MINISTRY OF HEALTH

ORDER
on approval of Regulations for the marketing authorisation procedure used by the National Medicines Agency for medicinal products for human use already authorised in EU Member States following the centralised procedure and the variation and renewal of such marketing authorisations

Taking into account provisions of Government Ordinance No. 152/1999 on medicinal products for human use, approved with changes and completions through Law No. 336/2002, with further changes and completions, and ale of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

on seeing The Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 9.278/2006,

based on Government Decision No. 168/2005 on organisation and functioning of the Ministry of Health, with further changes and completions,

the minister of health hereby issues the following order:

Article 1. – Approval of Regulations for the marketing authorisation procedure used by the National Medicines Agency for medicinal products for human use already authorised in EU Member States following the centralised procedure and the variation and renewal of such marketing authorisations, according to Annexes I–V which are integral part of this order.

Article 2. – Applications for marketing authorisation submitted under this order provisions are only admitted at the National Medicines Agency before 31 August 2006.

Article 3. – Applications for variation of marketing authorisation and applications for renewal of marketing authorisation number for medicinal products for human use already authorised through this procedure are only admitted before 30 June 2006.

Article 4. – Provisions of this order are only in force before Romania's accession to the European Union.

Article 5. – The National Medicines Agency shall carry out provisions of the present order.

Article 6. – All contrary provisions shall be repealed on this order coming into force.

Article 7. – The present order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Gheorghe Eugen Nicolăescu

Bucharest, 12 April 2006.
No. 398.

ANNEX 1

REGULATIONS
for the marketing authorisation procedure used by the National Medicines Agency for medicinal products for human use already authorised in EU Member States following the centralised procedure and the variation and renewal of such marketing authorisations

CHAPTER I
Introduction

Article 1. – These Regulations describe an authorization procedure which can be used by the National Medicines Agency (*NMA)* as Signatory of the New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (nCADREAC) as active member for granting a marketing authorisation of a medicinal product which has been authorized in European Union (EU) following the Centralised Procedure including the subsequent variations and renewals of such marketing authorizations.

Article 2. – The procedure described in these Regulations relates to marketing authorisations which were granted by the European Commission (EC) on the basis of the scientific expertise of the CHMP (Committee for Medicinal Products for Human use), the scientific body of the European Medicines Agency (EMEA) responsible for giving a scientific opinion on medicinal products processed via the centralized procedure), and the recognition of this expertise by the NMA.

Article 3. – The procedure described in these Regulations offers the possibility of harmonization of Summary of Product Characteristics (*SPC*), Labelling and documentation for a product between EU Member States (*MS*s) and Romania.

Article 4. – The procedure described in these Regulations can only be initiated at the EU Marketing Authorisation Holder (MAH)'s request.

CHAPTER II
Principles

Article 5. – This procedure allows innovative medicinal products authorised by the centralised procedure to become available to patients in Romania without unnecessary delay.

Article 6. – The expertise of EMEA represents the best available, consolidated regulatory expertise in the region.

Article 7. – It can be assumed that in the procedure described in these Regulations differences in medical practice between the EU–MS and Romania are generally not of major importance for public health, hence the expertise of the EMEA can be assumed to be relevant for Romania.

Article 8. – The medicinal products authorised by the centralised procedure are under continuous supervision of the EMEA and its scientific bodies, which guarantee that reports on serious adverse reactions are evaluated, that periodic safety update reports (PSUR) are reviewed at regular periods, that manufacturing facilities are inspected and that appropriate measures are taken, if necessary; marketing authorisations of these products are regularly reassessed and renewed in the EU.

Article 9. – Recognition of the expertise of the EMEA by NMA by adoption of this simplified procedure is less evaluation resource–intensive and provides an enhanced regulatory process.

Article 10. – Given that Romania has expressed interest in becoming a EU member state, which will involve full participation in the procedure, earlier involvement will have long term benefits. The introduction of common practices and mechanisms describes in these Regulations for recognition of EMEA expertise and EC decisions is advantageous for NMA, EU authorities and for applicants because the establishment of common standards and communication interfaces will facilitate mechanisms for integration of Romania into EU.

