DECISION

no. 24/11.10.2013

on approval of the Implementation rules related to the NAMMD procedure for consultation by a notified body concerning grant of scientific opinion on the quality and safety of the ancillary medicinal substance incorporated as an integral part into a medical device

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 158/18.02.2013, reunited on summons of the NAMMD President in the ordinary meeting of 11.10.2013, in accordance with Article 12 (5) of Emergency Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, hereby adopts the following

DECISION

Sole article. - The Implementation rules related to the NAMMD procedure for consultation by a notified body concerning grant of scientific opinion on the quality and safety of the ancillary medicinal substance incorporated as an integral part into a medical device are approved, in accordance with the Annexes, which are integral parts of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no.24/11.10.2013

IMPLEMENTATION RULES RELATED TO THE NAMMD PROCEDURE FOR CONSULTATION BY A NOTIFIED BODY CONCERNING GRANT OF SCIENTIFIC OPINION ON THE QUALITY AND SAFETY OF THE ANCILLARY MEDICINAL SUBSTANCE INCORPORATED AS AN INTEGRAL PART INTO A MEDICAL DEVICE

CHAPTER I
General provisions

Article 1. – These Rules are issued for implementation of provisions of Article 7.4.2., 7.4.4. and 7.4.5. of Annex 1 to Government Decision no. 54/2009 on marketing conditions for medical devices.

Article 2. – They establish the consultation process of the National Agency for Medicines and Medical Devices (NAMMD) by a notified body for authorisation for placement on the market of medical devices incorporating, as an integral part, an ancillary active substance (hereinafter "ancillary medicinal substance").

CHAPTER II
Consultation procedure

Article 3. - For devices incorporating, as an integral part, an ancillary medicinal substance, the notified body, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, will seek a scientific opinion from the NAMMD (competent authority in the field of the medicinal product) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device.

Article 4. – (1) The aspect of "usefulness" relates to the rationale for using the medicinal substance in relation to the specific intended purpose of the device.

(2) It refers to the suitability of the medicinal substance to achieve its intended action, and to whether the potential inherent risks (aspect of "safety") due to the medicinal substance are justified in relation to the benefit to be obtained within the intended purpose of the device.

Article 5. - By means of the consultation process, the NAMMD may make available relevant information concerning risks related to the use of the substance (e.g. resulting from pharmacovigilance).

II.1 Submission of application for initial consultations in view of grant of a scientific opinion about the quality and safety of an ancillary medicinal substance incorporated, as an integral part, into a medical device

Article 6. - To start the initial consultation procedure, the notified body submits to the NAMMD, on behalf of the device's manufacturer, a cover letter, signed in original and accompanied by the payment form, at least 15 days prior to submission of the application.

Article 7. – After payment confirmation, the notified body submits to the NAMMD an application for initial consultation for grant of a scientific opinion, as shown in Annex 1, which is integral part of this Decision.

Article 8. – The application for initial consultation must be accompanied by the documents and information mentioned in Annex 2, which is integral part of this Decision, in

accordance with the EU Common Technical Document (CTD) specified in the "*Notice to Applicants*", volume 2B "Rules governing medicinal products in the European Union", used in the applications for authorisation of a medicinal product.

Article 9. - An individual application for grant of a scientific opinion is submitted for each medical device incorporating one or several ancillary medicinal substances subject to NAMMD consultation.

Article 10. – (1) The supporting documentation is submitted in electronic format (CD/DVD).

(2) The application for initial consultation for grant of a scientific opinion is submitted on paper and signed in original.

(3) The documentation is submitted in English/Romanian, except for the labelling (submitted in both English and Romanian).

Article 11. – (1) Fees for grant of a scientific opinion are those established through Order of the Minister of Health on approval of NAMMD Scientific Council Decision no. 3/22.08.2013, published in the Official Gazette of Romania, Part I.

(2) If needed, adjustments of the associated tariff are made during/at the end of the consultation procedure.

II.2 Procedure for grant of scientific opinion

Article 12. – Within 30 days as of receipt of the application for initial consultation for grant of scientific opinion and the supporting scientific documentation**,** the NAMMD validates the application.

Article 13. – If, during the application validation stage, it is found that the supporting documentation should be supplemented with administrative and technical documents/information, the notified body receives the list containing the applications for supplementation required in view of validation.

Article 14. – The application for supplementary consultation submitted to the NAMMD is only valid after receipt and assessment of all required documents; otherwise, the application is invalidated, without bringing any prejudice to the notified body's right to submit another consultation application, properly documented.

Article 15. – The NAMMD informs on paper the notified body about the validation/invalidation of the application. The 210-day period specified under Article 4.3 of Annex 2 to Government Decision no. 54/2009 starts passing from the moment of validation.

