medical Devices an application for renewal of the marketing authorisations for medicinal products for human use, whose mock-up is stipulated in Annex 3, the payment form of the tax and tariff corresponding to the product type, the consolidated version of the quality, safety and efficacy dossier, including any variation occurred from the grant of authorisation.

(3) In addition to previously mentioned documents and materials, the dossier of adverse reactions reported during the previous 5 years, namely the Periodic Safety Update Report (PSUR) is submitted to the National Agency for Medicines and Medical Devices.

(4) The applicant shall present the documents mentioned in the application for marketing authorisation renewal.

Art. 38. - (1) The steps of the renewal procedure of the authorisation are the same as those mentioned in Chapter III. The assessment of the dossier submitted by the applicant for the renewal of the marketing authorisation is assessed by the National Procedure Department and, for biological medicinal products, by the Biological Product Evaluation and Control Department, except for pharmacovigilance data (PSURs) for synthesis products authorised through national procedure, assessed by the European Procedure Department.

(2) Depending on expiry date of the marketing authorisation granted before entry into force of Law no. 95/2006, as amended, the marketing authorisation holder must apply for its renewal as provided in Article 37 (2).

(3) Following marketing authorisation renewal, the manufacturer/holder must see to the enforcement of the previsions mentioned in Article 728 of Law 95/2006, as amended.

(4) Once renewed, based on the provisions of Art. 730 (5) of law No. 95/2006, as amended, the marketing authorisation is available for an unlimited period, except for the circumstances stipulated by the Law.

CHAPTER VII
Marketing authorisation suspension and withdrawal

Art. 39. - In case of risk to public health, the National Agency for Medicines and Medical Devices may, on Minister of Public Health request or by referring the matter to itself, suspend or withdraw the marketing authorisation of a medicinal product for human use.

Art. 40. - (1) In line with cu Article 828 and 830 of Law 95/2006, as amended, the National Agency for Medicines and Medical Devices shall suspend, withdraw or amend a marketing authorisation of a medicinal product for human use in case of proof of the following:

a) The medicinal product is harmful under normal conditions of use;

b) The medicinal product lacks therapeutic efficacy;

c) The risk-benefit balance is not positive under the normal conditions of use;

d) The medicinal product qualitative and quantitative composition is not as declared;

e) Particulars supporting the application as provided for in Article 702 or Articles 704, 705, 706, 707 and 708 of Law 95/2006 are incorrect or have not been amended in accordance with Article 29;

f) Controls carried out on the medicinal product and/or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Article 702 (4), i) of Law 95/2006;

g) One of the requirements laid down in Article 749 of Law 95/2006, as amended, ceases to be met.

(2) Discontinuance ceases when the issues underlying the respective decision have been solved, and the marketing authorisation commission decides upon the cancellation of the imposed measure.

After 3 suspensions of the marketing authorisation, generated by circumstances legitimating its suspension, the marketing authorisation may be withdrawn.

Art. 41. - Marketing authorisation may be also withdrawn in result of request by the medicinal product manufacturer or respective marketing authorisation holder.

Art. 42. – After communication to the Ministry of Health and, on a case-by-case basis, to the National Health Insurance House of the NAMMD decision on the change, cancellation or withdrawal of the marketing authorisation, this shall equally be communicated to the Marketing Authorisation Holder.

CHAPTER VIII
Supervision of medicinal products for human use

Art. 43. - (1) The National Agency for Medicines and Medical Devices monitors whether the efficacy, safety and quality of medicinal products for human use are confirmed in therapeutic use after authorisation for marketing. To this end, the National Agency for Medicines and Medical Devices shall:

a) Check up the distribution chain via the inspection activity of the Pharmaceutical Inspection Department in view of assessing the quality of medicinal products which have been authorised for marketing in Romania (sampling and control of local samples, settlement of complaints, rapid alerts etc.);

b) Receive, through the National Pharmacovigilance System, information from marketing authorisation holders, doctors and other healthcare professionals regarding adverse reactions, intoxications, interactions, resistance development, lack of efficacy, misuse, medicinal product abuse as well as other

pharmacovigilance data reported for certain medicinal products for human use authorised for marketing in Romania;

c) Apply, in its pharmacovigilance activity, the provisions of guidelines on collection, verification and presentation of adverse reactions according to Article 818 of Law 95/2006, as amended;

d) Evaluate and interpret information received on quality, safety and efficacy of medicinal products for human use and propose the required administrative measures according to Article 819 of Law 95/2006, as amended;

e) Take part in the settlement of certain notifications related to the potential existence of certain counterfeited medicinal products.

(2) For immunological products and products derived from human blood/plasma imported from EU Member States, pending marketing in Romania after authorisation, Marketing Authorisation Holders are requested to submit to the National Agency for Medicines and Medical Devices the compliance certificate for the imported batch, issued by the control authority of the respective Member State.

(3) For immunological products and products derived from human blood/plasma for which the official batch release has been performed by a control authority in a EU Member State, the National Agency for Medicines and Medical Devices approves the marketing of the respective biological product on Romanian territory, exclusively based upon the compliance certificate issued by the respective control authority.

(4) The National Agency for Medicines and Medical Devices performs the official batch release in view of marketing of immunological products and products derived from human blood/plasma in Romania, from import (coming from third countries) and EU Member States, whose batches haven't been officially released in the EU, due to various reasons. In such cases, the MAH shall submit to the National Agency for Medicines and Medical Devices the following:

a) relevant samples for the batch to be marketing in Romania, in view of laboratory testing;

b) the summary of the batch protocol;

c) a copy of the compliance certificate issued by the manufacturer.

Art. 44. - Annexes 1 - 3 are integral parts of these Regulations.

ANNEX 1
to Regulations

APPLICATION FOR MARKETING AUTHORISATION
OF MEDICINAL PRODUCTS FOR HUMAN USE

SUMMARY OF THE DOSSIER

●●●●●

APPLICATION FOR MARKTING AUTHORISATION:
ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use, submitted to:

a) The European Medicines Agency through centralised procedure; or

b) The National Agency for Medicines and Medical Devices, through national/mutual recognition/decentralised procedure.

Separate application is submitted for each strength and pharmaceutical form of the medicinal product for human use.

For the centralised procedure, a mixed application is allowed (Where deemed necessary, information shall be successively provided for each pharmaceutical form and strength).

Declaration and signature

Name of the medicinal product:
Strength:
Pharmaceutical form:
Active substance(s):
Applicant:

Person authorised on behalf of the Applicant* for communication with the National Agency for Medicines and Medical Devices, during the authorisation procedure**:**

It is hereby confirmed that all existing data relevant to the quality, safety and efficacy of the medicinal product for human use have been supplied in the dossier, according to the rules.

It is hereby confirmed that the fees and tariffs shall be paid in accordance with the Norms established by the National Agency for Medicines and Medical Devices **.

On behalf of the applicant:

……..
Signature:

……
Name *

……
Function

……..……. ……
Place Date (year, month, day)

* Please attach the letter of authorisation issued by the applicant for the person responsible for communication with the National Agency for Medicines and Medical Devices/signature right on behalf of the applicant, in Annex 6.4.

** If taxes have been paid, please attach the proof in Annex 6.1 – see information on payment in the *Notice to Applicants*, Volume 2 A, cap. 7.

Summary

Declaration and signature

1. Type of application

1.1. This application concerns:

1.2. Designation as orphan medicinal product

1.3. Application for change of an existing marketing authorisation referring to Order of the Minister of Public Health No. 874/2006 on approval of the Norms on the administrative procedure of the National Agency for Medicines and Medical Devices on handling variations.

1.4. The application for marketing authorisation is submitted in accordance with Law No. 95/2006 on healthcare reform, as amended, Title XVII – The medicinal product.

1.5. The application for marketing authorisation is submitted in accordance with Art. 704 (1), Art. 704 (5), Art. 727 and 785 of Law No. 95/2006, as amended, Title XVII – The medicinal product and with Art. 14 (7)-(9) 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 an European Medicines Agency.

2. Particularities of the application for marketing authorisation of a medicinal product for human use

2.1. ATC code(s) and name(s)

2.2. Pharmaceutical form, strength, route of administration, container and package size

2.3 Legal status

2.4. Marketing Authorisation Holder/Contact person/Company

2.5. Manufacturers

2.6. Qualitative and quantitative composition

3. Scientific counselling

4. Paediatric development programme

5. Other marketing authorisation applications

6. Documents attached to the application (where required)

1. Type of application

NOTE:

The following sections should be completed where appropriate.

1.1. This application concerns:

❍ 1.1.1. The centralised procedure (in accordance with Regulation (EC) No. 726/2004

❍ YES ❍ NO

❍ „Mandatory field of application" [Art. 3 (1)]

❍ Annex 1 (Biotechnology products)

❍ Annex 3 (New active substance for mandatory indications) Date of approval by the Committee for Medicinal Products for Human Use (*CHMP*): (yyyy-mm-dd)

❍ Annex 4 (Medicinal product designed as orphan)

❍ „Optional field of application" [Art. 3 (2)]

❍ Art. 3 (2) a) (New active substance) Date of approval by the CHMP: (yyyy-mm-dd)

❍ Art. 3 (2) b) (Substantial innovation or interest of the patients at Community level)

❍ „Generic medicinal product of a medicinal product authorised through centralised procedure" [Art. 3 (3)]

❍ Rapporteur: (Name of CHMP member) ❍ CoRapporteur: (Name of CHMP member)

❍ 1.1.2. Mutual Recognition Procedure [in accordance with Art. 736 (2) of Law No. 95/2006, as amended, Title XVII – The medicinal product]

❍ YES ❍ NO

- Reference Member State:
- Date of authorisation: (yyyy-mm-dd):
- Marketing authorisation number:

(a copy of the marketing authorisation shall be provided. - see Section 5.2)

❍ First use

- Concerned Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Common date proposed for renewal:

Specify whether a waiver/change occurred in the cycle of the RPAS - Periodic Safety Update Report

Periodic Safety Update Report – *PSUR*, in view of harmonisation with the substance birthdate.

❍ „Repeat use" first wave (Also fill in section 5.2.)

▪ Interested Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Please copy the boxes above for subsequent the following procedures.

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Common date agreed for renewal:

❍ 1.1.3. Decentralised procedure [in accordance with Art. 736 (3) of Law No. 95/2006, as amended, Title XVII „The medicinal product"

❍ YES ❍ NO

▪ Reference Member State:
▪ Procedure number:
▪ Interested Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

▪ Specify whether an exemption to/change of the PSUR cycle has been requested in view of harmonisation with the substance birthdate.

❍ 1.1.4. National procedure

▪ Member State:
▪ Application number, if available:
▪ Specify whether an exemption to/change of the PSUR cycle has been requested in view of harmonisation with the substance birthdate.

1.2. Information about the orphan medicinal product

1.2.1. This medicinal product has been proposed as an orphan medicinal product:

❍ No

❍ Yes Number of procedure for designation as an orphan medicinal product:

❍ Pending

❍ Designed as orphan medicinal product
Date (yyyy-mm-dd):
Based on the „substantial benefit" criterion: ❍ Yes

❍ No

Number in the Community register of orphan medicinal products:

☐ Please attach the copy of the decision concerning designation as orphan medicinal product (Annex 6.18)

❍ Designation as orphan medicinal product has been refused.
Date (yyyy-mm-dd):
Reference number of Commission decision:

❍ Designation as orphan medicinal product has been refused.
Date (yyyy-mm-dd):

Information concerning marketing exclusivity of orphan medicinal products
Is there other medicinal product designated as orphan for an ailment connected to the indication proposed via this application:
❍ No
❍ Yes
The following designation(s) as orphan medicinal product(s) is (are) specified:

Does any of the orphan medicinal products own a marketing authorisation in the European Union?
❍ No
❍ Yes
Please specify:
- Invented name, strength, pharmaceutical form of the authorised medicinal product: ……
- Marketing Authorisation Holder: …….
- Date of authorisation: …….

If YES, the medicinal product for which this application is submitted is considered „similar" to any authorised orphan medicinal product(s) [as stipulated in Art. 3 of Regulation (EC) No. 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'].

❍ No (fill in module 1.7.1)
❍ Yes (fill in modules 1.7.1 and 1.7.2)

1.3. This is an application for change of an existing marketing authorisation referring to Order of the Minister of Public Health No. 874 /2006, where deemed necessary.
❍ YES (Please fill in the section below, as well as section 1.4.)
❍ NO (Fill in section 1.4. only)

Please specify:

☐ Quality change in the declared active substance, undefined as the new active substance

❍ Replacement with a different salt/ester, mixture/by-product (of the same therapeutic entity)
❍ Replacement with a different isomer, isomer mixture, isolated isomer mixture
❍ Replacement of a biological substance or of a biotechnology product
❍ new ligands or coupling devices for radiopharmaceuticals
❍ change of the extraction diluent or of the balance between the herbal medicinal product and the herbal preparation

☐ change of bioavailability
☐ change of pharmacokinetics
☐ change/addition of a new strength/activity
☐ change/addition of a new pharmaceutical form
☐ change/addition of a new manner of administration

NOTE:
The applicant of this marketing authorisation application should be the same as the already existing MAH.
This section should be filled in without being detrimental to the provisions of Art. 702 (3), Art. 704 (1), Art. 705, 706, 707 and 726 of Law No. 95/2006, as amended, Title XVII – "The medicinal product".

● For marketing authorisations in the European Union/Romania:
- Name of the Marketing Authorisation Holder;
- Invented name, strength and pharmaceutical form of the existing product;
- Authorisation number(s).

1.4. A marketing authorisation submitted in accordance with the following articles of Law No. 95/2006, as amended, Title XVII – The medicinal product.

NOTE:
This section must be filled in for any type of application for marketing authorisation, including the applications mentioned in section 1.3.
For further details, please consult the Notice to Applicants, Volume 2A, Chapter 1.

1.4.1. ❍ Art. 702 (4) of Law No. 95/2006, as amended, Title XVII – The medicinal product (full dossier containing administrative, preclinical and clinical data on quality*)
❍ New active substance

NOTE:
Compound of a product still unauthorised by a competent authority or in the European Community (for the centralised procedure)
❍ Known active substance

NOTE:
Compound of a product already authorised by a competent authority or in the European Community
- The Marketing Authorisation Holder is the same or differs.

1.4.2. ❍ Art. 704 (1) and (2) of Law No. 95/2006, as amended, Title XVII – The medicinal product – marketing authorisation application for generic medicinal products

NOTE:
Application for generic medicinal products, as defined in Art. 704 (2) b) referring to the so-called reference medicinal products authorised for marketing in a Member State or in the European Community.
Complete administrative and quality information, corresponding clinical and preclinical information, when required.
See Notice to Applicants, Volume 2A, Chapter 1.
■ Reference medicinal product which is or was authorised for less than 6/10 years in the European Economic Area *(EEA):*

▪ Name of the product, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ First authorisation: date (yyyy-mm-dd) Member State (EEA)/European Community:
■ Reference Medicinal Product authorised in the European Union/Romania:
▪ Product name, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ Authorisation number(s):
■ Medicinal products used in bioequivalence studies, where deemed necessary:
▪ Name of the product, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ Reference Member State which purchased the reference product:

1.4.3. ❍ Art. 704 (3) of Law No. 95/2006, as amended, Title XVII – The medicinal product – „hybrid" (mixed) application

NOTE:
An application for marketing authorisation of a medicinal product referring to a so-called reference medicinal product authorised for marketing in a Member State or in the European Community (e.g. different pharmaceutical form, different therapeutic indications)
- Complete administrative and quality information, preclinical and clinical data in accordance with the regulations (Notice to Applicants, Volume 2A, Chapter 1)
■ Reference medicinal product which is or was authorised for less than 6/10 years in the European Economic Area *(EEA):*
▪ Name of the product, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ First authorisation: date (yyyy-mm-dd) Member State (EEA)/European Community:
■ Reference Medicinal Product authorised in the European Union/Romania:
▪ Name of the product, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ Authorisation number(s):

- * For extensions of complete marketing authorisation applications, reference can only be made to preclinical and clinical data.

■ Medicinal products used in bioequivalence studies, where required
▪ Name of the product, strength and pharmaceutical form:
▪ Marketing Authorisation Holder:
▪ Member State from where the reference medicinal product has been purchased:
■ Differences occurred after comparing the product with the original product:
☐ Changes in the active substance(s)
☐ Changes in therapeutic indications
☐ Changes in pharmaceutical form
☐ Change in strength (changes in amount of active substance(s))
☐ Change in route of administration
☐ Bioequivalence cannot be proved through bioavailability studies

1.4.4. ❍ Art. 704 (4) of Law No. 95/2006, as amended, Title XVII – The medicinal product – application for authorisation of similar biological products

NOTE:

Application for authorisation of a product concerning a reference biological product

Complete administrative and quality information, preclinical and clinical information in accordance with the regulations (Notice to Applicants, Volume 2A, Chapter 1)

■ Reference medicinal product which is or was authorised for less than 6/10 years in the European Economic Area *(EEA):*

- Name of the product, strength and pharmaceutical form:
- Marketing Authorisation Holder:
- First authorisation: date (yyyy-mm-dd) Member State (EEA)/European Community:

■ Reference Medicinal Product authorised in the European Union/Romania:

- Name of the product, strength and pharmaceutical form:
- Marketing Authorisation Holder:
- Marketing authorisation number(s):

■ Medicinal product used in bioequivalence studies, where required

- Name of the product, strength and pharmaceutical form:
- Marketing Authorisation Holder:
- Member State from where the reference medicinal product has been purchased:

1.4.5. ❍ Art. 705 of Law No. 95/2006, as amended, Title XVII – The medicinal product – for medicinal products having a well-established use (bibliographic application)

NOTE:

For further details please consult the Notice to Applicants, Volume 2A, Chapter 1.