Article 11. – The NMA retains its responsibilities for granting of marketing authorisations within Romania.

Article 12. – The acceptance of EMEA expertise is not binding on NMA. In cases of doubts and questions raised to the EMEA expertise, additional documents to the dossier submitted to EMEA may be required or assessment according to national procedure may be carried out.

Article 13. – If recognition is not possible because of serious public health concerns, the EMEA and the applicant should be notified accordingly.

Article 14. – The recognition of EMEA expertise implies the acceptance of EU Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL) and labelling. The checking of the appropriateness of translations of the SPC, PIL and Labelling is under the responsibility of NMA. The NMA notifies the EMEA of any modifications of SPC, PIL and Labelling.

Article 15. – The recognition of EMEA expertise also implies recognition that "good practices" (Good Manufacturing Practices–GMP, Good Clinical Practices–GCP, Good Laboratory Practices–GLP) have been verified (unless clearly otherwise stated).

Article 16. – Use of the present procedure provides the NMA appropriate mechanisms for exchange of information with EU–MS authorities on centrally authorised products.

Article 17. – NMA informs EU authorities on all relevant post–marketing experience and all regulatory actions taken with respect to each product authorised according to the described procedure and vice versa.

Article 18. – Marketing authorisation in Romania and the EU is based on identical dossiers, even if only selected parts of the dossier may be individually required by the NMA.

Article 19. – Recognition of an EMEA expertise by the NMA is at the request of an applicant and therefore assumes that applicants request this recognition and agree to provide the same dossier and to support full exchange of "confidential" information between NMA concerned and EU authorities.

Article 20. – As a rule, medicinal products considered "harmonised" with EU centrally authorised products differ only in their defined parameters (MAH, not all package sizes are necessarily authorised in Romania and, in substantiated cases, the name of the medicinal product).

Article 21. – The simplified common procedure for extensions, variations and renewals of marketing authorisation is acceptable by the NMA in cases where the simplified procedure had been used for marketing authorisation.

Article 22. – Protection of intellectual property rights and confidentiality of submitted documents remain national concerns and local legislation is applicable.

Article 23. – Marketing authorisation as well as other fees and tariffs for NMA activities are charged according to national legislation.

Article 24. – There is no link between the procedure described in these Regulations and inclusion of thus authorised medicinal products into national reimbursement schemes.

Article 25. – Re–import of products authorised according to this procedure is outside the scope of these Regulations.

CHAPTER III
Responsibilities of concerned parties

Article 26. – The applicant/MAH in Romania ensures that the dossier submitted are identical to the dossier of a product authorised in the EU by the centralised procedure, that all subsequent variations to this dossier, once accepted in the EU, are also submitted and implemented in Romania without unnecessary delay, and that all urgent safety measures are implemented simultaneously in the EU and Romania.

Article 27. – The MAH in the EU informs the EMEA on submission of an application for authorisation in Romania, indicating the name of the medicinal product, the Community Marketing Authorisation number, the MAH in the EU as well as the proposed MAH in Romania. A copy of this information is to be provided to the NMA.

Article 28. – The MAH in the EU declares that he agrees that the EMEA may make available to the NMA any information on the quality, safety and efficacy of the above product. The extent of this information shall not exceed that which is made available to EU–MSs by the EMEA. A copy of this declaration should be provided to the NMA.

Article 29. – The EMEA includes this information in relevant databases and undertake to notify the NMA of urgent pharmacovigilance or other safety information once such information is discussed at CHMP level and the CHMP has adopted an opinion on the measures to ensure the safe and effective use of the medicinal product concerned, without prejudice to the outcome of the Commission Decision Making Procedure. Once the Commission Decision is available, the MAH in Romania notifies the NMA without delay.

Article 30. – In case of an Urgent Safety Restriction (USR) procedure, the EMEA informs the NMA without delay of the outcome of the USR procedure, introducing provisional changes to the product information

Article 31. – The NMA undertakes to inform the EMEA at the end of the marketing authorisation or renewal process on its outcome and give the following information: national marketing authorisation number, name, pharmaceutical form/s and strength/s of the product, INN or common name of the active ingredient/s, name of the MAH and authorised package sizes in Romania, information on modifications of SPC, PIL and/or Labelling (specifying differences) or, in case of disagreement with the Commission Decision, the scientific conclusions which led to such disagreement.