Article 16. – Following validation, the documentation is allocated in view of assessment, in accordance with the provisions of Article 7.4.1. of Annex 1 to Government Decision no. 54/2009: "the quality, safety and usefulness of the incorporated ancillary medicinal substance must be assessed through analogy with the methods shown in Order of the Minister of Public Health no. 906/2006 on approval of the Analytical, pharmacotoxicological and clinical Rules and protocols in respect of the testing of medicinal products, as amended.

(2) The assessment is performed in accordance with the recommendations of the corresponding scientific guidelines.

Article 17. – If, during the assessment process, new documents/information must be forwarded, the NAMMD will require the notified body to forward the respective documents/information and the procedure will be suspended (*stop-clock*) until a complete response document is received.

Article 18. – (1) The request and submission of supplementary information are performed just once during assessment.

(2) The request for supplementary documents/information is forwarded to the notified body together with a schedule specifying the deadline for submission of the requested information.

Article 19. – Documentation assessment is completed by grant of a final report referring to the favourable/unfavourable scientific opinion.

The supplementary consultation procedure is completed by grant of an updated scientific opinion, irrespective of potential impact of the respective information upon the risk-benefit balance of incorporation of the ancillary medicinal substance into the medical device.

Article 20. – The final assessment report is presented during the meeting of the NAMMD Marketing authorisation Commission and resolves upon grant of a favourable/unfavourable scientific opinion.

Article 21. – The favourable/unfavourable scientific opinion is issued following the Marketing Authorisation Commission respective decision.

Article 22. – The NAMMD decision on grant of an unfavourable scientific opinion is taken if, upon assessment of documentation, the quality and safety of the incorporated ancillary medicinal substance are found noncompliant with the provisions of Order of the Minister of Health no. 906/2006 on approval of the Analytical, pharmacotoxicological and clinical Rules and protocols in respect of the testing of medicinal products, as amended.

Article 23. – (1) The favourable/unfavourable scientific opinion on the NAMMD is forwarded to the notified body.

(2) The unfavourable scientific opinion is accompanied by a justificatory report based on the conclusions of the final assessment report.

II.3 Notification of the National Agency for Medicines and Medical Devices by the notified body concerning the decision taken

Article 24. – The notified body takes into account the NAMMD decision when making a decision for approval of introduction of the medical device on the market.

Article 25. – In accordance with Article 4.3 of Annex 2 to Government Decision no. 54/2009, the notified body informs the NAMMD about the adopted decision. If other than the scientific opinion issued by the Agency, the notified body highlights this fact in the submitted information.

CHAPTER III
The supplementary consultation procedure in case of change of the ancillary medicinal substance incorporated, as an integral part, in a medical device

Article 26. – (1) If there is any change in the design or manufacture of the device, which could have an effect on the quality, safety or usefulness of the drug substance in the device or in respect of amended or additional data, a supplementary consultation is required by the notified body from the NAMMD, in accordance with Article 7.4.4. of Annex 1 to Government Decision no. 54/2009.

(2) The NAMMD assesses the maintenance of the initial quality and safety degree of the ancillary medicinal substance and makes sure that the amendments did not have any impact upon the report established between the benefits and risks of incorporating the substance into the medical device.

Article 27. - Examples of amendments that may require a Supplementary Consultation include:

- Change of the supplier of the ancillary medicinal substance or intermediate processor;
- Change of the formulation or grade of the medicinal substance or an intermediate;
- Significant change of the manufacturing process or change of the specification of the medicinal substance as notified by the manufacturer;
- Changes of quality control tests relevant to the active substance during the manufacturing process;

- Change of the manufacturing process for the incorporation of the medicinal substance into the device;
- Change of packaging;
- Change of the method of sterilisation;
- Extension of shelf life;
- Changes to the intended use of the device;
- Some changes in the design of the device, which may impact on the availability or release of the medicinal substance (e.g. device size increase if the quantity of the medicinal substance per device is increased, change of device surface area);

This list is intended for guidance and is not prescriptive or exhaustive.

III.1 Submission of the applications for supplementary consultation in view of amendment of the terms of the scientific opinion, initiated by the notified body

Article 28. – In view of starting the supplementary consultation procedure, the notified body submits to the NAMMD a cover letter, signed in original and accompanied by the payment form, at least 15 days prior to submission of the application.

Article 29. – After confirmation of the payment, the notified body submits to the NAMMD the application for supplementary consultation, as shown in Annex 3, which is integral part of this Decision.

Article 30. – The application for supplementary consultation is accompanied by supporting documents and information, submitted in accordance with the format of the EU Common Technical Document (CTD) specified in "Notice to Applicants", volume 2B "Rules governing medicinal products in the European Union".

Article 31. – An individual application is submitted for each medical device incorporating an ancillary medicinal substance subject to supplementary consultation.