Only preclinical and clinical data can be mentioned for the applications in view of bibliographic extensions.

1.4.6. ❍ Art. 706 of Law No. 95/2006, as amended, Title XVII – The medicinal product – application for authorisation of a fixed combination

NOTE:

Complete administrative and quality information, preclinical and clinical information only for combinations.

Only preclinical and clinical data can be mentioned for line extension applications for fix combinations.

1.4.7. ❍ Art. 707 of Law No. 95/2006, as amended, Title XVII – "The medicinal product" – informed consent application

NOTE:

Marketing Authorisation Application for a product having the same qualitative and quantitative composition in terms of the active substance and the same pharmaceutical form as an authorised product whose MAH consented to the use of the respective information in view of supporting this application.

Complete administrative data is submitted in accordance with the pharmaceutical, clinical and preclinical information.

The authorised product and the marketing authorisation application may have the same/different Marketing Authorisation Holder.

Product authorised in the European Union/Romania:

- Name of the product, strength and pharmaceutical form:
- Marketing Authorisation Holder:
- Marketing Authorisation Number(s):

☐ Please attach the agreement of the MAH of the already authorised product (Annex 6.2).

1.4.8. ❍ Art. 714 of Law No. 95/2006, as amended, Title XVII – The medicinal product – application for authorisation of traditional herbal medicinal products

NOTE:
Complete application (see Notice to Applicants, Volume 2A, Chapter 1)

1.5. This application should be taken into account with the following articles of Law No. 95/2006, as amended, Title XVII – The medicinal product or with the articles of Regulation (EC) No. 726/2004

1.5.1. ❍ Conditional approval

NOTE: Only for centralised procedure in accordance with Art. 14 (7) of Regulation (EC) No. 726/2004.

1.5.2. ❍ Exceptional circumstances

NOTE: In accordance with Art. 727 of Law No. 95/2006 and Art. 14 (8) of Regulation (EC) No. 726/2004.

1.5.3. ❍ Accelerated evaluation

NOTE:
Only for centralised procedure in accordance with Art. 14 (9) of Regulation (EC) No. 726/2004.
Date of CHMP approval:
(yyyy-mm-dd)

1.5.4. ❍ Art. 704 (1) of Law No. 95/2006, as amended (one-year data exclusivity for a new indication)

1.5.5. ❍ Art. 704 (5) of Law No. 95/2006, as amended (one-year data exclusivity for a new indication)

1.5.6. ❍ Art. 785 of Law No. 95/2006, as amended (one-year data exclusivity for change of classification)

2. Marketing Authorisation Application particulars

2.1. Name/Name and ATC code

2.1.1. Proposed (invented) name of the medicinal product in the Community/Member State/Iceland/Liechtenstein/Norway:

☐ If different (invented) names in different Member States are proposed in a mutual recognition procedure, these are to be listed in Annex 6.19.

2.1.2. Name of the active substance(s):
NOTE:
Only one name should be given in the following order of priority: International Non-proprietary Name (INN*), European Pharmacopoeia, the Romanian Pharmacopoeia, common name scientific name;

_____
- * The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant [for further details, consult the SPC Guidelines)].

2.1.3. Pharmacotherapeutic group (Please use current ATC code):

ATC code: Pharmacotherapeutic group:

If no ATC code has been assigned, please indicate if an application for ATC code has been made:

2.2. Pharmaceutical form, strength, route of administration, container and pack size(s)

2.2.1. Pharmaceutical form and strength (please use current list of standard terms – European Pharmacopoeia)
Pharmaceutical form:

Active substance(s) Strength(s):

2.2.2. Route of administration (please use current list of standard terms – European Pharmacopoeia)

2.2.3. Container, closure and administration device(s), including description of material from which it is constructed (please use current list of standard terms. - European Pharmacopoeia)

For each type of packaging, please give:
2.2.3.1. Packaging size:

NOTE:
For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member should be listed.
2.2.3.2. Proposed shelf life:

2.2.3.3. Proposed shelf life (after first opening container):
2.2.3.4. Proposed shelf life (after reconstitution or dilution):
2.2.3.5. Storage conditions:
2.2.3.6. Proposed storage conditions after first opening:
☐ Attach list of Mock-ups or Samples/specimens sent with the application, as appropriate.
(See Notice to Applicant, Volume 2A, Chapter 7, Annex 6.17)

2.3. Legal status

2.3.1. Proposed dispensing/classification
(Classification under Article 695 (19) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended)

❍ subject to medical prescription
❍ not subject to medical prescription

2.3.2. For medicinal products subject to medical prescription:

☐ Medicinal product on prescription which may be renewed (if applicable)
☐ Medicinal product on prescription which may not be renewed (if applicable)
☐ Medicinal product on special prescription*
☐ Medicinal product on restricted prescription*

Applicants are required to indicate which categories they are requesting, however, the NMA reserves the right to apply only those categories provided for in Law No. 95/ 2006 on healthcare reform, Title XVII, The Medicinal Product, as amended.

** For further information, please refer to Article 781 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product.*

2.3.3. Supply for products not subject to medical prescription

❍ Supply through pharmacies only
❍ Supply through non-pharmacy outlets and pharmacies (if applicable)

2.3.4. Promotion for products not subject to medical prescription

❍ Promotion to healthcare professionals only
❍ Promotion to the general public and healthcare professionals

2.4. Marketing authorisation holder/Contact person/Company

2.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in Romania

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Contact person at this address:

☐ Attach proof of establishment of the applicant in Romania or European Economic Area (Annex 6.3)

2.4.2. Person/Company authorised for communication with the National Medicines Agency during authorisation procedure in Romania:

Name: ☐ If different from point 2.4.1 above, attach letter of authorisation (Annex 6.4)
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

2.4.3. Person/Company authorised for communication between the marketing authorisation holder and the National Agency for Medicines and Medical Devices, after authorisation, in Romania, if different from Person/Company under 2.4.2

Name: ☐ If different from point 2.4.1 above, attach letter of authorisation (Annex 6.4)
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

2.4.4. Qualified person in the European Economic Area for Pharmacovigilance

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:
☐ Attach C.V. of qualified person (Annex 6.5)

2.4.5. Person in charge of scientific service of the marketing authorisation holder in the European Economic Area as referred to in Article 809 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended

Name of contact person:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

2.5. Manufacturers

NOTE:
ALL manufacturing and control sites mentioned throughout the entire authorisation dossier MUST have references regarding their names, detailed addresses and activities.

2.5.1. Authorised manufacturer(s) (or importer) responsible for batch release in the European Economic Area in accordance with Articles 748 and 760 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended:

Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

- Manufacturing Authorisation number:
- ☐ Attach copy of manufacturing authorisation(s) (Annex 6.6)
- ☐ Attach justification if more than one manufacturer responsible for batch release are proposed (Annex 6.7)

For blood products and vaccines:
Details of the state laboratory or laboratory designated for that purpose (OMCL), where the official batch release takes place (in accordance with Articles 823 (1), 825, 826 (1) and (2) and 827 of Law No. 95/2006, Title XVII, The Medicinal Product, as amended, for products authorised in the EEA)
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

2.5.1.1. Contact person in the EEA for product defects and recalls, as defined in Article 790 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended
Name:
Address:
Country:
Telephone 24 h:
Telefax:
E-mail:

2.5.1.2. Batch control/testing arrangements
Site(s) in EEA or in countries where a mutual recognition agreement or other Community arrangements apply where batch control/testing takes place (if different from 2.5.1., as required by Article 760 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended):
Company name:
Address:
Country:

Telephone:
Telefax:
E-mail:
Please provide brief description of control test carried out by the laboratory(ies) concerned.

2.5.2. Manufacturer(s) of the medicinal product and site(s) of manufacture (including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product)

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Please provide brief description of functions performed by manufacturer of dosage form/assembler etc.:

☐ Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 6.8)

- If the manufacturing site is in the EEA:
  - Manufacturing Authorisation number

☐ Attach a copy of the Manufacturing Authorisation required under Art. 748 of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (Annex 6.6)

- Name of qualified person:
(if not mentioned in the manufacturing authorisation)

- If the manufacturing site is outside the EEA:

- Where MRA or other Community arrangements apply, attach equivalent of Manufacturing Authorisation. (Annex 6.6)
- The site has been inspected for GMP Compliance by an EEA authority or by an authority of countries where MRA or other Community arrangements apply within the terms of the agreement.

❍ YES ❍ NO

☐ If YES, please provide in Annex 6.9, for each site, a statement from the competent authority which carried out the inspection, including:

- Last GMP inspection date
- Name of competent authority which carried out the inspection
- Category of products and activities inspected
- Outcome: GMP compliant: ❍ YES ❍ NO
- The site has been inspected for GMP Compliance by any other authority including those of countries where MRA or other Community arrangements apply but not within the respective territory?

❍ YES ❍ NO

☐ If YES, please provide the inspection report in Annex 6.9.
Including: - last GMP inspection date (yyyy-mm-dd)
- Name of competent authority which carried out the inspection
- Category of products and activities inspected
- Outcome: ❍ Positive ❍ Negative

2.5.3. Manufacturer(s) of the active substance and site(s) of manufacture

NOTE:
All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. For biotech products, include all sites of storage of master and working cell bank and preparation of working cell banks.
Substance:
Name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Please provide brief description of manufacturing steps performed by manufacturing site:

☐ Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 6.8)
☐ For each active substance, a statement of the qualified person of the MAH(s) mentioned in section 2.5.1 and a statement of the qualified person of the MAH(s) mentioned in section 2.5.2 shall be submitted, where the active substance is used as a starting material, attesting the fact that the manufacturer(s) of active substance mentioned in section 2.5.3 operate in accordance with the Good Manufacturing Practice rules for active substances.
• The European Pharmacopoeia has issued a Certificate of suitability for the active substance(s)

❍ YES ❍ NO

If YES, please specify:
- Substance:
- Name of the manufacturer:
- reference number:
- date of last update (yyyy-mm-dd):
☐ Please provide a copy of the certificate in Annex 6.10.
• Is there any standard dossier of the European product (European Drug Master File - *EDMF*) for the reference/original active substance(s)

❍ YES ❍ NO

If YES, please specify:
- Substance:
- Name of the manufacturer:

- reference number for the European Medicines Agency (EMA)/competent authority:

- date of submission (yyyy-mm-dd):
- date of last update (yyyy-mm-dd):
- reference number for the European Medicines Agency (EMA)/competent authority:

- date of submission (yyyy-mm-dd):
- date of last update (yyyy-mm-dd):

☐ Please attach letter of access for Community/Member State authorities where the application is made (please refer to European DMF procedure) (Annex 6.10)

☐ Please attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (Annex 6.11)

• There is an EMEA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2011 on the Community code relating to medicinal products for human use, being used for this application for marketing authorisation

❍ YES ❍ NO

If YES, please specify:

- Substance name:
- Name of the VAMF Certificate Holder/VAMF Applicant:
- reference number of application/certificate:
- date of submission (if pending) (yyyy-mm-dd):
- date of approval or last update (if approved) (yyyy-mm-dd):

☐ Please attach copy in Annex 6.20

(Section to be copied/completed as per however many VAMFs may be cross-referenced)
Where an active substance manufacturer has been inspected by an EEA Country, the following information shall be included in Annex 6.9 for each manufacturing site:

- Last inspection date by an EEA country (yyyy-mm-dd)
- Name of competent authority which carried out the inspection
- Type of inspection (pre/post-authorisation/special/re-inspection)
- Categories of ingredients and activities inspected
- Outcome: ❍ Positive ❍ Negative

2.5.4. Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes.
For each contract company, specify the state where analytical tests have been performed and where clinical data are collected and given:
Title of the study:
Protocol code:

EudraCT Number:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Duty performed according to contract:

2.6. Qualitative and quantitative composition

2.6.1. Qualitative and quantitative composition – Active substance(s) and excipient(s):
A note is to be given as to which quantity the composition refers (e.g. 1 capsule)

Please list the active substance(s) separately from the excipient(s).

Name of the active substance(s)	Quantity	Unit	Reference/Monograph standard

etc.

Name of excipient(s)/*	Quantity	Unit	Reference/Monograph standard

etc.

*Note: Only one name for each substance should be given in the following order of priority: INN**, European Pharmacopoeia, Romanian Pharmacopoeia, Common name, Scientific name

**The active substance should be declared by its recommended INN accompanied by its salt or hydrate form if relevant (for further details, please consult the SPC Guideline)

Details of any overdose are stated below:
- Active substance:
- Excipient(s):

2.6.2. List materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product

NONE ☐

Name	Function*			Animal origin susceptible to TSE**	Other animal origin	Human origin	Certificate of suitability for EST (state number)
	AS	EX	R				
1.	❍	❍	❍	❍	❍	❍	❍
2.	❍	❍	❍	❍	❍	❍	❍
3.	❍	❍	❍	❍	❍	❍	❍
4.	❍	❍	❍	❍	❍	❍	❍

etc.

* AS= Active substance, EX = excipient (including starting materials used in the manufacture of the active substance/excipient) R= reagent/culture medium (including those used in the preparation of master and working cell banks)

** EST = transmissible spongiform encephalopathy

☐ If a European Pharmacopoeia Certificate of Suitability for TSE is available according to Resolution AP/CSP (99)4 of the Council of Europe, please attach in Annex 6.12

2.6.3. There is an EMEA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this application for marketing authorisation

❍ YES ❍ NO

If YES, please give:

- Substance referring to PMF:

function*

AS	EX	R
❍	❍	❍

- Name of the PMF Certificate Holder/PMF applicant:
- Number of Application/ Certificate:
- Date of submission (if pending) (yyyy-mm-dd):
- Date of approval or last update (if approved) (yyyy-mm-dd):

☐ Please provide copy in Annex 6.21

* SA = Active substance, EX = excipient (including starting materials used in the manufacture of the active substance/excipient), R = reagent/culture medium (including those used in the preparation of master and working cell banks)

(Section to be copied/completed as per however many PMFs may be cross-referenced)

2.6.4. The medicinal product for human use contains or consists of genetically modified organisms within the meaning of Directive 2001/18/EC

❍ YES ❍ NO

If YES, the product complies with Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms (GMOs) and repealing Council Directive 90/220/EEC?

❍ YES ❍ NO

☐ Please attach a copy of the written consent of the competent authorities to the deliberate release into the environment of the Genetically Modified Organisms for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 6.13)

3. Scientific Advice

3.1. Formal scientific advice has been given by the CHMP for this medicinal product.

❍ YES ❍ NO

If YES, please give:
Data (yyyy-mm-dd):
Reference:
☐ Please attach copy of the scientific letter (Annex 6.14)

3.2. Scientific advice has been given by Member State(s) for this medicinal product:

❍ YES ❍ NO
If YES,
Member State(s): Date (yyyy-mm-dd):

4. Paediatric Development Programme

4.1. There is a paediatric development programme for this medicinal product:

❍ YES ❍ NO
Please indicate the relevant section(s) in the dossier if included:

5. Other Marketing Authorisation Applications

5.1. Please fill in the section below for the applications authorised through national procedure, in accordance with Art. 702 (4) m)-o) of Law No. 95/2006, as amended, Title XVII „The medicinal product":

5.1.1. Is (are) there any Member State(s) where an application for authorisation for the same product has been submitted

❍ YES ❍ NO
If YES, Section 5.2 must be completed

5.1.2. There is/are other Member State(s) where an authorisation is granted for the same* medicinal product.

❍ YES ❍ NO

If YES, Section 5.2 must be completed and copy of authorisation provided.

There are differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, in accord with Article 722 or Article 723 of Law no. 95/2006 on healthcare reform, as amended, Title XVII, The Medicinal Product).

❍ YES ❍ NO
If YES, please elaborate:

5.1.3. There is/are other Member State(s) where an authorisation has been refused/ suspended/revoked by competent authorities for the same* medicinal product.

❍ YES ❍ NO
If YES, please complete section 5.2.

* Note: "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees".

5.2. Marketing authorisation applications for the same product in the EEA (e.g. medicinal products with same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies or which are "licensees".

Note: Please refer to Commission Communication 98/C229/03

☐ Countries which have authorised the medicinal product:
Country:
Date of authorisation (yyyy-mm-dd):
Invented name:
Authorisation number:
☐ Please provide copy of the marketing authorisation (Annex 6.15)
☐ Countries in which authorisation of the medicinal product is pending
Country:
Date of submission (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product has been refused
Country:
Date of refusal (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant, before authorisation)
Country:
Date of withdrawal (yyyy-mm-dd):
Invented name:
Grounds for withdrawal:
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant, after authorisation)
Country:
Date of withdrawal (yyyy-mm-dd):
Authorisation number:

Invented name:
Grounds for withdrawal:
☐ Countries whose competent authorities have suspended/revoked authorisation of the medicinal product
Country:
Date of suspension/revocation (yyyy-mm-dd):
Grounds for suspension/revocation:
Invented name:

5.3. Multiple applications for marketing authorisation for the same product:
Multiple applications for marketing authorisation:
Name of the other products:
Date of submission of the application(s) (yyyy-mm-dd):
Applicant(s):
☐ Copies of the correspondence with the European Commission are attached in case of the authorisation through centralised procedure (Annex 6.16)

5.4. Marketing authorisation applications for the same product in the EEA ((‘same product’ means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applications belonging to the same mother company or group of companies OR which are ‘licensees’.)