Article 32. – At the end of the variation to marketing authorisation process, the NMA informs the EMEA on its outcome only in cases of refusal of the variation or modification of the Commission Decision or the change of data formerly reported to the EMEA.

Article 33. – The NMA sends to the EMEA yearly an overview of all approved variations. A copy of this information should be made available to the applicant. In order to facilitate the processing of this information, a reference to the community marketing authorisation is made.

Article 34. – The NMA also undertakes to inform the EMEA of any urgent pharmacovigilance or other safety information occurring on their territory. In case of any

disagreement with or modification of the Commission Decision the NMA undertakes to also inform all other nCADREAC Competent Authorities concerned.

Article 35. – The NMA keeps the products authorised following this procedure as much as possible harmonised with the products authorised in EU. The difference between these products and products centrally authorised in the EU, if any, shall be in predefined parameters (MAH, not all package sizes are necessarily authorised in Romania and, in substantiated cases, the name of the medicinal product).

Article 36. – In the case of differences in SPC, these are identified and made known to the EMEA by the NMA.

Article 37. – According to Regulation 726/2004/EC, on Romania's accession to the EU, EMEA granted Marketing Authorisation (MA) decisions through such Centralised Authorisation Procedure (CAP) "extend automatically" to Romania.

Article 38. – One of the consequences of automatic extension of a CAP MA is the consequent automatic" inapplicability" of the national MA for medicinal products, which are as a result considered to be in conflict with the centralized MA. Use of this current type of procedure has been shown to facilitate this phasing in process.

CHAPTER IV
Marketing authorisation procedure

Article 39. – The EU–MAH initiates the procedure and notifies the EMEA (see Annex 1) on submission of an application to the NMA, indicating:

– the name of the product in the EU, pharmaceutical form(s), strength(s) authorised in the EU;

– INN or common name of the active substance(s);

– the Community Marketing Authorisation number(s);

– the EU MAH;

– the proposed MAH in Romania;

– the proposed name of the product in Romania.

Article 40. – In addition to Article 39 provisions, the EU MAH declares that the EMEA and the European Commission may make available to the NMA any information in relation to the quality, safety and efficacy of the above medicinal product, using the form attached as Annex II; the EMEA subsequently includes this information in the relevant database.

Article 41. – The applicant (i.e. MAH proposed in Romania) submits the application to the NMA. Furthermore, the proposed MAH proposed in Romania certifies that the application is identical with the application accepted in the EU with the exception of the following parameters, where relevant: MAH, pack sizes (not all pack sizes are necessarily authorised in Romania), the name of the medicinal product (in substantiated cases only).

Article 42. – Applications for marketing authorisation through simplified procedure are submitted to the NMA after the final EC decision has been issued.

Article 43. – The applicant shall submit the following documents to the NMA**:**

a) The filled–in appropriate national application form for the marketing authorisation of a medicinal product;

b) Modules 1, 2 and 3 of the dossier as accepted by the EMEA and detailed list of contents of modules 4 and 5, on paper; in case of electronic submission of modules 4 and 5, these can also be required on paper whenever the NMA will think it appropriate;

c) Proposed SPC, PIL and the Labelling in Romanian (translations of approved texts);

d) Final CHMP Assessment Report including all annexes and CHMP Report;

e) Final Commission Decision including all annexes

f) Declaration by the applicant that:

– the dossier submitted is identical to the dossier of a product authorised in the EU by the centralised procedure, including all information submitted to support any variation which has been applied for and accepted at the time of submission to the NMA of the application for marketing authorisation as well as information concerning post–authorisation commitments, if any;

– all subsequent variations to this dossier, once accepted in the EU, will also be submitted and implemented without delay by the applicant in Romania;

– all urgent safety measures will be immediately notified to the NMA and implemented according to local regulatory requirements simultaneously as in the EU or as soon as possible;