☐ Countries which have authorised the medicinal product:
Country:
Date of authorisation (yyyy-mm-dd):
Invented name:
☐ Countries in which an application for authorisation has been submitted
Country:
date of submission of the application (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product is pending
Country:
Date of refusal (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant before authorisation)
Country:
Date of withdrawal (yyyy-mm-dd):
Invented name:
Grounds for withdrawal:
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant after authorisation)
Country:
Date of withdrawal (yyyy-mm-dd):
Authorisation number:
Invented name:
Grounds for withdrawal:
☐ Countries whose competent authorities have suspended/revoked authorisation of the medicinal product
Country:

Date of suspension/revocation: (yyyy-mm-dd):
Grounds for suspension/revocation:
Invented name:

6. Annexed documents (where applicable)

☐ 6.1. Proof of payment
☐ 6.2. Consent of the Marketing Authorisation Holder for the reference medicinal product who allows an applicant to make use of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications (for informed consent marketing authorisation applications)
☐ 6.3. Proof of establishment of the applicant in the EEA
☐ 6.4. Letter of authorisation for communication on behalf of the applicant/marketing authorisation holder
☐ 6.5. Curriculum Vitae of the Qualified Person for Pharmacovigilance

☐ 6.6. Manufacturing Authorisation required under Article 748 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended (or equivalent, outside of the EEA where MRA or other Community arrangements apply). A reference to EudraGMP will suffice when available.
☐ 6.7. Justification for more than one manufacturer responsible for batch release in the EEA

☐ 6.8. Flow-chart indicating all sites involved in the manufacturing process of the medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.
☐ 6.9. Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s)/(not older than 3 years). References to EudraGMP will suffice when available. Where applicable a summary of other GMP inspections performed in the last 2 years.
☐ 6.10. Letter(s) of access to Active Substance Master File(s) or copy of European Pharmacopoeia Certificate(s) of suitability
☐ 6.11. Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I to Order of the Minister of Health No. 906/2006 on approval of Analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products, with further amendments (transposing Annex I of Directive 2001/83/EC)
☐ 6.12. European Pharmacopoeia Certificate(s) of suitability for TSE
☐ 6.13. Written consent(s) of the competent authorities regarding genetically modified organisms release in the environment
☐ 6.14. Scientific advice given by CHMP.
☐ 6.15. Copy(ies) of Marketing Authorisation(s) granted in an EEA country or third country under Article 702 (4) m)-o) of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product and the equivalent in third countries on request (photocopies of the pages which give the Marketing authorisation number, date of authorisation and pages which have been signed by the competent authorities).

☐ 6.16. Correspondence with European Commission regarding multiple applications.
☐ 6.17. List of Mock-ups or Samples/specimens sent with the application, as appropriate.
☐ 6.18. Copy of the decision for assignment as orphan medicinal product.
☐ 6.19. List of proposed (invented) names and marketing authorisation holders in the concerned member states.
☐ 6.20. Copy of EMEA certificate for a Vaccine Antigen Master File (VAMF)
☐ 6.21. Copy of EMEA certificate for Plasma Master File (PMF)
☐ 6.22. For each active substance, attach a declaration from the Qualified Person of the manufacturing authorisation holder, mentioned in Section 2.5.1, and from each qualified person of each manufacturing authorisation holder (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance manufacturer(s) referred to in Section 2.5.3 operate in compliance with the detailed guidelines on good manufacturing practice for active substance. This does not apply to blood or blood components.

ANNEX 2
to Regulations

APPLICATION FOR MARKETING AUTHORISATION
OF HOMEOPATHIC MEDICINAL PRODUCTS FOR HUMAN USE

SUMMARY OF THE DOSSIER

●●●●●

APPLICATION FOR MARKETING AUTHORISATION:
ADMINISTRATIVE DATA

The Marketing Authorisation application is needed in view of obtaining a marketing authorisation for medicinal products for human use, submitted to:

a) The European Medicines Agency through centralised procedure, or

b) The National Agency for Medicines and Medical Devices, through national/mutual recognition/decentralised procedure.

Separate application is submitted for each strength and pharmaceutical form of the medicinal product for human use.

Mixed applications are accepted for the centralised procedure. (Information related to the each pharmaceutical form and strength is successively provided where deemed necessary.)

Declaration and signature:

Invented name:

Pharmaceutical form:
Homeopathic stock(s) and strength(s):
Applicant:
Person authorised on behalf of the Applicant for communication* with the National Agency for Medicines and Medical Devices, during authorisation procedure:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product for human use have been supplied in the dossier, as appropriate.

It is hereby confirmed that fees will be paid according to the National Agency for Medicines and Medical Devices**.

On behalf of the applicant:

.....
Signature
.....
Name*
.....
Function
.....

Site Date (year, month, day)

_____

** Please attach letter of authorisation for communication with NMA/signing on behalf of the applicant.*

*** If payment has been performed, please attach the proof in Annex 4.1- see information about payment of taxes included in the Notice to Applicants, Volume 2A, Chapter 7.*

1. Type of application

N O T E:

The following sections should be completed where appropriate.

1.1. This application concerns:

❍ 1.1.1. The Mutual Recognition Procedure (in accordance with Art. 736 (2) of Law No. 95/2006 on healthcare reform, as amended, Title XVII „The medicinal product", as amended)

❍ YES ❍ NO

- Reference Member State:
- Date of authorisation: (yyyy-mm-dd):
- Marketing authorisation number:

(please provide a copy of the marketing authorisation – see section 5.2.)

❍ First use

- Interested Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Common date of renewal:

Please specify if a waiver or amendment of PSUR-cycle (Periodic Safety Update Report) is applied for, to harmonise with a substance birthdate.

❍ „Repeat use" – first stage (Please fill in section 5.2 as well.)

- Interested Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Please copy the boxes above for the following procedures.

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Common date agreed for renewal:

❍ 1.1.2. Decentralised procedure [in accordance with Art. 736 (3) of Law No. 95/2006, Title XVII „The medicinal product", as amended]

❍ YES ❍ NO

- Reference Member State:
- Reference Member State:
- Procedure number:
- Interested Member State(s):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

- Please specify if a waiver or amendment of PSUR-cycle (Periodic Safety Update Report) is applied for, to harmonise with a substance birthdate.

❍ 1.1.3. National procedure

- Member State
- Application number, if available
- Please specify if a waiver or amendment of PSUR-cycle (Periodic Safety Update Report) is applied for, to harmonise with a substance birthdate.

1.2. This is an application for variation of a marketing authorisation in place with reference to the Order of the Minister of Health No. 874/2006, where applicable.

❍ YES (please complete the section below and Section 1.3.)

❍ NO **(**please complete Section 1.3 only)

Please state:

☐ Qualitative change in declared active substance not defined as a new active substance

❍ Replacement by a different salt/ester, complex/derivative (same therapeutic moiety)

❍ Replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer

❍ Replacement of a biological substance or product of biotechnology

❍ New ligand or coupling mechanism for a radiopharmaceutical

❍ Change to the extraction solvent or the radio of herbal drug to herbal drug

☐ Change of bioavailability

☐ Change of pharmacokinetics

☐ Change or addition of a new strength/ potency

☐ Change or addition of a new pharmaceutical form
☐ Change or addition of a new route of administration

NOTE*:*
The applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation.

This section should be completed without prejudice to the provisions of Articles 702 (1) and (4), 704 (1), 708 (1) and (7) and 726 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended.

● For existing marketing authorisation in the Community/Member State where the application is made:

- Name of the Marketing Authorisation Holder:
- Invented name, strength, pharmaceutical form of the existing medicinal product:
- Marketing Authorisation number:

1.3. This application for Marketing Authorisation is submitted in accordance with the following articles of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended.

N O T E*:*
Section to be completed for any application, including applications referred to in Section 1.3

❍ 1.3.1. Article 711 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended (simplified registration procedure)
❍ 1.3.2. Article 713 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended (marketing authorisation procedure)

1.4. Administrative data/dossier requirements

Art. 711 – Simplified authorisation procedure

Parts of the dossier	Submitted in the Authorisation dossier	
Module 1	❍	
Manufacturing authorisation	❍	
Mock-ups of outer and immediate packaging and of package leaflet	❍	
Module 2	❍	
Module 3	❍	
Module 4	❍	
Justification of the product's homeopathic nature	❍	

Art. 713 – Marketing Authorisation Procedure

Parts of the dossier	Existing requirements in the Authorisation dossier	
Module 1	❍	
Manufacturing authorisation	❍	
SPC in national language	❍	
Leaflet in national language	❍	
Mock-ups of outer and immediate packaging and of package leaflet	❍	
Module 2	❍	
Module 3	❍	
Module 4	❍	
Justification of the product's homeopathic nature	❍	

2. Marketing authorisation application particulars

2.1. Name(s)

2.1.1. Invented name of the homeopathic medicinal product for human use

□ If different (invented) names in different Member States are proposed in a mutual recognition, these are to be listed in Annex 4.18.

2.1.2. Name of the Homeopathic stock(s) and strengths[1]

[1] *The following order of priority should be used: Scientific name of the European Pharmacopoeia or National Pharmacopoeia or, in absence of a monograph, a Scientific Latin name (botanical scientific name) followed by the Homeopathic(s) name(s).*

2.2. Pharmaceutical form, route of administration, container and packaging size

2.2.1. Pharmaceutical form (please use current list of standard terms according to the European Pharmacopoeia):

2.2.2. Route(s) of administration (please use current list of standard terms according to the European Pharmacopoeia):

2.2.3. Container, closure and administration device(s), including description of material from which it is constructed (please use current list of standard terms according to the European Pharmacopoeia):

For each type of packaging, please provide:

2.2.3.1.1. Packaging size(s):
N O T E:

For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member should be listed.
2.2.3.2. Proposed shelf life:
2.2.3.3. Proposed shelf life (after first opening container):
2.2.3.4. Proposed shelf life (after reconstitution or dilution):
2.2.3.5. Proposed storage conditions:
2.2.3.6. Proposed storage conditions after first opening container:
□ Please attach list of mock-ups or samples/specimens sent with the application, as appropriate (please refer to Notice to Applicants, Volume 2A, Chapter 7) (4.17)

2.3. Legal status

2.3.1. Proposed dispensing/classification

[Under Article 695 (19) of Law No. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended]

❍ Subject to medical prescription
❍ Not subject to medical prescription

2.3.2. For products subject to medical prescription:

☐ Product on prescription which may be renewed (if applicable)
☐ Product on prescription which may not be renewed (if applicable)
☐ Product on special prescription*
☐ Product on restricted prescription*

Applicants are invited to indicate which categories they are requesting, however, the National Agency for Medicines and Medical Devices reserves the right to apply only those categories provided for in Law No. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended.

* For further information, please check Art. 781 of Law No. 95/2006, Title XVII „The Medicinal Product", as amended.

2.3.3. Supply for products not subject to medical prescription:

❍ Supply through pharmacies only

❍ Supply through non-pharmacy outlets and pharmacies(if applicable)

2.3.4. Promotion for products not subject to medical prescription:

❍ Promotion for healthcare professionals only

❍ Promotion to the general public and healthcare professionals

2.4. Marketing authorisation holder/Contact person/Company

2.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in Romania

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Contact person at this address
☐ Please attach proof of establishment of the applicant in Romania or The European Economic Area (EEA) (Annex 4.3)

2.4.2. Person/Company authorised for communication with the National Agency for Medicines and Medical Devices during authorisation procedure in Romania:

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

☐ If different from 2.4.1 above, please attach letter of authorisation (Annex 4.4).

2.4.3. Person/Company authorised for communication between the marketing authorisation holder and the National Agency for Medicines and Medical Devices, after authorisation in Romania, if different from Person/Company under 2.4.2.

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

☐ If different from 2.4.1 above, please attach letter of authorisation (Annex 4.4).

2.4.4. Qualified person for Pharmacovigilance in the EEA
Name:
Company name:
Address:
Country:
Telephone 24 h:
Telefax:
E-mail:
☐ Please provide C.V. of qualified person (Annex 4.5)

2.5. Manufacturers

2.5.1. Authorised manufacturer(s) (or importer) responsible for batch release in Romania in accordance with Articles 748 and 760 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended **(**as shown in the package leaflet and where applicable in the labelling):

Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

- Manufacturing authorisation number:
- ☐ Attach copy of manufacturing authorisation(s)(Annex 4.6)
- ☐ Attach justification if more than one manufacturer responsible for batch release is proposed (Annex 4.7)

2.5.1.1. Batch control/Testing arrangements
Site(s) in EEA or in countries with MRA/another agreement in operation, where batch control/testing takes place (if different from 2.5.1):

Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

2.5.2. Manufacturer(s) of the homeopathic medicinal product and Site(s) of manufacture
(Please give including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the Homeopathic medicinal product):

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:
Please provide brief description of functions performed by manufacturer of dosage form/assembler etc.:

☐ Please attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 4.8)

• If the manufacturing site is in the EEA:
- Manufacturing authorisation number
(under Article 748 of Law no. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product"):
☐ Please attach copy of manufacturing authorisation (s) (Annex 4.6)
- Name of qualified person:
(If not mentioned in the manufacturing authorisation)

• If the manufacturing site is outside the EEA:

☐ Where MRA/another community agreement is in operation, attach equivalent of manufacturing authorisation (Annex 4.6)

The site has been inspected for GMP Compliance by an EEA authority or by an authority of countries where mutual recognition agreement/another community agreement is in operation ❍ YES ❍ NO

☐ If YES, please provide in Annex 4.9, for each site, a statement from the competent authority which carried out the inspection, including:
- Last GMP inspection date
- Name of competent authority which carried out the inspection
- Type of inspection (pre/post-authorisation/special/re-inspection)
- Category of products and activities inspected
- Outcome: GMP compliant: ❍ NO ❍ YES

2.5.3. Manufacturer (s) of the dilutions and Site(s) of manufacture
(If different from manufacturer of the finished homeopathic medicinal product)
Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

Please provide brief description of functions performed by manufacturer of dosage form/assembler etc.:

☐ Please attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 4.8)

• If the manufacturing site is in the EEA:
- Manufacturing Authorisation number
(under Article 748 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended):

☐ Please attach copy of manufacturing authorisation (s) (Annex 4.6)

- Name of qualified person:
(if not mentioned in the Manufacturing Authorisation)

• If the manufacturing site is outside the EEA:

☐ Where MRA/another community agreement is in operation, attach equivalent of manufacturing authorisation (Annex 4.6)

- The site has been inspected for GMP Compliance by an EEA authority or by an authority of countries where MRA/another community agreement is in operation

❍ YES ❍ NO

☐ If YES, please provide in Annex 4.9, for each site, a statement from the competent authority which carried out the inspection, including:

- last GMP inspection date
- name of competent authority which carried out the inspection
- type of inspection (pre/post-authorisation/special/re-inspection)
- category of products and activities inspected
- outcome: GMP compliant: ❍ NO ❍ YES

2.5.4. Manufacturer(s) of the Homeopathic stock(s):

NOTE:
Only the final manufacturer(s) to be mentioned

Substance:
Name:
Address:
Country:
Telephone:
Telefax:
E-mail:

• A European Pharmacopoeia Certificate of suitability has been issued for the active substance(s)

❍ YES ❍ NO

If YES, please specify:
- substance:
- name of the manufacturer:
- reference number:
- date of last update (yyyy-mm-dd):

☐ Please provide copy in Annex 4.10

• There is a European Drug Master File to be used for the active substance(s) reference/original

❍ YES ❍ NO

If YES, please specify:
- substance:
- name of the manufacturer:
- reference number for EMA/competent authority:

- date of submission (yyyy-mm-dd):
- date of last update (yyyy-mm-dd):

☐ Please attach letter of access for Community/Member State authorities where the application is made (please refer to European DMF procedure for active substance) (Annex 4.10)

☐ Please attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Article Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended. (Annex 4.11)

Where an active substance manufacturer has been inspected by an EEA Country, the following information is provided in Annex 4.9 for each manufacturing site:

- Last inspection date by an EEA country (year-month-day)
- Name of competent authority which carried out the inspection
- Type of inspection (pre/post-authorisation/special/re-inspection)
- Categories of substance and activities inspected
- Outcome: ❍ Positive ❍ Negative

2.5.5. Source/manufacturer(s) of the raw material(s):

Raw material:
Name:
Address:
Country:
Telephone:
Telefax:
E-mail:

- A European Pharmacopoeia Certificate of suitability has been issued for the raw material(s)

❍ YES ❍ NO

If YES, please specify:
- raw material:
- name of the manufacturer:
- reference number:
- date of last update (yyyy-mm-dd):

☐ Please provide copy in Annex 4.10.

Where an active substance manufacturer has been inspected by an EEA Country, the following information is provided in Annex 4.9 for each manufacturing site:
- last inspection date by an EEA country (year-month-day)
- name of competent authority which carried out the inspection
- type of inspection (pre/post-authorisation/special/re-inspection)
- categories of substance and activities inspected
- outcome: ❍ Positive ❍ Negative

2.6. Qualitative and quantitative composition

2.6.1. Qualitative and quantitative composition in terms of the homeopathic active substance(s) and the excipient(s):

A note should be given as to which quantity the composition refers (e.g. 1 capsule)
List the homeopathic active substance(s) separately from the excipient(s).

Name of homeopathic active substance*	Quantity	Unit	Reference/Monograph standard
1.			
2.			
3.			
etc.			

Name of excipients**	Quantity	Unit	Reference/Monograph standard
1.			
2.			
3.			
etc.			

*The following order of priority should be used: Scientific Latin name of the European Pharmacopoeia or of the Romanian Pharmacopoeia or, in absence of a monograph, a scientific Latin name (botanical scientific name...) followed by the Homeopathic name

** Only one name for each substance should be given in the following order of priority: INN, European Pharmacopoeia, the Romanian Pharmacopoeia, Common name, scientific name

2.6.2. List of materials of animal/human origin contained or used in the manufacturing process of the homeopathic medicinal product

NONE ☐

Name	Function* HSA	EX	R	Animal origin susceptible to TSE**	Other animal origin	Human origin	Certificate of suitability for TSE (State no.)	
1.	❍	❍	❍	❍	❍	❍	❍	
2.	❍	❍	❍	❍	❍	❍	❍	
3.	❍	❍	❍	❍	❍	❍	❍	
4.	❍	❍	❍	❍	❍	❍	❍	etc.

* HAS= homeopathic active substance; EX=excipient (including starting materials used in the manufacture of the active substance/excipient) R=reagent/culture medium (including those used in the preparation of master and working cell banks)
** EST= transmissible spongiform encephalopathy

☐ If a European Pharmacopoeia Certificate of Suitability for TSE is available according to Article Resolution AP/CSP (99)4 of the Council of Europe, please attach in Annex 4.12

3. Other marketing authorisation applications

3.1. For national applications, please complete the section below, in accordance with Art. 702 (4) m)-o) of Law No. 95/2006, Title XVII, "The medicinal product", as amended.
3.1.1. There is/are other Member State(s) where an application for the same product is pending:

❍ YES ❍ NO
If YES, please complete Section 3.2.

3.1.2. There is/are other Member State(s) where an authorisation/registration is granted for the same medicinal product:
❍ YES ❍ NO
If YES, please complete Section 3.2 and provide copy.

There are differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, under Article 722 and 723 of Law No.95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended).
❍ YES ❍ NO
If YES, please give:

3.1.3. There is another Member State(s) where an authorisation/registration has been refused/suspended/ revoked by competent authorities for the same* product

❍ YES ❍ NO
If YES, please complete Section 3.2.

* 'Same product' means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applications belonging to the same mother company or group of companies OR which are 'licensees'.

3.2. Marketing authorisation/registration applications for the same homeopathic medicinal product in the EEA *('same product' means same qualitative and quantitative composition in active substance(s)and having the same pharmaceutical form from applications belonging to the same mother company or group of companies OR which are 'licensees'.)*
NOTE: Please refer to Commission Communication No. 98/C229/03 on the Community marketing authorisation procedures for medicinal products.

☐ Countries which have authorised the medicinal product
country:
date of authorisation (yyyy-mm-dd):
invented name:
authorisation number:
☐ Please attach copy of marketing authorisation/registration (Annex 4.15)
☐ Countries in which authorisation of the medicinal product is pending
country:
date of submission (yyyy-mm-dd):

☐ Countries in which authorisation of the medicinal product has been refused
country:
date of refusal (yyyy-mm-dd):

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant before authorisation)
country:
date of withdrawal (yyyy-mm-dd):
invented name:
grounds for withdrawal:
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant after authorisation)
country:
date of withdrawal (yyyy-mm-dd):
authorisation number:
invented name:
grounds for withdrawal:
☐ Countries whose competent authorities have suspended/revoked authorisation of the medicinal product
country:
date of suspension/revocation (yyyy-mm-dd):
grounds for suspension/revocation:
invented name:

3.3. For multiple applications of the same homeopathic medicinal product:

Multiple applications for:
Name of the other product(s):
Date of submission (yyyy-mm-dd):
Applicant(s):

3.4. Marketing authorisation applications for the same homeopathic medicinal product, outside the EEA (i.e. for products having the same qualitative and quantitative compositions as regards the active substance(s), having the same pharmaceutical form, coming from applicants belonging to the same mother company or group of companies OR which are "licensees".)
Note: Please refer to Commission Communication 98/C229/03

☐ Countries which have authorised the medicinal product
country:
date of authorisation (yyyy-mm-dd):
invented name:
authorisation number:
☐ Countries in which the authorisation of the medicinal product is pending
Country:
Date of submission (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product has been refused (by the applicant prior to authorisation):
Country:
Date of refusal (yyyy-mm-dd):
☐ Countries in which authorisation of the medicinal product has been withdrawn (by the applicant prior to authorisation)

Country:
Date of withdrawal (yyyy-mm-dd):
Invented name:
Grounds for withdrawal:

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the applicant prior to authorisation)

Country:
Date of withdrawal (yyyy-mm-dd)
Authorisation number:
Invented name:
Grounds for withdrawal:

☐ Countries whose competent authorities have suspended/revoked authorisation of the medicinal product

Country:
Date of suspension/revocation (yyyy-mm-dd):
Grounds for suspension/revocation:
Invented name:

4. Attached documents (where applicable)

☐ 4.1. Proof of payment

☐ 4.2. Consent of the Marketing Authorisation Holder for the reference medicinal product who allows an applicant to make use of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications (for informed consent marketing authorisation applications)

☐ 4.3. Proof of establishment of the applicant in the EEA

☐ 4.4. Letter of authorisation for communication on behalf of the applicant/marketing authorisation holder

☐ 4.5. Curriculum Vitae of the Qualified Person for Pharmacovigilance

☐ 4.6. Manufacturing Authorisation required under Article 748 of Law No. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended (or equivalent, outside of the EEA where MRA or other Community arrangements apply). A reference to EudraGMP will suffice when available.

☐ 4.7. Justification for more than one manufacturer responsible for batch release in the EEA

☐ 4.8. Flow-chart indicating all sites involved in the manufacturing process of the medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

☐ 4.9. Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s)/(not older than 3 years). References to EudraGMP will suffice when available. Where applicable a summary of other GMP inspections performed in the last 2 years.

☐ 4.10. Letter(s) of access to Active Substance Master File(s) or copy of European Pharmacopoeia Certificate(s) of suitability

☐ 4.11. Copy of the written confirmation of the active substance manufacturer to inform the applicant in case of the modification of the manufacturing process or specifications, in accordance with the Annex to the Order of the Minister of Public Health No. 906/2006 on approval of the Analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products, as amended (transposing the Annex to Directive

2003/63/EC of 25 June 2003, amending Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, related to the Community Code concerning medicinal products for human use)

☐ 4.12. European Pharmacopoeia Certificate(s) of suitability for TSE

☐ 4.13. Written consent(s) of the competent authorities regarding genetically modified organisms release in the environment

☐ 4.14. Scientific advice given by CHMP

☐ 4.15. Copy(ies) of Marketing Authorisation(s) granted in an EEA country or third country under Article 702 (4) m)-o) of Law No. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended, and the equivalent in third countries on request (photocopies of the pages which give the Marketing authorisation number, Date of authorisation and pages which have been signed by the competent authorities).

☐ 4.16. Correspondence with European Commission regarding multiple applications.

☐ 4.17. List of Mock-ups or Samples/specimens sent with the application, as appropriate.

☐ 4.18. List of proposed (invented) names and marketing authorisation holders in the concerned member states.

☐ 4.19. Copy of EMEA certificate for a Vaccine Antigen Master File (VAMF)

☐ 4.20. Copy of EMEA certificate for Plasma Master File (PMF)

☐ 4.21. For each active substance, attach a declaration from the Qualified Person of the manufacturing authorisation holder, mentioned in Section 2.5.1, and from the qualified person of each manufacturing authorisation holder (i.e. located in EEA), mentioned in Section 2.5.2, where the active substance is used as a starting material that the active substance manufacturer(s) referred to in Section 2.5.3, operating in accordance with the Rules on Good Manufacturing Practice for active substances. This does not apply to blood or blood components.

ANNEX 3
to Regulations

APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS FOR HUMAN USE

AUTHORISATION VIA NATIONAL PROCEDURE (MRP) ☐ Authorisation number via MRP[1]: _/_/__/
AUTHORISATION VIA COMMUNITY PROCEDURE: ☐
AUTHORISATION ONLY VIA NATIONAL PROCEDURE: ☐
REFERENCE MEMBER STATE

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

INTERESTED MEMBER STATE:

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐	None			☐

Is the medicinal product on the market?

☐ YES ☐ NO

If YES, in what Member States is it marketed[2]?

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HU	☐	IS	☐	IE	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

Invented name:	Name and address of the Marketing Authorisation Holder:
Active substance(s):	
Pharmaceutical classification (group + ATC code):	
Pharmaceutical form and strength[3]:	Name and address of the contact person[4]:
Route of administration[3]:	
Target species[3]:	
MA Number[3]:	Telephone: Fax: E-mail: Applicant's reference:

Date of first authorisation in Reference Member State/Community:	Date of first authorisation in Romania: Date of expiry of current authorisation in Romania::
Date of expiry of current authorisation in Reference Member State/Community:	
	Date agreed for renewal of authorisation:

1 For medicinal products for human use: number to be completed by the Marketing Authorisation Holder, reflecting the correct sequence of the number within the Mutual Recognition Procedure, in accordance with Volume 2A, Chapter 2.7. Numbering System for the Procedures for Mutual Recognition and Decentralised Procedures, in accordance with the overview on the European Commission website (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm).

2 For medicinal products authorised through centralised procedure, a separate Annex shall be submitted, containing a list of EU Member States/Norway/Iceland where the respective product is marketed.

3 For centrally authorised products, the above information, including container and packaging size(s), should be provided as a table in a separate Annex (according to Annex A attached to the CHMP opinion)

4 As mentioned in section 2.4.3 or Part 1A of the dossier. If different, attach letter of authorisation.

AUTHORISED MANUFACTURERS

Authorised manufacturers (or importers) responsible for batch release in Romania/EEA (according to Articles 748 and 760 of Law No. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended)

Name:

Address:

Country:

Telephone: Telefax: E-mail:

Further manufacturers responsible for batch release can be detailed in the text field below, in the same format as shown above.

For blood products and vaccines:

State laboratory or laboratory designated for official batch release, as accordance with Articles 823 (1), 825, 826 and 827 of Law no. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended.

Name:

Address:

Country:

Telephone: Telefax: E-mail:

Further manufacturers responsible for batch release can be detailed in the text field below, in the same format as shown above.

Site(s) in Romania or the EEA, where batch control/testing takes place, as required by Article 760 of Law no. 95/2006 on healthcare reform, Title XVII, "The Medicinal Product", as amended, if different from above:

Name:

Address:

Country:

Telephone: Telefax: E-mail:

Further sites can be detailed below, in the same format as shown above.

Manufacturer(s) of the medicinal product and site(s) of manufacture (including diluent and solvent manufacturing sites):

Name:

Address:

Country:

Telephone: Telefax: E-mail:

Brief description of functions performed by manufacturer of dosage form/assembler etc.:

Further manufacturers can be detailed below, in the same format as shown above.

Manufacturer(s) of active substance(s)

NOTE: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Importer or supplier details alone are not sufficient.

Name:

Address:

Country:

Telephone: Telefax: E-mail:

Further active substance manufacturers can be detailed below, in the same format as shown above.

QUALITATIVE AND QUANTITATIVE COMPOSITION (ACTIVE SUBSTANCE AND EXCIPIENTS)
(For centrally authorised products the composition should be provided separately in tabular format as part of the Quality Expert Statement).
A note should be given as to which quantity the composition refers (e.g. 1 capsule).
List the active substances separately from the excipients.

Name of the active substance(s)*	Quantity	Unit	Standard monograph
Name of the excipient(s)*	Quantity	Unit	Standard monograph

Overdose details shall not be included in these forms; these shall be stated below:

- active substance(s)

- excipient(s)

*Only one name for each substance should be given in the following order of priority: INN, European Pharmacopoeia, The Romanian Pharmacopoeia, common name, scientific name. The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.

[If revised product information (SPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form.]

PRESENT SPC TEXT	PROPOSED SPC TEXT

DOCUMENTS ATTACHED TO THE RENEWAL APPLICATION

Module 1:

☐ 1.0. Cover letter
☐ 1.1. Table of contents
☐ 1.2. Renewal Application Form with the following annexes:
☐ A list of all authorised product presentations for which renewal is required in tabular format
Details related to the contact persons:
☐ • Qualified person in the European Economic Area *(EEA)* for Pharmacovigilance;
☐ • Contact person in the EEA with overall responsibility for product defects and recalls;
☐ • Contact person for scientific service in the EEA in charge of information about the marketed medicinal products.
☐ • List of EU Member States/Norway/Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date
☐ • Chronological list of all post-authorisation submissions since grant of the Marketing Authorisation or last renewal: a list of all approved or pending Type IA/IB/II variations, approved or pending; extensions, notifications under Article 771 (3) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended; urgent safety

restrictions, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the changes

☐ • Chronological list of follow-up measures and, for centrally authorised medicinal products, any specific obligations submitted from the date of authorisation/latest renewal, stating the application field, status, date of submission and date of conclusion (if applicable)

☐ • Reviewed list of follow-up measures for post-authorisation remainders/commitments and, for centrally authorised medicinal products, any specific obligations and a signed (if applicable) letter of commitment

☐ • A statement or, when available, a certificate of GMP compliance, (authorised by the competent authority, not more than three years old, for the manufacturer(s) of the finished medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, if available.

☐ • For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcomes

☐ • A declaration by the Qualified Person (QP) of each of the Manufacturing Authorisation Holders (i.e. located in the EEA), listed in the application form where the active substance(s) has/have been used as starting material(s) and have been obtained in accordance with the GMP Guidelines for starting materials, as adopted by the European Community[5].

☐ • Where different, a declaration by the Qualified Person of the Manufacturing Authorisation Holder(s) listed in the application form as responsible for batch release, stating that the batches have been obtained in accordance with the GMP guidelines for starting materials, as adopted by the European Community[5].

☐ 1.3.1 SPC, Labelling and Package Leaflet

☐ 1.3.2 Specimen/sample (only for centralised authorities)

☐ 1.4 Information about the expert's qualification and experience

☐ 1.4.1 For quality documents (signature + CV)

☐ 1.4.2 For nonclinical documents(signature + CV) – (if needed – only for centrally authorised medicinal products)

☐ 1.4.3 For clinical documents(signature + CV)

Module 2

☐ 2.3 Quality Overall Summary (Quality Expert Statement)

☐ 2.4 Non-clinical Summary (Non-clinical Expert Statement – if applicable – only for centrally authorised medicinal products)

☐ 2.5 Clinical Summary (Clinical Expert Statement)

Module 5

☐ 5.3.6 Reports on Post-marketing experience (Periodic Safety Update Report and Summary Bridging Report if applicable)

[5] In case of several qualified persons, a single statement of one of the qualified persons, related to the fact that the active substance(s) used as starting material(s) has/have been obtained in accordance with the Guidelines on the Good Manufacturing Practice for starting materials, as adopted by the European Community, provided that:

- The statement is signed by all concerned qualified persons;
- The statement is based on a technical agreement in accordance with the description in chapter 7 of the GMP Guideline and the qualified person making the statement is the one assigned by the agreement as specifically responsible for the compliance with the GMP Guideline on compliance with GMP Guidelines on account of the active substance manufacturer(s).

I hereby make application for the above Marketing Authorisation to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 728 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, as amended. The product conforms with current CHMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authorities.

Fees will be paid in accordance with NAMMD payment rules Amount/Currency:

Main signatory…… Function……..

Print name…… Date

Second signatory…….. Function……...

(where appropriate)

Print name…… Date

DECISION

No. 12/07.06.2010

on approval of the Norms on the classification for supply of medicinal products for human use

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order no. 1027/09.05.2005, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.06.2007, in accord with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law no. 594/2002, as further amended, agrees on the following

DECISION

Art. 1. – The Norms on the classification for supply of medicinal products for human use are approved, in accordance with the Annex which is integral part of this Decision.

Art. 2. – On this Decision coming into force, NMA Scientific Council Decision No. 8/21.02.2003, approved through Order of the Minister of Health No. 679/16.07.2003 on approval of the Norms on the classification for supply of medicinal products for human use is approved.

Art. 3. – This Decision is approved through Order of the Minister of Health and is published in the Official Gazette of Romania, Part I.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,
Acad. Prof. Dr. Victor Voicu

MINISTRY OF HEALTH

ORDER
on approval of the Norms on the classification for supply of medicinal products for human use

On seeing the common report for approval No. Cs. A. 13.8169/2010 of the Medicinal Product Policy Directorate,

Taking into account:

- the provisions of Title XVII, The medicinal product' of Law No. 95/2006 on healthcare reform, as amended;

- Government Decision No. 734/2010 on the organisation and functioning of the National Agency for Medicines and Medical Devices,

based on Government Decision No. 144/2010 on the organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. 1. – The Norms on the classification for supply of medicinal product for human use, mentioned in the Annex which is integral part of this Order are approved.

Art. 2. – The National Agency for Medicines and Medical Devices shall comply with the provisions of this Order.