– in the case where the marketing authorisation will be suspended or withdrawn in the EU (either by the initiative of the MAH or by the EC), the NMA will be notified immediately;

g) Copy of the declaration by MAH in the EU (the Declaration is sent to the EMEA) that:

– an application is being submitted in Romania, indicating the name of the product, the Community Marketing Authorisation number, the MAH in the EU as well as the proposed MAH in Romania;

– he agrees that the EMEA may make available to the NMA any information to the quality, safety and efficacy of the product concerned (the extent of this information shall not exceed that which is made available to EU–MSs by the EMEA);

h) List of all resolved/notable post–authorisation commitments;

i) If the application is submitted later than 6 months after the date of the Commission Decision, then the latest available Periodic Safety Update Report (PSUR), which should include any new pharmacovigilance data, shall be submitted.

j) Similarly, if any variations to the marketing authorisation in the EU have been applied for and accepted at the time of submission of the application for marketing authorisation in Romania, relevant details should be provided. The information submitted to the EMEA to support these variations should also be submitted in the NMA and may be annexed to the original dossier (see Annex IV). The following documents are also provided:

– list of all variations to the marketing authorisation that have been approved in the EU, safety, transfer or renewal approved procedures at the time of submission of the application to the NMA;

– Commission Decisions granting marketing authorisation in the EU for the medicinal product for human use, Commission Decision amending the marketing authorisation as a consequence of an approved type II variation, approved application according to Annex II to Regulation no. 1.085/2003/EC, MA Renewal, Annual Reassessment, transfer of the marketing authorisation or safety procedure, if issued by European Commission, as well as for an approved type IA, IB variation (every six months);

– Notifications on a type IB variation to the terms of the marketing authorisation, issued by the EMEA;–

– Notifications of the minor changes in Labelling or Package Leaflet not connected with the SPC (Notification according to Art. 61.3 of Directive 2001/83/EC as amended);

– Acknowledgement of receipt of a valid notification for type IA variation to the terms of the marketing authorisation

– Variation assessment reports, if issued

k) Samples as specified in Annex IV.

Article 44. – The NMA informs the EMEA (the Head of Unit EMEA Post–Authorisation Evaluation of Medicines for Human Use), with copy to the applicant, at the end of the procedure on its outcome using the form provided in Annex III.

Article 45. – In case of a favourable outcome (i.e. recognition of the Commission Decision granting the EU marketing authorisation), the following information is provided:

– Name of the medicinal product in Romania

– National Marketing Authorisation Number(s)

– Name of the MAH in Romania

– Date of issue of national Marketing Authorisation(s)

– Authorised pharmaceutical form(s), strength(s), pack size(s)

– Any differences between SPC, PL, and labelling approved in Romania and the EU where relevant.

Article 46. – In case of disagreement with the Commission Decision granting the EU marketing authorisation, the scientific conclusions which led to such disagreement are communicated.

Article 47. – The NMA also informs the other nCADREAC Competent Authorities concerned in case of any disagreement with or modification of the EC Decision.

Article 48. – Upon receipt of information regarding the outcome of the procedure, the EMEA will include such information in the relevant database.

Article 49. – The EMEA will keep its CHMP scientific committee informed about the finalisation of any procedure which has resulted in a disagreement with or modification of the EC Decision initiated in accordance with the above described framework.

Article 50. – Where necessary, the EMEA informs the NMA of the CHMP's consideration of the issue (especially in case of disagreement with the EC Decision).

CHAPTER V
Variations to the marketing authorisation

Article 51. – Similar procedure as for marketing authorisation will be used for processing such applications.

Article 52. – An application is submitted within two months of the acceptance of a change in the EU, i.e. type IA, type IB variation, type II variation or Notification of the minor changes in labelling or package leaflet not connected with the SPC (Notification under art. 61.3 of Directive 2001/83/EC as amended), was approved. The appropriate national application form for variation to MA is to be used.

Article 53. – The period of time expected by the NMA for issue a decision on variation is given in Annex IV.