Art. 3. – On this Order coming into force, Order of the Minister of Health No. 679/2003 on approval of the Regulations concerning the classification for supply of medicinal products for human use, published in the Official Gazette of Romania, Part I, No. 556 of 1 August 2003 is repealed.

Art. 4. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Cseke Attila

Bucharest, 31 December 2010.
No. 1.602.

ANNEX

NORMS
on the classification for supply of medicinal products for human use

Art. 1. - (1) These Norms regulate the manner of classification for supply of medicinal products for human use.

(2) These Norms apply to medicinal products authorised for marketing in Romania through national, mutual recognition and decentralised procedures.

(3) These Norms are set up in accordance with the provisions of Chapter VI "The classification of medicinal products" of Title XVII – The medicinal product of Law No. 95/2006 on healthcare reform, as amended.

Art. 2. - (1) The subcategories of medicinal products released only by medical prescription are established by the National Medicines Agency in accordance with Art. 780 (2) of Law No. 95/2006, as amended.

(2) The expressions used for the classification subcategories for supply of medicinal products for human use are the following:

a) *PRF* – medicinal products released by medical prescription stored in pharmacies (non-renewable), in accordance with Art. 780 (2) a) of Law No. 95/2006, as amended;

b*) P6L* – medicinal products released by medical prescription not stored in pharmacies (renewable), in accordance with Art. 780 (2) a) of Law No. 95/2006, as amended; the medical prescription can be used for 6 months as of release;

c) *PS* – Medicinal products released by special medical prescription (narcotics and psychotropic products), in accordance with Art. 781 (2) first paragraph of Law No. 95/2006, as amended;

d) *PR* – Medicinal products released by restrictive medical prescription, reserved for use in certain specialised fields, in accordance with Art. 780 (2) c) corroborated with Art. 781 (3) of Law No. 95/2006, as amended.

Art. 3. – Medicinal products noncompliant with the aforementioned criteria can be classified as medicinal products released without medical prescription.

Art. 4. – The classification for supply of medicinal products for human use shall be stated in the marketing authorisation, and the classification subcategory shall be stated in Annex 3 to the marketing authorisation, namely "Information on the label".

Art. 5. - (1) These norms apply to all medicinal products authorised after their coming into force.

(2) In case of medicinal products previously authorised for marketing, these norms apply on renewal of authorisation.

Art. 6. – For medicinal products authorised prior to the coming into force of these norms, up to the renewal of the authorisation or within a year from these norms coming into force (in view of medicinal products having an unlimited

marketing authorisation), the expressions used for the classification subcategories shall be made equivalent with the adopted expressions through these norms, as follows:

- P-RF with PRF;
- P-6L with P6L;
- P-TS with PS;
- S with PR.

DECISION
No. 35/13.12.2010

on completion of Scientific Council Decision No. 16/07.06.2010 on change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics, approved through SCD No. 6/23.03.2010

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on the Order of the Minister of Health No. 1123/18.08.2010, summoned by the NAMMD President in the ordinary meeting of 13.12.2010, in accordance with Art. 12 (5) of Government Ordinance No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, adopts the following

DECISION

Art. 1. - Point 5) of the Annex to Scientific Council Decision No. 16/07.06.2010 shall read as follows:

”5) Marketing authorisation holders as well as companies conducting consultation with target patient groups on their behalf are to be accredited and regularly subject to inspection by the National Agency for Medicines and Medical Devices (NAMMD), based on documentation approved by the NAMMD President and validated by the Scientific Council.”

Art. 2. – The completion of the Annex to Scientific Council Decision No. 16/07.06.2010 is approved, with the following points:

“6) There is an unlimited number of accreditations for Marketing Authorisation Holders and for the companies performing consultation with target patient groups.

7) Tests related to consultations with target patient groups may be conducted by any internal/external operator who follows the rules and requirements stipulated in the national regulatory legislation.

8) In case the report concerning the outcomes of consultations with target patient groups is performed by an operator accredited by the NAMMD, the Agency considers that the respective procedures have been followed, thus enjoying swift assessment and approval.

9) For reports containing the outcomes of the consultations with target patient groups performed by an operator unaccredited by the NAMMD, the entire assessment procedure shall similarly involve the check-up of the respective operator’s compliance with the criteria concerning its technical and professional ability to ensure the quality system issued by the NAMMD.”

Art. 3. – The criteria on the accreditation and surveillance of the operators performing consultations with target patient groups are approved in accordance with Annex 1 as well as with the Request form of the Accreditation certificate in accordance with Annex 2 which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 2/22.02.2011

on posting on the NAMMD website of certain data in clinical trials authorised by the NAMMD

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.02.2011, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. – For purposes of observance of basic medical research principles provided in the Helsinki Declaration and in line with Regulation (EC) 726/2004 on establishing by the European Medicines Agency of a data base for medicinal products authorised in the European Union to be made publicly available, the NAMMD will post clinical trial information on its own website, according to the European Guidance ENTR/F/2/SF D (2009) 3687, whose overall purpose is to provide the general public relevant data of public health interest.

Art. 2. - (1) Such information related to ongoing or completed clinical trials may be of interest for patients and their careers as well as for healthcare professionals.

(2) Other potential beneficiaries may include the pharmaceutical industry, academics, the scientific community and regulation bodies.

Art. 3. – At the same time, improved transparency of information may contribute to development of new research supporting design of higher quality trials, requiring fewer patients and avoiding ineffectual duplication.

Art. 4. – Clinical trial information to be made public are given in the attached Table, which is integral part of this decision.

Art. 5. - (1) For implementation of this provision, applicants are to submit a document containing information under Article 4, at the same time with their request for clinical trial approval.

(2) Data in the document in question are updated every time changes occur in information provided in the annex.

Art. 6. - Provisions of this decision enter into force on the date of NAMMD posting on its website of the manner of operation of the data base for information in authorised clinical trials to be made publicly available.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

DECISION
No. 5/22.02.2011

on approval of mandatory monthly reporting of marketing in Romania, i.e. of medicinal product for human use sales by authorised wholesale distributors

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.02.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. – Mandatory monthly reporting to the NAMMD by wholesale distributors of trade operations with medicinal product for human use in their own portfolio is hereby approved.

The end purpose is to ensure medicinal product traceability over the entire chain from manufacture and/or distribution to the level of community pharmacy, hospital pharmacy, drugstore, check accuracy of prescription and dispensation of on-prescription or over-the-counter medicinal products, identify counterfeit medicines and prevent their penetration of the distribution chain as well as to combat duplicate medicinal product outlets and respectively warrant prompt recall of noncompliant medicinal product batches or in circumstances of health emergency.

Art. 2. – The report will be submitted to the NAMMD – the Pharmaceutical Inspection department, and will consist of the following:

- List of medicinal products for human use entered released from the inventory of authorised importers/wholesalers according to Order of the Ministry of Health No. 312/2009 and Order of the Ministry of Public Health No. 1964/2008, respectively, on the various types of import/wholesale distribution, including the amounts, manufacturing batches, medicinal product provider(s) and beneficiary(ies), respectively, as well as identification data of fiscal accompanying documents (number, batch, invoicing date and/or advice of delivery).

- List of medicinal products for human use released from the inventory of Romanian manufacturers authorised in line with Minister of Health Order no. 312/2009, including the amounts, manufacturing batches, medicinal product provider(s) and beneficiary(ies), respectively, as well as identification data of fiscal accompanying documents (number, batch, invoicing date and/or advice of delivery).

Art. 3. – (1) The report is performed electronically and accompanied by a sworn statement of the company legal representative conduction reporting on the accuracy of data submitted.

(2) It is mandatory that the first report contain a mention of the Romanian distributor's/importer's/manufacturer's stock on reporting.

(3) The reporting format as well as the e-mail address for submission will be posted on the NAMMD website before 01.05.2011.

Art. 4. – This decision comes into force on 01.05.2011.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

DECISION
No. 7/22.02.2011

on approval of Regulations on set up of documentation in support of applications for waiver from legal provisions in force on packaging/labelling of medicinal products for human use authorised for marketing, other than as mentioned in the Annex to Order of the Minister of Public Health No. 872/2006

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.02.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. – In view of enforcing the NMA President Decision No. 172/29.03.2010 concerning the assessment of the applications for waiver from legal provisions in force on packaging/labelling of medicinal products for human use authorised for marketing, other than as mentioned in the Annex to Order of the Minister of Public Health No. 872/2006, the applicants should submit to the NAMMD Registry – document distribution and release at least the following documents and information:

- the application specifying the medicinal product for temporary waiver from the marketing authorisation's (MA) legal provisions in force (the exact size of the packaging shall be specified) concerning the manner of imprinting of the primary/secondary packaging and/or of the leaflet and of the arguments brought by the applicant to support the submitted application;
- specification of the manufacturing batch, expiry date and amount of the medicinal product to be marketed in Romania with a packaging having a waiver from labelling in accordance with the MA provisions in force;
- a draft of the primary/secondary packaging or sample of the primary/secondary packaging for the medicinal product requiring the waiver, namely the draft proposal for relabelling/repackaging, as required;
- a service contract with an authorised manufacturing unit which performs the relabelling/repackaging of the medicinal product, as required;

- the situation of the medicinal product's marketing from the authorisation date to the application date;
- the approximate date on which the medicinal product shall be marketed in accordance with the MA and its legal provisions in force.

Art. 2. – Only the applications for waiver from legal provisions in force on packaging/labelling of medicinal products authorised for marketing following the applicant's self-notification concerning non-compliances in the imprinting of the primary/secondary packaging and/or in the product's leaflet shall be accepted for evaluation.

These non-compliances may be:

- minor – which do not affect the safety of the medicinal product's administration in patients
- major – which, under certain circumstances, may affect the safety of the medicinal product's administration in patients
- critical – which may lead to serious accidents; in this situation, the recall and disposal of the medicinal product are required.

Art. 3. – The product categories for which the NAMMD may consider the applications for waiver from legal provisions in force on the packaging/labelling of medicinal products are the following:

- Medicinal product categories having a unique International Non-proprietary Name (INN) in Romania;
- Medicinal products solely for hospital use;
- Medicinal products for advanced therapy, oncological medicinal products, medicinal products for rare disorders etc.
- Medicinal products for which the Ministry of Health has issued an authorisation for supply of medicinal products for special needs;
- Medicinal products which, at the moment of request, represent a therapeutic need;
- Medicinal products included in national healthcare programs of the Ministry of Health and the National Health Insurance House.

Art. 4. – (1) In case of obtaining a favourable opinion from the NAMMD, the applicant must forward the entire amount for which the waiver has been granted, to the authorised manufacturer conducting the process of relabelling/repackaging of the medicinal product; subsequently, the manufacturer shall perform these operations only for the amount and manufacturing batches waived through the approval of the NAMMD.

(2) After finishing the relabelling/repackaging of the entire quantity for which the exemption was approved, the applicant must forward to the NAMMD a copy of the declaration(s) of compliance issued by the qualified person who released the manufacturing batch.

Art. 5. – The inspectors of the NAMMD Pharmaceutical Inspection Department (PID) shall take into consideration the observance of the provisions of this decision, when evaluating the targeted and distributed applications sent by the NAMMD president to the PID.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

Medicinal product batches recalled during the 1st quarter of 2011

No. crt.	Product recalled	Pharma-ceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
1	Ebixa 10mg/g	Oral drops, solution	10 mg/g	Memantinum	H. LUNDBECK A/S - Denmark/ H. LUNDBECK A/S - Denmark	All batches	Recall agreed with the European Medicines Agency up to the wholesale distributor level as a consequence of the change of the manner of expression of the product's strength on the leaflet and package.	Destruction	07.01.2011
2	Ketard 200mg	Prolonged-release capsules	200 mg	Ketoprofenum	LABORMED PHARMA S.A. - ROMANIA/ LABORMED PHARMA S.A. - Romania	0010010073 (exp. 07.2012)	Voluntary withdrawal initiated by the manufacturer; noncompliant with parameter „Failure test"	Destruction	17.01.2011
3	Strepsils Clasic, lozenges, box with 1 blister x 12 lozenges	Lozenges	-	Combinations	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain/ RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain	7V, 3X, 2V, 5W, 4Y	Voluntary withdrawal initiated by the MAH	Destruction	31.01.2011
4	Strepsils Mentol şi Eucaliptol, lozenges, box with 1 blister x 12 lozenges	Lozenges	-	Combinations	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain/ RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain	5W, 5W2, 3X, 5X, 6X	Voluntary withdrawal initiated by the MAH	Destruction	31.01.2011

No. crt.	Product recalled	Pharma-ceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
5	Strepsils Miere şi Lămâie, lozenges, box with 1 blister x 12 lozenges	Lozenges	-	Combinations	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain/ RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain	13T, 18T, 1V, 1V, 20V, 2W, 13X, 19X, 11Y, 22Y	Voluntary withdrawal initiated by the MAH	Destruction	31.01.2011
6	Strepsils Miere şi Lămâie, lozenges, box with 2 blisters x 12 lozenges	Lozenges	-	Combinations	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain/ RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain	26T, 19T2, 9V, 17V, 16V, 35V, 14X, 13X, 24X, 10Y, 11Y, 3Z	Voluntary withdrawal initiated by the MAH	Destruction	03.03.2011
7	Strepsils Mentol şi Eucaliptol, lozenges, box with 2 blisters x 12 lozenges	Lozenges	-	Combinations	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain/ RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED – Great Britain	3T, 15T, 1V, 11V, 1W, 5W, 4X, 6X, 3Y, 2Z	Voluntary withdrawal initiated by the MAH	Destruction	03.02.2011
8	MOVALIS 15mg	Suppositories	15 mg	Meloxicamum	INSTITUTO DE ANGELI SRL – Italy/ BOEHRINGER INGELHEIM INTERNATIONAL GMBH - Germany	All batches	Voluntary withdrawal initiated by the MAH as a consequence of finding results other than found throughout stability studies	Destruction	03.02.2011

No. crt.	Product recalled	Pharma-ceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
9	CLAFEN 10mg/g	Cream	10mg/g	Diclofenacum	ANTIBIOTICE SA-Romania/ ANTIBIOTICE SA-Romania	U361393 (exp.05.2013)	Presence of the Clotrimazol cream leaflet inside the outer packaging of Clafen	Recall/ Remedy of noncompliant batch	03.02.2011
10	MASTODYNON	Oral drops, solution	-	-	BIONORICA AG – Germany/ BIONORICA AG - Germany	0000047785 (exp.06.2013)	Non-compliant batch concerning „Description”	Destruction	03.03.2011

Marketing authorisation/renewal applications submitted to the NAMMD during the 4th quarter of 2010

During the 4th quarter of 2010, 528 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - Drugs for acid related disorders
A03 - Drugs for functional gastrointestinal disorders
A04 – Antiemetics and antinauseants
A05 – Bile and liver therapy
A06 - Laxatives
A07 - Antidiarrheals, intestinal antiinflammatory/antiinfective agents
A10 - Drugs used in diabetes
A12 - Mineral supplements
A16 – Other alimentary tract and metabolism products
B01 - Antithrombotic agents
B02 - Antihemorrhagics
B05 - Blood substitutes and perfusion solutions
C01 – Cardiac therapy
C03 - Diuretics
C04 - Peripheral vasodilators
C08 – Calcium channel blockers
C09 - Agents acting on the renin–angiotensin system
C10 - Lipid modifying agents
D01 - Antifungals for dermatological use
D03 - Preparations for treatment of wounds and ulcers
D05 - Antipsoriatics
D07 – Corticosteroids for dermatological use
D10 - Anti–acne preparations
G01 - Gynaecological anti–infectives and antiseptics
G03 - Sex hormones and modulators of the genital system
G04 - Urologicals
H01 - Pituitary and hypothalamic hormones
H02 – Corticosteroids for systemic use
H03 - Thyroid therapy
H05 – Calcium homeostasis
J01 - Antibacterials for systemic use
J04 - Antimycobacterials

J05 – Antivirals for systemic use
J06 – Immune sera and immunoglobulins
J07 - Vaccines
L01 – Antineoplastic agents
L02 – Endocrine therapy
L04 - Immunosuppressants
M01 - Anti–inflammatory and anti–rheumatic medicinal products
N01 - Anaesthetics
N02 - Analgesics
N03 - Antiepileptics
N04 - Anti–parkinson drugs
N05 - Psycholeptics
N06 – Psychoanaleptics
N07 - Other nervous system drugs
R02 - Throat preparations
R03 - Drugs for obstructive airway diseases
R05 - Cough and cold preparations
R06 - Antihistamines for systemic use
S01 - Ophthalmologicals
V08 – Contrast media
Xn – Preparations for bee therapy

Medicinal products authorised for marketing by the NAMMD during the 4th quarter of 2010

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ACICLOVIRUM	ACICLOVIR FARMEX 200 mg	capsules	200mg	FARMEX COMPANY S.R.L.	ROMANIA	2878	2010	01
ACIDUM PAMIDRONICUM	CLASTODRON 3 mg/ml	concentrate for solution for infusion	3mg/ml	ACTAVIS GROUP PTC EHF	ICELAND	2973	2010	09
ACIDUM PAMIDRONICUM	CLASTODRON 6 mg/ml	concentrate for solution for infusion	6mg/ml	ACTAVIS GROUP PTC EHF	ICELAND	2974	2010	04
ACIDUM PAMIDRONICUM	CLASTODRON 9 mg/ml	concentrate for solution for infusion	9mg/ml	ACTAVIS GROUP PTC EHF	ICELAND	2975	2010	04
ACIDUM RISEDRONICUM	ACTONEL SAPTAMANAL 35mg	film-coated tablets	35mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	2853	2010	06
ACIDUM RISEDRONICUM	RIGAT 35 mg	film-coated tablets	35mg	VALE PHARMACEUTICALS LTD.	IRELAND	3118	2010	02
ACIDUM TIOCTICUM (ALFA-LIPOICUM)	THIOCTACID 600 HR (see N07XN03)	film-coated tablets	600mg	MEDA PHARMA GMBH & CO. KG	GERMANY	2852	2010	03
ACIDUM TIOCTICUM (ALFA-LIPOICUM)	THIOCTACID 600 HR (see A16AX01)	film-coated tablets	600mg	MEDA PHARMA GMBH & CO. KG	GERMANY	2852	2010	03
ALBUMINUM HUMANUM	ALBUNORM 250 g/l	solution for infusion	250g/l	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	2981	2010	02
AMBROXOLUM	FLAVAMED 60 mg	effervescent tablets	60mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	3009	2010	02
AMBROXOLUM	FLAVAMED FORTE 30mg/5 ml	oral solution	30mg/ 5ml	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	3010	2010	01
AMISULPRIDUM	PRIDOSIL 200 mg	tablets	200mg	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	2818	2010	13
AMISULPRIDUM	PRIDOSIL 400 mg	film-coated tablets	400mg	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	2819	2010	13
ANASTROZOLUM	ANASTROZOL ATB 1 mg	film-coated tablets	1mg	ANTIBIOTICE S.A.	ROMANIA	2919	2010	03
ANASTROZOLUM	ANASTROZOL TEVA 1 mg	film-coated tablets	1mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3020	2010	16

ATORVASTATINUM	TORVACARD 10 mg	film-coated tablets	10mg	ZENTIVA K.S.	CZECH REPUBLIC	2798	2010	04
ATORVASTATINUM	TORVACARD 20 mg	film-coated tablets	20mg	ZENTIVA K.S.	CZECH REPUBLIC	2799	2010	04
ATORVASTATINUM	TORVACARD 40 mg	film-coated tablets	40mg	ZENTIVA K.S.	CZECH REPUBLIC	2800	2010	04
ATORVASTATINUM	TULIP 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	2855	2010	09
ATORVASTATINUM	TULIP 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	2856	2010	08
ATORVASTATINUM	TULIP 40 mg	film-coated tablets	40mg	SANDOZ S.R.L.	ROMANIA	2857	2010	08
ATORVASTATINUM	TULIP 80 mg	film-coated tablets	80mg	SANDOZ S.R.L.	ROMANIA	2858	2010	08
ATORVASTATINUM	SORTIS 5 mg	chewable tablets	5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2890	2010	01
ATORVASTATINUM	SORTIS 10 mg	chewable tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2891	2010	01
ATORVASTATINUM	SORTIS 20 mg	chewable tablets	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2892	2010	01
ATORVASTATINUM	SORTIS 40 mg	chewable tablets	40mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2893	2010	01
ATORVASTATINUM	ATILEN 10 mg	film-coated tablets	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2894	2010	15
ATORVASTATINUM	ATILEN 20 mg	film-coated tablets	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2895	2010	15
ATORVASTATINUM	ATILEN 40 mg	film-coated tablets	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2896	2010	15
ATORVASTATINUM	ATILEN 80 mg	film-coated tablets	80mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2897	2010	15
ATORVASTATINUM	XAMARA 10 mg	film-coated tablets	10mg	DR. REDDY'S LABORATORIES	ROMANIA	2966	2010	07
ATORVASTATINUM	XAMARA 20 mg	film-coated tablets	20mg	DR. REDDY'S LABORATORIES	ROMANIA	2967	2010	06
ATORVASTATINUM	XAMARA 40 mg	film-coated tablets	40mg	DR. REDDY'S LABORATORIES	ROMANIA	2968	2010	05
ATORVASTATINUM	XAMARA 80 mg	film-coated tablets	80mg	DR. REDDY'S LABORATORIES	ROMANIA	2969	2010	05
ATORVASTATINUM	TORVAZIN 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2939	2010	03

ATORVASTATINUM	TORVAZIN 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2940	2010	03
ATORVASTATINUM	TORVAZIN 40 mg	film-coated tablets	40mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2941	2010	03
ATORVASTATINUM	SORTIS 10 mg	film-coated tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2949	2010	03
ATORVASTATINUM	SORTIS 20 mg	film-coated tablets	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2950	2010	03
ATORVASTATINUM	SORTIS 40 mg	film-coated tablets	40mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2951	2010	05
ATORVASTATINUM	SORTIS 80 mg	film-coated tablets	80mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2952	2010	05
ATORVASTATINUM	ATORVASTATINA TEVA 10 mg	film-coated tablets	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3125	2010	09
ATORVASTATINUM	ATORVASTATINA TEVA 20 mg	film-coated tablets	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3126	2010	09
ATORVASTATINUM	ATORVASTATINA TEVA 40 mg	film-coated tablets	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3127	2010	09
ATORVASTATINUM	ATORVASTATINA TEVA 80 mg	film-coated tablets	80mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3128	2010	09
BETAHISTINUM	BETAHISTINA LPH 8 mg	tablets	8mg	LABORMED PHARMA S.A.	ROMANIA	3076	2010	03
BETAHISTINUM	BETAHISTINA LPH 16 mg	tablets	16mg	LABORMED PHARMA S.A.	ROMANIA	3077	2010	03
BEZAFIBRATUM	BEZAFIBRAT FARMEX 200 mg	tablets	200mg	FARMEX COMPANY S.R.L.	ROMANIA	3054	2010	01
BICALUTAMIDUM	BICALUTAMIDA ACCORD 50 mg	film-coated tablets	50mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2948	2010	09
BISACODYLUM	STADALAX 5 mg	gastroresistant pills	5mg	STADA ARZNEIMITTEL AG	GERMANY	3061	2010	03
BISACODYLUM	LAXAMAG 10 mg	suppositories	10mg	MAGISTRA C&C S.R.L.	ROMANIA	3062	2010	01
BISOPROLOLUM	SUPRACARD 5 mg	tablets	5mg	VALE PHARMACEUTICALS LIMITED	IRELAND	2957	2010	09
BISOPROLOLUM	SUPRACARD 10 mg	tablets	10mg	VALE PHARMACEUTICALS LIMITED	IRELAND	2958	2010	09
BROMAZEPAMUM	CALMEPAM 1.5 mg	tablets	1.5mg	GLAXOSMITHKLINE (GSK)	ROMANIA	3102	2010	02
BROMAZEPAMUM	CALMEPAM 3 mg	tablets	3mg	GLAXOSMITHKLINE (GSK)	ROMANIA	3103	2010	01
BROMAZEPAMUM	CALMEPAM 3 mg	tablets	3mg	GLAXOSMITHKLINE (GSK)	ROMANIA	3103	2010	02
CANDESARTANUM CILEXETIL	DOLNIX 4 mg	tablets	4mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3070	2010	02

CANDESARTANUM CILEXETIL	DOLNIX 8 mg	tablets	8mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3071	2010	02
CANDESARTANUM CILEXETIL	DOLNIX 16 mg	tablets	16mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3072	2010	02
CANDESARTANUM CILEXETIL	DOLNIX 32 mg	tablets	32mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3073	2010	02
CEFTRIAXONUM	SEFTRION 2 g	powder for solution for infusion	2g	EIPICO MED SRL	ROMANIA	2937	2010	01
CISPLATINUM	CISPLATINA ACCORD 1 mg/ml	concentrate for solution for infusion	1mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3117	2010	03
CLOPIDOGRELUM	CLOPIDOGREL INVENT FARMA 75 mg	film-coated tablets	75mg	INVENT FARMA, S.L.	SPAIN	3105	2010	08
COMBINATIONS	CEMOLPLUS 500 mg/3 mg	tablets	500mg/ 3mg	SANOSAN S.R.L.	ROMANIA	2873	2010	01
COMBINATIONS	CEMOLSINUS 500 mg/3 mg/50 mg	tablets	500mg/ 3mg/ 50mg	SANOSAN S.R.L.	ROMANIA	2874	2010	01
COMBINATIONS	CROMALLERG 0.5 mg/40 mg/ml	eye drops, solution	0.5mg/ 40mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	2875	2010	01
COMBINATIONS	PROCTOLIZIN 10 mg/20 mg/ 50 mg/gram	cream	10mg/ 20mg/ 50mg/gr	FITERMAN PHARMA S.R.L.	ROMANIA	2876	2010	01
COMBINATIONS	SANADOR PLUS 300 mg/30 mg	tablets	300mg/ 30mg	LAROPHARM S.R.L.	ROMANIA	2989	2010	01
COMBINATIONS	NEUROMULTIVIT	film-coated tablets		LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	3060	2010	02
COMBINATIONS	EFISEN C 300 mg/30 mg	tablets	300mg/ 30mg	SOLACIUM PHARMA S.R.L.	ROMANIA	3055	2010	01
COMBINATIONS	HEMORZON	suppositories		ANTIBIOTICE SA	ROMANIA	3067	2010	02
COMBINATIONS	ASPACO	tablets		BIO EEL S.R.L.	ROMANIA	3094	2010	01
COMBINATIONS	IBUSINUS 200 mg/30 mg	film-coated tablets	200mg/ 30mg	SOLACIUM PHARMA S.R.L.	ROMANIA	3080	2010	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ HYDROCHLORO-THIAZIDUM)	CO-DOLNIX 16 mg/12.5 mg	tablets	16mg/ 12.5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3075	2010	02

COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	DORZOLAMIDA/ TIMOLOL TEVA 20 mg/5mg/ml	eye drops, solution	20mg/ 5mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3035	2010	04
COMBINATIONS (FOSINOPRILUM+ HYDROCHLOROTHIAZIDUM)	MONOTENS HCT 20mg/12.5mg	tablets	20mg/ 12.5mg	PHARMASWISS MEDICINES SRL	ROMANIA	2811	2010	07
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LORISTA HL 100 mg/12.5 mg	film-coated tablets	100mg/ 12.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3018	2010	12
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LOSARTAN/ HIDROCLOROTIAZIDA TECNIMEDE 100 mg/25 mg	film-coated tablets	100mg/ 25mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL S.A.	PORTUGAL	3131	2010	04
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LOSARTAN/ HIDROCLOROTIAZIDA TECNIMEDE 50 mg/12.5 mg	film-coated tablets	50mg/ 12.5mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL S.A.	PORTUGAL	3129	2010	04
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LOSARTAN/ HIDROCLOROTIAZIDA TECNIMEDE 100 mg/12.5 mg	film-coated tablets	100mg/ 12.5mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL S.A.	PORTUGAL	3130	2010	04
COMBINATIONS (METFORMINUM+ GLIBENCLAMIDUM)	FORMAGLIBEN 500 mg/5 mg	film-coated tablets	500mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	2901	2010	05
COMBINATIONS (METFORMINUM+ GLIBENCLAMIDUM)	FORMAGLIBEN 500 mg/2.5 mg	film-coated tablets	500mg/ 2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	2900	2010	05
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PANINDORIL 2 mg/0.625 mg	tablets	2mg/ 0.625mg	SANDOZ S.R.L.	ROMANIA	3091	2010	20
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PANINDORIL 4 mg/1.25 mg	tablets	4mg/ 1.25mg	SANDOZ S.R.L.	ROMANIA	3092	2010	20
COMBINATIONS (QUINAPRILUM+ HYDROCHLOROTHIAZIDUM)	QUINAPRIL/ HIDROCLOROTIAZIDA AUROBINDO 10/12.5mg	film-coated tablets	10/ 12.5mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3015	2010	17
COMBINATIONS (QUINAPRILUM+ HYDROCHLOROTHIAZIDUM)	QUINAPRIL/ HIDROCLOROTIAZIDA AUROBINDO 20/12.5mg	film-coated tablets	20/ 12.5mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3016	2010	17

COMBINATIONS (QUINAPRILUM+ HYDROCHLOROTHIAZIDUM)	QUINAPRIL/ HIDROCLOROTIAZIDA AUROBINDO 20/25mg	film-coated tablets	20/ 25mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3017	2010	17
COMBINATIONS (RUTOSIDUM + ACIDUM ASCORBICUM)	RUTINOSCORBIN 25 mg/100 mg	film-coated tablets	25mg/ 100mg	GLAXOSMITHKLINE PHARMACEUTICALS S.A.	POLAND	2850	2010	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	LINEROL 37.5 mg/325 mg	film-coated tablets	37.5mg/ 325mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	3008	2010	04
DEXRAZOXANUM	PROCARD 20 mg/ml	powder for solution for infusion	20mg/ml	CYATHUS EXQUIRERE PHARMAFORSCHUNGS GMBH	AUSTRIA	2863	2010	02
DICLOFENACUM	CLAFEN 100 mg	suppositories	100mg	ANTIBIOTICE SA	ROMANIA	2990	2010	02
DICLOFENACUM	DICLOFENAC OZONE 10 mg/g	gel	10mg/g	SOLACIUM PHARMA S.R.L.	ROMANIA	3082	2010	01
DOCETAXELUM	DOCETAXEL CADUCEUS 20 mg/0.5 ml	concentrate + solvent for solution for infusion	20mg/ 0.5ml	CADUCEUS PHARMA LTD.	GREAT BRITAIN	2929	2010	01
DOCETAXELUM	DOCETAXEL CADUCEUS 80 mg/ 2 ml	concentrate + solvent for solution for infusion	80mg/ 2ml	CADUCEUS PHARMA LTD.	GREAT BRITAIN	2930	2010	01
DONEPEZILUM	DONECTIL 5 mg	orodispersible tablets	5mg	ICN POLFA RZESZOW S.A.	POLAND	2834	2010	16
DONEPEZILUM	DONECTIL 10 mg	orodispersible tablets	10mg	ICN POLFA RZESZOW S.A.	POLAND	2835	2010	16
DONEPEZILUM	ALZEPIL 5 mg	orodispersible tablets	5mg	PESERI TRADING	CYPRUS	2898	2010	18
DONEPEZILUM	ALZEPIL 10 mg	orodispersible tablets	10mg	PESERI TRADING	CYPRUS	2899	2010	18
DONEPEZILUM	DONEPEZIL BLUEFISH 5 mg	film-coated tablets	5mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3028	2010	04
DONEPEZILUM	DONEPEZIL BLUEFISH 10 mg	film-coated tablets	10mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3029	2010	04
DONEPEZILUM	DONEPEZIL MYLAN 5 mg	orodispersible tablets	5mg	GENERICS (UK) LIMITED	GREAT BRITAIN	3132	2010	13
DONEPEZILUM	DONEPEZIL MYLAN 10 mg	orodispersible tablets	10mg	GENERICS (UK) LIMITED	GREAT BRITAIN	3133	2010	13
ERDOSTEINUM	ERDOMED 175 mg/5 ml	powder for oral suspension	175mg/ 5ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	3063	2010	01

ERDOSTEINUM	ERDOMED 225 mg	granules for oral suspension	225mg	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	3064	2010	01
ESOMEPRAZOLUM	HELIDES 20 mg	gastroresistant capsules	20mg	ETHYPHARM	FRANCE	3068	2010	18
ESOMEPRAZOLUM	HELIDES 40 mg	gastroresistant capsules	40mg	ETHYPHARM	FRANCE	3069	2010	18
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 20mg	gastroresistant capsules	20mg	TERAPIA S.A.	ROMANIA	3045	2010	11
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 40mg	gastroresistant capsules	40mg	TERAPIA S.A.	ROMANIA	3046	2010	11
ETIONAMIDUM	ETIONAMIDA ATB 250 mg	film-coated tablets	250mg	ANTIBIOTICE S.A.	ROMANIA	2918	2010	01
EXEMESTANUM	EXEMESTAN CORIS 25 mg	film-coated tablets	25mg	CORIS PHARMA S.R.L.	ROMANIA	2938	2010	03
CLOTTING FACTOR IX	OCTANINE F 500 IU	powder + solvent for solution for infusion	500 IU	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	2982	2010	01
CLOTTING FACTOR IX	OCTANINE F 1000 IU	powder + solvent for solution for infusion	1000IU	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	2983	2010	01
CLOTTING FACTOR VIII	HAEMOCTIN SDH 250	powder + solvent for solution for injection	50IU/ml	BIOTEST PHARMA GMBH	GERMANY	2868	2010	01
CLOTTING FACTOR VIII	HAEMOCTIN SDH 500	powder + solvent for solution for injection	50IU/ml	BIOTEST PHARMA GMBH	GERMANY	2869	2010	01
CLOTTING FACTOR VIII	HAEMOCTIN SDH 1000	powder + solvent for solution for injection	100IU/ ml	BIOTEST PHARMA GMBH	GERMANY	2870	2010	01
FERRI CARBOXYMALTOSUM	FERINJECT 50 mg iron/ml	solution for injection/infusion	50mg/ml	VIFOR FRANCE SA	FRANCE	2864	2010	04
FOSINOPRILUM	MONOTENS 10 mg	tablets	10mg	PHARMASWISS CESKA REPUBLIKA S.R.O	CZECH REPUBLIC	2812	2010	13
FOSINOPRILUM	MONOTENS 20 mg	tablets	20mg	PHARMASWISS CESKA REPUBLIKA S.R.O	CZECH REPUBLIC	2813	2010	13