Article 54. – Documents to be submitted by the MAH to the NMA are as follows:

– the appropriate filled–in national application form for the variation to marketing authorisation of a medicinal product;

– the supporting documentation for the variation as accepted by the EMEA (submitted, if regards module 1, 2 or 3 of the dossier, otherwise only a list of supporting documentation; details of language requirements, electronic application possibilities, number of copies, samples/substances, fees etc. are comparable to the application for authorisation, according to Annex IV);

– Commission Decision on type II variation amending the terms of marketing authorisation of a medicinal product, including all annexes;

– Letter of European Commission (fax) on type II variation not amending the terms of marketing authorisation of a medicinal product;

– CHMP opinion on type II variation, including all annexes;

– Notification on a type IB variation to the terms of the marketing authorisation, including all annexes, issued by the EMEA;

– Notification of the minor changes in labelling or package leaflet not connected with the SPC (Notification under art. 61.3 of Directive 2001/83/EC as amended);

– Acknowledgement of receipt of a valid notification for type IA variation to the terms of the marketing authorisation;

– Variation assessment report, if issued.

Article 55. – The MAH proposed in Romania submits the variation application to the NMA accompanied by the particulars described in Annex IV.

Article 56. – At the end of the procedure, the NMA informs the EMEA (attention of the Head of Unit EMEA Post–Authorisation Evaluation of Medicines for Human Use) only:

– in cases of refusal of the variation application, indicating the scientific conclusions which led to such refusal;

– in cases of modification of the Commission Decision granting the variation to the terms of the marketing authorisation, indicating the scientific conclusions which led to such modification;

– in cases of changes to the data (i.e. change in the name of the medicinal product in Romania, change in the name of the MAH in Romania, change in the authorised pack sizes in Romania, change in formerly specified differences in SPC, PIL and/or Labelling resulted from above mentioned differences).

Article 57. – Where relevant, the EMEA will keep the CHMP informed about the outcome of the variation procedure.

Article 58. – Where necessary, the EMEA informs the NMA of the CHMP's consideration of the issue (especially in case of disagreement with EC Decision).

Article 59. – The NMA will also inform the other nCADREAC CA concerned in case of any disagreement with or modification of the EC Decision.

Article 60. – The MAH proposed in Romania will be informed on the outcome in all cases.

Article 61. – The NMA sends the EMEA a yearly overview of all finalized Variation application procedures. The EMEA subsequently includes this information in the relevant database.

CHAPTER VI
Handling of pharmacovigilance information

Article 62. – In case of urgent pharmacovigilance or other safety information occurring on the territory of Romania, having an impact on the benefit/risk ratio of the medicinal product, the NMA informs the EMEA (attention of the Head of Unit EMEA Post–Authorisation Evaluation of Medicines for Human Use).

Article 63. – The EMEA informs the NMA of urgent pharmacovigilance or other safety information having an impact on the benefit/risk ratio of the medicinal product and necessitating a change to the marketing authorisation (withdrawal, suspension, amendment of product information) immediately once such information is discussed at CHMP level and the CHMP has adopted an opinion on the measures to ensure the safe and effective use of the medicinal product concerned, without prejudice to the outcome of the EC Decision procedure.

Article 64. – Once the EC Decision is available, the MAH proposed in Romania notifies the NMA without delay.

Article 65. – In case of an USR procedure, the EMEA informs the NMA of the outcome of the USR procedure introducing provisional changes to the product information once such procedure is finalised.

Article 66. – In accordance with Articles 24(3) of Regulation EC 726/2004, Article 104(6) of Directive 2001/83/EC as amended, Periodic Safety Update Reports (PSURs) shall be submitted to the EMEA and the Member States immediately upon request or at least every six months after authorisation until the placing on the market.

Article 67. – PSURs shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the Community market and once a year for the following two years. Thereafter, the reports shall be submitted at three–yearly intervals, or immediately upon request.

Article 68. – For products approved before 20 November 2005, transitional arrangements will apply with respect to PSURs submissions.

Article 69. – PSURs are assessed by the EMEA/CHMP and if needed, the appropriate action is taken. These actions are notified to NMA by the MAH in Romania as a variation, a suspension or withdrawal.

Article 70. – PSURs shall be submitted to the NMA after the marketing authorisation has been issued at the same time as in the EU.

CHAPTER VII
Renewals of marketing authorisations

Article 71. – Renewal of marketing authorisation should be applied for in periods specified by national legislation of Romania.

Article 72. – The MAH proposed in Romania submits the renewal application to the NMA accompanied by the following particulars:

– EC Decision on the renewal of marketing authorisation of the medicinal product including all annexes;

– CHMP Opinion on renewal of marketing authorisation of the medicinal product, issued by EMEA, including all annexes;

– Assessment Report of CHMP or a supplement to the initial assessment report, if issued;

– All the documents submitted by the applicant to the EMEA for renewal, including PSURs;

– Declaration of the MAH, that at the time of renewal the product is identical with the product marketed in the EU or that it differs only in specified parameters; modifications of SPC, PIL and Labelling will be identified;

– List of all variations, safety procedures, MA transfer or renewal approved in Romania since authorisation to the time application for authorisation renewal submission;

– List of all approved variations during this period in the EU;

– SPC, PIL and Labelling in Romanian;

– If there are any specific requirements, they will be publicly announced.

Article 73. – At the end of the MA renewal procedure, the NMA informs the EMEA (attention of the Head of Unit EMEA Post–Authorisation Evaluation of Medicines for Human Use) with a copy to the MAH of the outcome of the renewal process as described in Annex III.

Article 74. – The EMEA will keep the CHMP informed about the outcome of the Renewal application which resulted in a disagreement with or modification of the EC Decision and, where necessary, informs the NMA of the CHMP's consideration of the issue (especially in case of disagreement with the EC Decision).

Article 75. – The NMA will also inform the other nCADREAC Competent Authorities concerned in case of any disagreement or modification of the EC Decision.

CHAPTER VIII
Retrospective inclusion of EU centralised medicinal products in the common nCADREAC simplified system

Article 76. – The most practical timing of the procedure is at the time of renewal of marketing authorisation of the medicinal product.

Article 77. – The NMA evaluates the status of harmonisation of the medicinal product in question and identifies all variations that are necessary to reach harmonisation as described in Chapter IV.

Article 78. – The MAH in the EU notifies the EMEA on the intention to include the product in question in the common simplified system retrospectively and declares that the EMEA and the European Commission may make available to the NMA any information related to the product in question as described in Chapter IV, using the form in Annex II.

Article 79. – The EMEA sends the overview of all accepted variations related to the product in question to the NMA.

Article 80. – The MAH in Romania informs the NMA on the intention to include the product retrospectively in the common nCADREAC simplified system and on the status of harmonisation of the product. He applies for all necessary variations, using the variation procedures described in Chapter V and submits all those documents required by the present procedure both for marketing authorisation and for variations and also the final approval documents issued, which have not been already submitted within the national authorisation procedure.

Article 81. – At least the following documents shall be submitted:

− copy of Approval of Information Sharing between the EMEA, the European Commission and the nCADREAC DRA,

− declaration by the MAH in Romania that he will keep the product in question harmonised in Romania with the EU and, in the case where the marketing authorisation will be suspended or withdrawn in the EU, NMA will be notified immediately as required by the present procedure.

Article 82. – If after processing all of the submitted variations the NMA agrees with the fact that the product is harmonised with the current EU status, it informs the EMEA using the form in Annex III, that the product in question can be included in the common nCADREAC simplified system. The copy of this report is sent to the MAH in Romania and in specific cases mentioned in the present procedure also to other nCADREAC Competent Authorities concerned.

Article 83. – The EMEA includes the product in its database.

ANNEX II

Text in italics should be replaced by the data specific to individual submissions.