FOSINOPRILUM	FENOSIMED 5 mg	tablets	5mg	NUCLEUS EHF	ICELAND	3005	2010	13
FOSINOPRILUM	FENOSIMED 10 mg	tablets	10mg	NUCLEUS EHF	ICELAND	3006	2010	13
FOSINOPRILUM	FENOSIMED 20 mg	tablets	20mg	NUCLEUS EHF	ICELAND	3007	2010	13
GEMCITABINUM	GEMCITABINA ATB 200 mg	powder for solution for infusion	200mg	ANTIBIOTICE S.A.	ROMANIA	3078	2010	01
GEMCITABINUM	GEMCITABINA ATB 1000 mg	powder for solution for infusion	1000mg	ANTIBIOTICE S.A.	ROMANIA	3079	2010	01
GINKGO BILOBA	GINKGO BILOBA BIOFARM 80 mg (see N06DX02)	film-coated tablets	80mg	BIOFARM S.A.	ROMANIA	2920	2010	02
GINKGO BILOBA	GINKGO BILOBA BIOFARM 80 mg (see C04AXN1)	film-coated tablets	80mg	BIOFARM S.A.	ROMANIA	2920	2010	02
GLICLAZIDUM	ADOZID MR 30 mg	prolonged-release tablets	30mg	LABORMED PHARMA S.A.	ROMANIA	2877	2010	02
GRANISETRONUM	KYTRIL 1 mg	film-coated tablets	1mg	ROCHE ROMANIA S.R.L.	ROMANIA	3066	2010	01
HOMEOPATHIC PRODUCTS	AFLUBIN	oral drops, solution		RICHARD BITTNER AG	AUSTRIA	3095	2010	02
HOMEOPATHIC PRODUCTS	PUMPAN	oral drops, solution		RICHARD BITTNER AG	AUSTRIA	3096	2010	02
IDARUBICINUM	IDARUBICIN TEVA 1 mg/ml	solution for injection	1mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3036	2010	02
HEPATITIS B IMMUNOGLOBULIN	HEPATECT CP 50 IU/ml	solution for infusion	50 IU/ml	BIOTEST PHARMA GMBH	GERMANY	3038	2010	03
IRINOTECANUM	IRINOTECAN CORIS 20 mg/ml	concentrate for solution for infusion	20mg/ml	CORIS PHARMA S.R.L.	ROMANIA	2936	2010	02
IRINOTECANUM	IRINOTECAN DOCPHARMA 20 mg/ml	concentrate for solution for infusion	20mg/ml	DOCPHARMA N.V.	BELGIUM	2980	2010	02
ITOPRIDUM	ZIRID 50 mg	film-coated tablets	50mg	ZENTIVA, K.S.	CZECH REPUBLIC	2959	2010	02
KALII CHLORIDUM	CLORURA DE POTASIU KABI 150mg/ml	concentrate for solution for infusion	150mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	2955	2010	05
KETOROLACUM TROMETHAMIN	KETANOV 30 mg/ml	solution for injection	30mg/ml	TERAPIA S.A.	ROMANIA	2924	2010	01

LAMOTRIGINUM	LAMOTRIGINE AUROBINDO 25 mg	tablets	25mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	2963	2010	26
LAMOTRIGINUM	LAMOTRIGINE AUROBINDO 50 mg	tablets	50mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	2964	2010	26
LAMOTRIGINUM	LAMOTRIGINE AUROBINDO 100 mg	tablets	100mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	2965	2010	26
LATANOPROSTUM	XALAPROST 50 micrograms/ml	eye drops, solution	50micro-grams/ml	ICN POLFA RZESZOW S.A.	POLAND	2859	2010	03
LATANOPROSTUM	ARULATAN 50 micrograms/ml	eye drops, solution	50micro-grams/ml	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	GERMANY	3113	2010	03
LERCANIDIPINUM	PEGFEL 10 mg	film-coated tablets	10mg	DR. REDDY'S LABORATORIES LTD.	ROMANIA	2902	2010	02
LERCANIDIPINUM	PEGFEL 20 mg	film-coated tablets	20mg	DR. REDDY'S LABORATORIES LTD.	ROMANIA	2903	2010	02
LEVOCETIRIZINUM	CETIZAL 5 mg	film-coated tablets	5mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	2810	2010	14
LEVOFLOXACINUM	PLATILLA 250 mg	film-coated tablets	250mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3108	2010	04
LEVOFLOXACINUM	PLATILLA 500 mg	film-coated tablets	500mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3109	2010	04
LEVOFLOXACINUM	LEVOTOR 250 mg	film-coated tablets	250mg	TORRENT PHARMA GMBH	GERMANY	3089	2010	04
LEVOFLOXACINUM	LEVOTOR 500 mg	film-coated tablets	500mg	TORRENT PHARMA GMBH	GERMANY	3090	2010	04
LEVOFLOXACINUM	PLATILLA 5 mg/ml	solution for infusion	5mg/ml	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3110	2010	06
LINEZOLIDUM	LINEZOLID TEVA 600 mg	film-coated tablets	600mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3047	2010	14
LOSARTANUM	COZAAR 12.5 mg	film-coated tablets	12.5mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	2976	2010	10
LOSARTANUM	COZAAR 50 mg	film-coated tablets	50mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	2977	2010	18
LOSARTANUM	LOZAP 12.5	film-coated tablets	12.5mg	ZENTIVA A.S.	SLOVAKIA	3025	2010	06
LOSARTANUM	LOZAP 50	film-coated tablets	50mg	ZENTIVA A.S.	SLOVAKIA	3026	2010	06
LOSARTANUM	LOZAP 100	film-coated tablets	100mg	ZENTIVA A.S.	SLOVAKIA	3027	2010	06

MEDAZEPAMUM	MEDAZEPAM LPH 10mg	tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	2849	2010	01
MEROPENEMUM	MEROPENEM KABI 500 mg	powder for solution for injection/ infusion	500mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	2953	2010	04
MEROPENEMUM	MEROPENEM KABI 1g	powder for solution for injection/ infusion	1g	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	2954	2010	06
MEROPENEMUM	MEROPENEM SANDOZ 500 mg	powder for solution for injection/ infusion	500 mg	SANDOZ S.R.L.	ROMANIA	2978	2010	02
MEROPENEMUM	MEROPENEM SANDOZ 1g	powder for solution for injection/ infusion	1g	SANDOZ S.R.L.	ROMANIA	2979	2010	02
MEROPENEMUM	MEROPENEM HOSPIRA 500 mg	powder for solution for injection/ infusion	500mg	HOSPIRA UK LIMITED	GREAT BRITAIN	3106	2010	02
MEROPENEMUM	MEROPENEM HOSPIRA 1 g	powder for solution for injection/ infusion	1g	HOSPIRA UK LIMITED	GREAT BRITAIN	3107	2010	02
METFORMINUM	SIOFOR 850 mg	film-coated tablets	850mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	2851	2010	03
MICONAZOLUM	LORAMYC 50 mg	mucoadhesive buccal tablets	50mg	BIOALLIANCE PHARMA	FRANCE	2824	2010	01
MINOXIDILUM	ALOPEXY 5%	cutaneous solution	5%	PIERRE FABRE DERMATOLOGIE	FRANCE	3116	2010	04
MONTELUKASTUM	SPIROKAST 4 mg	chewable tablets	4mg	ZENTIVA, K.S.	CZECH REPUBLIC	2801	2010	06
MONTELUKASTUM	SPIROKAST 5 mg	chewable tablets	5mg	ZENTIVA, K.S.	CZECH REPUBLIC	2802	2010	06
MONTELUKASTUM	SPIROKAST 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	CZECH REPUBLIC	2803	2010	06
MONTELUKASTUM	MONTELUKAST PHARMATHEN 10 mg	film-coated tablets	10mg	PHARMATHEN SA	GREECE	3030	2010	01

MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL SANDOZ 500 mg	tablets	500mg	SANDOZ S.R.L.	ROMANIA	2848	2010	07
OLANZAPINUM	OLANZAPINA ACCORD 2.5 mg	film-coated tablets	2.5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2804	2010	04
OLANZAPINUM	OLANZAPINA ACCORD 5 mg	film-coated tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2805	2010	04
OLANZAPINUM	OLANZAPINA ACCORD 7.5 mg	film-coated tablets	7.5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2806	2010	04
OLANZAPINUM	OLANZAPINA ACCORD 10 mg	film-coated tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2807	2010	04
OLANZAPINUM	OLANZAPINA ACCORD 15 mg	film-coated tablets	15mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2808	2010	04
OLANZAPINUM	OLANZAPINA ACCORD 20 mg	film-coated tablets	20mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2809	2010	04
OLANZAPINUM	OLANZAPINA MEDANA 5 mg	film-coated tablets	5mg	MEDANA PHARMA SA	POLAND	2820	2010	01
OLANZAPINUM	OLANZAPINA MEDANA 10 mg	film-coated tablets	10mg	MEDANA PHARMA SA	POLAND	2821	2010	01
OLANZAPINUM	OLANZAPINA MEDANA 15 mg	film-coated tablets	15mg	MEDANA PHARMA SA	POLAND	2822	2010	01
OLANZAPINUM	OLANZAPINA MEDANA 20 mg	film-coated tablets	20mg	MEDANA PHARMA SA	POLAND	2823	2010	01
OLANZAPINUM	EGOLANZA 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2825	2010	01
OLANZAPINUM	EGOLANZA 7.5 mg	film-coated tablets	7.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2826	2010	02
OLANZAPINUM	EGOLANZA 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2827	2010	02
OLANZAPINUM	EGOLANZA 15 mg	film-coated tablets	15mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2828	2010	01
OLANZAPINUM	EGOLANZA 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICALS PLC	HUNGARY	2829	2010	01
OLANZAPINUM	OLANZAPINA TORRENT 2.5 mg	orodispersible tablets	2.5mg	TORRENT PHARMA GMBH	GERMANY	2991	2010	08
OLANZAPINUM	OLANZAPINA TORRENT 5 mg	orodispersible tablets	5mg	TORRENT PHARMA GMBH	GERMANY	2992	2010	08
OLANZAPINUM	OLANZAPINA TORRENT 7,5 mg	orodispersible tablets	7.5mg	TORRENT PHARMA GMBH	GERMANY	2993	2010	08

OLANZAPINUM	OLANZAPINA TORRENT 10 mg	orodispersible tablets	10mg	TORRENT PHARMA GMBH	GERMANY	2994	2010	08
OLANZAPINUM	OLANZAPINA TORRENT 15 mg	orodispersible tablets	15mg	TORRENT PHARMA GMBH	GERMANY	2995	2010	08
OLANZAPINUM	OLANZAPINA TORRENT 20 mg	orodispersible tablets	20mg	TORRENT PHARMA GMBH	GERMANY	2996	2010	08
OLANZAPINUM	OLANZAPINA SIGILLATA 5 mg	orodispersible tablets	5mg	SIGILLATA LTD	GREAT BRITAIN	3056	2010	08
OLANZAPINUM	OLANZAPINA SIGILLATA 10 mg	orodispersible tablets	10mg	SIGILLATA LTD	GREAT BRITAIN	3057	2010	08
OLANZAPINUM	OLANZAPINA SIGILLATA 15 mg	orodispersible tablets	15mg	SIGILLATA LTD	GREAT BRITAIN	3058	2010	08
OLANZAPINUM	OLANZAPINA SIGILLATA 20 mg	orodispersible tablets	20mg	SIGILLATA LTD	GREAT BRITAIN	3059	2010	08
OXYCODONUM	ALNAGON 5 mg	prolonged-release tablets	5mg	ZENTIVA, K.S.	CZECH REPUBLIC	2814	2010	20
OXYCODONUM	ALNAGON 10 mg	prolonged-release tablets	10mg	ZENTIVA, K.S.	CZECH REPUBLIC	2815	2010	20
OXYCODONUM	ALNAGON 20 mg	prolonged-release tablets	20mg	ZENTIVA, K.S.	CZECH REPUBLIC	2816	2010	20
OXYCODONUM	ALNAGON 40 mg	prolonged-release tablets	40mg	ZENTIVA, K.S.	CZECH REPUBLIC	2817	2010	20
PACLITAXELUM	PACLITAXEL ACCORD 6 mg/ml	concentrate for solution for infusion	6mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	2905	2010	03
PANTOPRAZOLUM	PANTOPRAZOL DIAMED 20 mg	gastroresistant tablets	20mg	DIAMED GMBH	GERMANY	2871	2010	08
PANTOPRAZOLUM	PANTOPRAZOL DIAMED 40 mg	gastroresistant tablets	40mg	DIAMED GMBH	GERMANY	2872	2010	08
PANTOPRAZOLUM	PANTOPRAZOL ACTAVIS 40 mg	powder for solution for injection	40mg	ACTAVIS GROUP PTC EHF	ICELAND	2904	2010	04
PIROXICAMUM	PIROXICAM OZONE 5 mg/g	gel	5mg/g	OZONE LABORATORIES PHARMA S.A.	ROMANIA	3097	2010	01
PRAMIPEXOLUM	PRAMIPEXOL TORRENT 0.088 mg	tablets	0.088mg	TORRENT PHARMA GMBH	GERMANY	2836	2010	04
PRAMIPEXOLUM	PRAMIPEXOL TORRENT 0.18 mg	tablets	0.18mg	TORRENT PHARMA GMBH	GERMANY	2837	2010	04
PRAMIPEXOLUM	PRAMIPEXOL TORRENT 0.35 mg	tablets	0.35mg	TORRENT PHARMA GMBH	GERMANY	2838	2010	04

PRAMIPEXOLUM	PRAMIPEXOL TORRENT 0.54 mg	tablets	0.54mg	TORRENT PHARMA GMBH	GERMANY	2839	2010	04
PRAMIPEXOLUM	PRAMIPEXOL TORRENT 0.7 mg	tablets	0.7mg	TORRENT PHARMA GMBH	GERMANY	2840	2010	04
PRAMIPEXOLUM	PRAMIPEXOL TORRENT 1.1 mg	tablets	1.1mg	TORRENT PHARMA GMBH	GERMANY	2841	2010	04
PRAMIPEXOLUM	RITMOREST 0.088 mg	tablets	0.088mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	2931	2010	04
PRAMIPEXOLUM	RITMOREST 0.18 mg	tablets	0.18mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	2932	2010	04
PRAMIPEXOLUM	RITMOREST 0.35 mg	tablets	0.35mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	2933	2010	04
PRAMIPEXOLUM	RITMOREST 0.7 mg	tablets	0.7mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	2934	2010	04
PRAMIPEXOLUM	RITMOREST 1.1 mg	tablets	1.1mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	2935	2010	04
PRAMIPEXOLUM	PRAMIPEXOL RANBAXY 0.18 mg	tablets	0.18mg	RANBAXY (UK) LIMITED	GREAT BRITAIN	2942	2010	02
PRAMIPEXOLUM	PRAMIPEXOL RANBAXY 0.7 mg	tablets	0.7mg	RANBAXY (UK) LIMITED	GREAT BRITAIN	2943	2010	02
PRAMIPEXOLUM	AXALANZ 0.088 mg	tablets	0.088mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2997	2010	04
PRAMIPEXOLUM	AXALANZ 0.18 mg	tablets	0.18mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2998	2010	04
PRAMIPEXOLUM	AXALANZ 0.35 mg	tablets	0.35mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2999	2010	04
PRAMIPEXOLUM	AXALANZ 0.7 mg	tablets	0.7mg	ALAPIS ROMANIA S.R.L.	ROMANIA	3000	2010	04
PRAMIPEXOLUM	AXALANZ 1.1 mg	tablets	1.1mg	ALAPIS ROMANIA S.R.L.	ROMANIA	3001	2010	04
PRAVASTATINUM	PRAVASTATINA SODICA VALE 10 mg	tablets	10mg	VALE PHARMACEUTICALS LTD	IRELAND	2915	2010	11
PRAVASTATINUM	PRAVASTATINA SODICA VALE 20 mg	tablets	20mg	VALE PHARMACEUTICALS LTD	IRELAND	2916	2010	11
PRAVASTATINUM	PRAVASTATINA SODICA VALE 40 mg	tablets	40mg	VALE PHARMACEUTICALS LTD	IRELAND	2917	2010	11
QUETIAPINUM	QUETIAPINA RATIOPHARM 25 mg	film-coated tablets	25mg	RATIOPHARM GMBH	GERMANY	2830	2010	29
QUETIAPINUM	QUETIAPINA RATIOPHARM 200 mg	film-coated tablets	200mg	RATIOPHARM GMBH	GERMANY	2832	2010	29
QUETIAPINUM	QUETIAPINA RATIOPHARM 300 mg	film-coated tablets	300mg	RATIOPHARM GMBH	GERMANY	2833	2010	29
QUETIAPINUM	NANTARID 25 mg	film-coated tablets	25mg	VALE PHARMACEUTICALS LTD.	IRELAND	2944	2010	02