Name of the medicinal product:
EU Marketing Authorisation number(s):

Approval of information sharing between the EMEA, the European Commission and the NMA

The *Marketing Authorisation Holder in the EU* hereby notifies to the European Medicines Agency-EMEA, 7 Westferry Circus, Canary Wharf, London El4, United Kingdom and the European Commission Directorate-General Enterprise and Industry, Directorate F–Consumer Goods, F2 Pharmaceuticals, Rue de la Loi 200, B-1049 Brussels, Belgium, of the submission of an application for the following medicinal product to the NMA:

name of the medicinal product, dosage form, strength, package size/s
(differences in brand name, if any)
proposed marketing authorisation holder in Romania

The *Marketing Authorisation Holder in the EU* agrees that the EMEA and the European Commission may make available to the NMA any information to the quality, safety and efficacy of the above product. The extent of this information shall not exceed that which is made available to EU Member States by the EMEA or European Commission.

The information will be used by the NMA in accordance with applicable laws and regulations for the marketing authorisation and safe use of medicinal products in Romania.

This Declaration is made as of the date first written below and remains valid for the period during which the product is authorised in the European Union and Romania, respectively. The copy of this declaration is sent to the NMA.

Date: **Signature of the Marketing Authorisation Holder**

…..... …….....

(First name, family name, Address)

ANNEX III

Text in italics should be replaced by the data specific to individual submissions.

Report on authorisation granted/variation approval/retrospective inclusion of the medicinal product subjected to the centralised procedure in the EU

Name of the product in the EU, pharmaceutical form/s, strength/s relevant to this report:
INN or common name of the active ingredient/s:
Community MA number/s of the product:
Name of the MA holder in the EU:

_____

□ *Report on acceptance/renewal of centralised MA*)*
□ *Report on disagreement with the EC Decision on MA**)*
□ *Report on refusal of variation, or EC Decision on variation or the change of data formerly reported to the EMEA**)*
□ *Report on retrospective inclusion of the product in the simplified nCADREAC system*
□ *Report on safety action/defective product**)*
□ *Request to the EMEA**)*

_____

*)Name of the product in Romania:
National marketing authorisation number(s):
Date of issue of national marketing authorisation decision:
Name of the marketing authorisation holder in Romania:
Authorised pharmaceutical form(s), strength(s), package size(s) in Romania:
Modification of SPC and PIL (specifying differences, except different name of the product, MA holder, national MA number)**):
Modifications of labelling (specifying differences, except different name of the product, MA holder, national MA number)**)

**) Explanatory notes:

_____

Enclosures:

.....
(Name and signature of responsible person within the NMA)

Date
…….

ANNEX IV

TABLE OF SPECIFIC NMA REQUIREMENTS

The information is valid at the time of this procedure coming into force.
If needed, the NMA will update presented data.

Country	Timing of submission	Expected handling time	Language of dossier	Number of copies to be submitted	Electronic submission	Need for samples and/or substances	Need for local representative	Fees and tariffs
Romania	After Commission Decision is issued	3 months for MA; 2 months for variation as of receipt of complete documentation	English or Romanian Labelling can be in Romanian, English or French	1 copy of the	CD–ROM presentation of Modules 4 and 5 may be submitted as Word, pdf, rtf, jpg. and tiff documents , together with paper documentation of identical content. SPC and Leaflet (final approved version) in Romanian, on 3,5 inch floppy diskette/CD–ROM using Word for Windows	No samples of the medicinal product on submission of application; if needed, the NMA may request a sample of the medicinal product during procedure development	Yes	MA: New active substance/ obtained through biotechnology/ biological product: 2105 € Variations: – type IA: 210 € – type IB: 330 € – type II: 460 € MA transfer: 300 €

ANNEX V

ACRONYMS

NMA = National Medicines Agency
nCADREAC = New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (nCADREAC)
EU = European Union
EC = European Commission
CHMP = Committee for Medicinal Products for Human Use
EMEA = European Medicines Agency
SPC = Summary of Product Characteristics
MS = Member State
MA = marketing authorisation
CAP = centralised authorisation procedure
MA–CAP = marketing authorisation for a medicinal product authorised through centralised authorisation procedure
MAH = marketing authorisation holder
PSUR = Periodic Safety Update Report
GMP = Good Manufacturing Practice
GCP = Good Clinical Practice
GLP = Good Laboratory Practice
EU–MS = Member States of the European Union
USR = Urgent Safety Restriction
INN = International Non–proprietary Name
CA = competent authority
CA–nCADREAC = competent authority of an nCADREAC signatory country