QUETIAPINUM	NANTARID 100 mg	film-coated tablets	100mg	VALE PHARMACEUTICALS LTD.	IRELAND	2945	2010	02
QUETIAPINUM	NANTARID 200 mg	film-coated tablets	200mg	VALE PHARMACEUTICALS LTD.	IRELAND	2946	2010	02
QUETIAPINUM	NANTARID 300 mg	film-coated tablets	300mg	VALE PHARMACEUTICALS LTD.	IRELAND	2947	2010	02
QUETIAPINUM	Q MIND 25 mg	film-coated tablets	25mg	TORRENT PHARMA GMBH	GERMANY	3083	2010	04
QUETIAPINUM	Q MIND 100 mg	film-coated tablets	100mg	TORRENT PHARMA GMBH	GERMANY	3084	2010	04
QUETIAPINUM	Q MIND 150 mg	film-coated tablets	150mg	TORRENT PHARMA GMBH	GERMANY	3085	2010	04
QUETIAPINUM	Q MIND 200 mg	film-coated tablets	200mg	TORRENT PHARMA GMBH	GERMANY	3086	2010	04
QUETIAPINUM	Q MIND 300 mg	film-coated tablets	300mg	TORRENT PHARMA GMBH	GERMANY	3087	2010	04
RABEPRAZOLUM	ACILESOL 10 mg	gastroresistant tablets	10 mg	ACTAVIS GROUP PTC EHF	ICELAND	3111	2010	12
RABEPRAZOLUM	ACILESOL 20 mg	gastroresistant tablets	20 mg	ACTAVIS GROUP PTC EHF	ICELAND	3112	2010	12
RALOXIFENUM	RALOXA 60 mg	film-coated tablets	60mg	SYNTHON BV	HOLAND	2862	2010	43
RAMIPRILUM	RAMIPRIL PFIZER 5mg	tablets	5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2846	2010	15
RAMIPRILUM	RAMIPRIL PFIZER 10mg	tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2847	2010	11
REMIFENTANILUM	REMIFENTANIL B. BRAUN 1 mg	powder for concentrate for solution for injection/ infusion	1mg	B. BRAUN MELSUNGEN AG	GERMANY	2883	2010	01
REMIFENTANILUM	REMIFENTANIL B. BRAUN 2 mg	powder for concentrate for solution for injection/ infusion	2mg	B. BRAUN MELSUNGEN AG	GERMANY	2884	2010	01
REMIFENTANILUM	REMIFENTANIL B. BRAUN 5 mg	powder for concentrate for solution for injection/ infusion	5mg	B. BRAUN MELSUNGEN AG	GERMANY	2885	2010	01

RISPERIDONUM	ALEPTOLAN 1 mg	film-coated tablets	1mg	FARMACEUTICA REMEDIA S.A.	ROMANIA	3031	2010	05
RISPERIDONUM	ALEPTOLAN 2 mg	film-coated tablets	2mg	FARMACEUTICA REMEDIA S.A.	ROMANIA	3032	2010	05
RISPERIDONUM	ALEPTOLAN 3 mg	film-coated tablets	3mg	FARMACEUTICA REMEDIA S.A.	ROMANIA	3033	2010	05
RISPERIDONUM	ALEPTOLAN 4 mg	film-coated tablets	4mg	FARMACEUTICA REMEDIA S.A.	ROMANIA	3034	2010	05
RIVASTIGMINUM	RIVASTIGMINA TORRENT 1.5 mg	capsules	1.5mg	TORRENT PHARMA GMBH	GERMANY	2886	2010	15
RIVASTIGMINUM	RIVASTIGMINA TORRENT 3 mg	capsules	3mg	TORRENT PHARMA GMBH	GERMANY	2887	2010	15
RIVASTIGMINUM	RIVASTIGMINA TORRENT 4.5 mg	capsules	4.5mg	TORRENT PHARMA GMBH	GERMANY	2888	2010	15
RIVASTIGMINUM	RIVASTIGMINA TORRENT 6 mg	capsules	6mg	TORRENT PHARMA GMBH	GERMANY	2889	2010	15
RIVASTIGMINUM	KERSTIPON 1.5 mg	capsules	1.5mg	PHARMATHEN S.A.	GREECE	3119	2010	01
RIVASTIGMINUM	KERSTIPON 3 mg	capsules	3mg	PHARMATHEN S.A.	GREECE	3120	2010	01
RIVASTIGMINUM	KERSTIPON 4.5 mg	capsules	4.5mg	PHARMATHEN S.A.	GREECE	3121	2010	01
RIVASTIGMINUM	KERSTIPON 6 mg	capsules	6mg	PHARMATHEN S.A.	GREECE	3122	2010	01
ROCURONIUM BROMIDE	ESMERON 10 mg/ml	solution for injection	10mg/ml	N.V. ORGANON	HOLAND	2988	2010	03
ROSUVASTATINUM	ZAHRON 5 mg	film-coated tablets	5mg	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A.	POLAND	2984	2010	06
ROSUVASTATINUM	ZAHRON 10 mg	film-coated tablets	10mg	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A.	POLAND	2985	2010	06
ROSUVASTATINUM	ZAHRON 20 mg	film-coated tablets	20mg	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A.	POLAND	2986	2010	06
ROSUVASTATINUM	ZAHRON 40 mg	film-coated tablets	40mg	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A.	POLAND	2987	2010	06
SILDENAFILUM	ECRITEN 25 mg	film-coated tablets	25mg	JELFA PHARMACEUTICAL COMPANY SA	POLAND	2865	2010	04
SILDENAFILUM	ECRITEN 50 mg	film-coated tablets	50mg	JELFA PHARMACEUTICAL COMPANY SA	POLAND	2866	2010	04
SILDENAFILUM	ECRITEN 100 mg	film-coated tablets	100mg	JELFA PHARMACEUTICAL COMPANY SA	POLAND	2867	2010	04

SILDENAFILUM	SILDENAFIL TECNIMEDE 25 mg	film-coated tablets	25mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL, S.A.	PORTUGAL	2970	2010	05
SILDENAFILUM	SILDENAFIL TECNIMEDE 50 mg	film-coated tablets	50mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL, S.A.	PORTUGAL	2971	2010	05
SILDENAFILUM	SILDENAFIL TECNIMEDE 100 mg	film-coated tablets	100mg	TECNIMEDE-SOCIEDADE TECNICO-MEDICINAL, S.A.	PORTUGAL	2972	2010	05
SILDENAFILUM	ENAFILZIL 25 mg	film-coated tablets	25mg	SIGILLATA LIMITED	GREAT BRITAIN	3002	2010	04
SILDENAFILUM	ENAFILZIL 50 mg	film-coated tablets	50mg	SIGILLATA LIMITED	GREAT BRITAIN	3003	2010	04
SILDENAFILUM	ENAFILZIL 100 mg	film-coated tablets	100mg	SIGILLATA LIMITED	GREAT BRITAIN	3004	2010	04
SIMETHICONUM	ESPUMISAN 100 mg/ml	oral drops, emulsion	100mg/ ml	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	3093	2010	02
SIMVASTATINUM	SIMVASTATINA PFIZER 10 mg	film-coated tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2842	2010	09
SIMVASTATINUM	SIMVASTATINA PFIZER 20 mg	film-coated tablets	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2843	2010	09
SIMVASTATINUM	SIMVASTATINA PFIZER 40 mg	film-coated tablets	40mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2844	2010	09
SIMVASTATINUM	SIMVASTATINA PFIZER 80 mg	film-coated tablets	80mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	2845	2010	09
SIMVASTATINUM	RANVOR 5 mg	film-coated tablets	5mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3098	2010	02
SIMVASTATINUM	RANVOR 20 mg	film-coated tablets	20mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3100	2010	02
SIMVASTATINUM	RANVOR 10 mg	film-coated tablets	10mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3099	2010	02
SIMVASTATINUM	RANVOR 40 mg	film-coated tablets	40mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3101	2010	02
SIMVASTATINUM	RANVOR 10 mg	film-coated tablets	10mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3099	2010	03
SIMVASTATINUM	RANVOR 20 mg	film-coated tablets	20mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3100	2010	03
SIMVASTATINUM	RANVOR 40 mg	film-coated tablets	40mg	RANBAXY U.K. LIMITED	GREAT BRITAIN	3101	2010	03
ORGAN PRESERVATION SOLUTION	CELSIOR	organ preservation solution		GENZYME EUROPE B.V.	HOLAND	3104	2010	01

SUMATRIPTANUM	IMIGRAN DR 50 mg	dispersible tablets	50mg	GLAXO WELLCOME UK LTD	GREAT BRITAIN	2921	2010	05
SUMATRIPTANUM	IMIGRAN DR 100 mg	dispersible tablets	100mg	GLAXO WELLCOME UK LTD	GREAT BRITAIN	2922	2010	05
TACROLIMUSUM	TACROLIMUSUM ACCORD 0.5 mg	capsules	0.5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3123	2010	05
TACROLIMUSUM	TACROLIMUSUM ACCORD 1 mg	capsules	1mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3124	2010	05
TC 99 M - PERTECHNETATE	ULTRATECHNEKOW FM	radionuclide generators	2.15-43GBq	MALLINCKRODT MEDICAL B.V.	HOLAND	2923	2010	01
TEMOZOLOMIDUM	ONKMOECK 180 mg	capsules	180mg	STADA HEMOFARM SRL	ROMANIA	3043	2010	02
TEMOZOLOMIDUM	ONKMOECK 5 mg	capsules	5mg	STADA HEMOFARM SRL	ROMANIA	3039	2010	02
TEMOZOLOMIDUM	ONKMOECK 20 mg	capsules	20mg	STADA HEMOFARM SRL	ROMANIA	3040	2010	02
TEMOZOLOMIDUM	ONKMOECK 100 mg	capsules	100mg	STADA HEMOFARM SRL	ROMANIA	3041	2010	02
TEMOZOLOMIDUM	ONKMOECK 140 mg	capsules	140mg	STADA HEMOFARM SRL	ROMANIA	3042	2010	02
TEMOZOLOMIDUM	ONKMOECK 250 mg	capsules	250mg	STADA HEMOFARM SRL	ROMANIA	3044	2010	02
TERBINAFINUM	TERBINAFINA OZONE 10 mg/g	cream	10mg/g	OZONE LABORATORIES PHARMA S.A.	ROMANIA	3081	2010	01
TOPIRAMATUM	ETOPRO 25 mg	film-coated tablets	25mg	ICN POLFA RZESZOW S.A.	POLAND	2879	2010	03
TOPIRAMATUM	ETOPRO 50 mg	film-coated tablets	50mg	ICN POLFA RZESZOW S.A.	POLAND	2880	2010	03
TOPIRAMATUM	ETOPRO 100 mg	film-coated tablets	100mg	ICN POLFA RZESZOW S.A.	POLAND	2881	2010	03
TOPIRAMATUM	ETOPRO 200 mg	film-coated tablets	200mg	ICN POLFA RZESZOW S.A.	POLAND	2882	2010	03
TOPIRAMATUM	TOPEPIL 25 mg	film-coated tablets	25mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2925	2010	04
TOPIRAMATUM	TOPEPIL 50 mg	film-coated tablets	50mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2926	2010	04
TOPIRAMATUM	TOPEPIL 100 mg	film-coated tablets	100mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2927	2010	04
TOPIRAMATUM	TOPEPIL 200 mg	film-coated tablets	200mg	ALAPIS ROMANIA S.R.L.	ROMANIA	2928	2010	04
TOPOTECAMUM	TOPOTECAN EBEWE 1 mg/ml	concentrate for sol. for inf.	1mg/ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	3019	2010	09
TRIMETAZIDINUM	OXCARDIN 20 mg	film-coated tablets	20mg	LABORMED PHARMA SA	ROMANIA	3052	2010	04
TRIMETAZIDINUM	OXCARDIN MR 35 mg	modified release tablets	35mg	LABORMED PHARMA SA	ROMANIA	3053	2010	03

INACTIVATED INFLUENZA VACCINE	VACCIN GRIPAL TRIVALENT PURIFICAT ŞI INACTIVAT	suspension for injection		INCDMI CANTACUZINO	ROMANIA	2854	2010	04
INACTIVATED INFLUENZA VACCINE	FLUARIX	suspension for injection in pre-filled syringe		GLAXOSMITHKLINE BIOLOGICALS S.A.	BELGIUM	3088	2010	06
VALSARTANUM	VALSARTAN TECNIMEDE 40 mg	film-coated tablets	40mg	TECNIMEDE-SOCIEDADE TECNICO MEDICINAL S.A.	PORTUGAL	2906	2010	05
VALSARTANUM	VALSARTAN TECNIMEDE 80 mg	film-coated tablets	80mg	TECNIMEDE-SOCIEDADE TECNICO MEDICINAL S.A.	PORTUGAL	2907	2010	05
VALSARTANUM	VALSARTAN TECNIMEDE 160 mg	film-coated tablets	160mg	TECNIMEDE-SOCIEDADE TECNICO MEDICINAL S.A.	PORTUGAL	2908	2010	05
VALSARTANUM	VANATEX 80 mg	film-coated tablets	80mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	2909	2010	01
VALSARTANUM	VANATEX 160 mg	film-coated tablets	160mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	2910	2010	01
VALSARTANUM	VALSARTAN TEVA 40 mg	capsules	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2960	2010	12
VALSARTANUM	VALSARTAN TEVA 80 mg	capsules	80mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2961	2010	11
VALSARTANUM	VALSARTAN TEVA 160 mg	capsules	160mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2962	2010	11
VALSARTANUM	VALSACOR 320 mg	film-coated tablets	320mg	KRKA, D.D., NOVO MESTO	SLOVENIA	2956	2010	11
VALSARTANUM	VALSARTAN JACOBSEN PHARMA 40 mg	film-coated tablets	40mg	JACOBSEN PHARMA AS	DENMARK	3011	2010	05
VALSARTANUM	VALSARTAN JACOBSEN PHARMA 80 mg	film-coated tablets	80mg	JACOBSEN PHARMA AS	DENMARK	3012	2010	05
VALSARTANUM	VALSARTAN JACOBSEN PHARMA 160 mg	film-coated tablets	160mg	JACOBSEN PHARMA AS	DENMARK	3013	2010	05
VALSARTANUM	VALSARTAN JACOBSEN PHARMA 320 mg	film-coated tablets	320mg	JACOBSEN PHARMA AS	DENMARK	3014	2010	06
VALSARTANUM	VAMADRID 40 mg	film-coated tablets	40mg	LABORATORIOS LICONSA, S.A.	SPAIN	3048	2010	06

VALSARTANUM	VAMADRID 80 mg	film-coated tablets	80mg	LABORATORIOS LICONSA, S.A.	SPAIN	3049	2010	06
VALSARTANUM	VAMADRID 160 mg	film-coated tablets	160mg	LABORATORIOS LICONSA, S.A.	SPAIN	3050	2010	06
VALSARTANUM	VAMADRID 320 mg	film-coated tablets	320mg	LABORATORIOS LICONSA, S.A.	SPAIN	3051	2010	06
VALSARTANUM	SIMALDOZ 320 mg	film-coated tablets	320mg	LABORATORIOS LICONSA, S.A.	SPAIN	3114	2010	06
VALSARTANUM	VALCATUNA 320 mg	film-coated tablets	320mg	LABORATORIOS LICONSA, S.A.	SPAIN	3115	2010	06
VANCOMYCINUM	VANCOMICINA NUCLEUS 500 mg	powder for concentrate for solution for infusion	500mg	NUCLEUS EHF	ICELAND	2860	2010	02
VANCOMYCINUM	VANCOMICINA NUCLEUS 1000 mg	powder for concentrate for solution for infusion	1000mg	NUCLEUS EHF	ICELAND	2861	2010	02
VERAPAMILUM	VEROGALID ER 240 mg	prolonged-release tablets	240mg	TEVA CZECH INDUSTRIES S.R.O.	CZECH REPUBLIC	3065	2010	04
ZIPRASIDONUM	PRAMAXIMA 20 mg	capsules	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2911	2010	10
ZIPRASIDONUM	PRAMAXIMA 40 mg	capsules	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2912	2010	10
ZIPRASIDONUM	PRAMAXIMA 80 mg	capsules	80mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	2914	2010	10

EMA newly centrally authorised medicinal products for which the European Commission issued a decision during the 4th quarter of 2010

INN	Invented name	Pharma-ceutical form	Strength	MA Holding Company	Country	MA Number		
COMBINATIONS (CANDESARTANUM CILEXETIL+ HYDROCHLOROTHIAZIDUM)	CO-DOLNIX 8 mg/12.5 mg	tablets	8 mg/ 12.5 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3074	2010	02
COMBINATIONS (TELMISARTANUM+AMLODIPINUM)	TWYNSTA 40 mg/5 mg	tablets	40 mg/ 5 mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	648	2010	07
COMBINATIONS (TELMISARTANUM+AMLODIPINUM)	TWYNSTA 40 mg/10 mg	tablets	40 mg/ 10 mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	648	2010	07
COMBINATIONS (TELMISARTANUM+AMLODIPINUM)	TWYNSTA 80 mg/5 mg	tablets	80 mg/ 5 mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	648	2010	07
COMBINATIONS (TELMISARTANUM+AMLODIPINUM)	TWYNSTA 80 mg/10 mg	tablets	80 mg/ 10 mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	648	2010	07
LEFLUNOMIDUM	LEFLUNOMIDA RATIOPHARM 10 mg	film-coated tablets	10 mg	RATIOPHARM GMBH	GERMANY	654	2010	02
LEFLUNOMIDUM	LEFLUNOMIDA RATIOPHARM 20 mg	film-coated tablets	20 mg	RATIOPHARM GMBH	GERMANY	654	2010	02
TICAGRELOR	BRILIQUE	film-coated tablets	90 mg	ASTRA ZENECA AB	SWEDEN	655	2010	06