Article 32. – (1) The documentation for supplementary consultation is submitted in electronic format (CD/DVD).

(2) The application for supplementary consultation is submitted on paper, signed in original.

(3) The documentation is submitted in English/Romanian, except for the labelling (submitted in both English and Romanian).

Article 33. – (1) Supplementary consultation fees are those established through Order of the Minister of Health on approval of NAMMD Scientific Council Decision no. 3/22.08.2013, published in the Official Gazette of Romania, Part I.

(2) If needed, adjustments of the associated tariff are made during/in the end of the supplementary consultation procedure.

III.2 Operation of the supplementary consultation procedure initiated by the notified body

Article 34. – The NAMMD checks the validity of the submitted application and informs in writing the notified body on application validation/invalidation.

Article 35. – If, in the validation stage of the application for supplementary consultation, the supporting documentation is found to require supplementation with administrative and technical documents/information, the notified body is forwarded the list containing the applications for supplementation required in view of validation of the application.

Article 36. – The application for supplementary consultation submitted to the NAMMD is only valid after receipt and assessment of all required documents.

Article 37. – The procedure starts on the date of validation confirmation on paper.

Article 38. – The assessment of applications for supplementary consultation is generally performed in a 60-day term, which can be prolonged by 30 days, in case of substantial amendments. This period excludes *stop-clocks*.

Article 39. – During assessment, the NAMMD may require the notified body to provide supplementary information.

Article 40. – The application for supplementary consultation is forwarded to the notified body together with a schedule specifying the deadline for submission of the requested information and, if required, the extension of the period for assessment.

Article 41. – (1) The procedure is discontinued until receipt of the required supplementary information.

(2) The discontinuation procedure consists of one month.

(3) If a longer discontinuation period is required, the notified body forwards the NAMMD an argumented application in this respect.

Article 42. - The target time for assessment of these applications is 30 to 60 days from receipt, but will vary depending on the complexity of the consultation.

Article 43. – (1) The final assessment report is discussed during the meeting of the Marketing Authorisation Commission, who decides upon grant of an updated favourable/unfavourable scientific opinion.

(2) The final assessment report is forwarded to the notified body.

(3) If an unfavourable updated scientific opinion is issued, it is accompanied by a justificatory document.

III.3.3 Further consultations on the same device initiated by the NAMMD

Article 44. – (1) If, following initial consultation, the NAMMD has obtained information about the ancillary medicinal substance, which may impact upon the established risk-benefit balance of incorporation of the ancillary medicinal substance into the medical device, based on Article 7.4.5. of Annex 1 to Government Decision no. 54/2009, it informs the notified body to that end.

(2) In the information address sent, the NAMMD requires the notified body to submit an application for supplementary consultation in view of updating the scientific opinion, also specifying the supporting documentation to be submitted.

Article 45. – The application validation and the supplementary consultation procedure follow the stages described in subsections III.1. and III.2.

Article 46. – The supplementary consultation procedure is completed by grant of an updated scientific opinion, regardless of the fact that the information has or has not an impact upon the risk-benefit balance of incorporation of the ancillary medicinal substance into the medical device.

III.4 Changes in the ancillary medicinal substance incorporated in a medical device, requiring the initiation of a new complete consultation procedure

Article 47. - Changes to the qualitative or quantitative composition relating to the active substance(s), or indications for use etc. would normally be subject to a new, full consultation.

Article 48. – Examples include:

a) quantitative change to, addition, replacement or deletion of one or several active substances;

b) variations relating to the use of the medical device

- addition of an indication in another therapeutic area;
- addition of or change to the route of administration.

ANNEX 1
to SCD no. 24/11.10.2013

APPLICATION FORM
INITIAL CONSULTATION FOR SCIENTIFIC OPINION

This form is to be filled in and submitted to the National Agency for Medicines and Medical Devices, in view of initial consultation for scientific opinion on the quality and safety of the ancillary active substance(s) incorporated as an integral part in the medical device.

An individual application form is to be submitted for each medical device incorporating one or several ancillary active substance(s).

1. Name of the medical device

2. Name of the ancillary active substance(s)*

**one name only, in the following order of preference: rINN, Ph.Eur. name, Romanian Pharmacopoeia name, Common Name, scientific name.*

3. Status of assessment of the ancillary active substance(s)
(please tick as appropriate)

- First assessment ☐
- Second assessment, with new manufacturer ☐
- Second assessment, with the same manufacturer ☐

4. Notified Body

Declaration and signature:

Name:

Address:

Country:

E-mail address:

Telephone no.:

Fax no.:

Name of the Contact Person assigned for communication with the National Agency for Medicines and Medical Devices during the consultation procedure:

This is to confirm that all data herein on the quality, safety and usefulness of the ancillary active substance(s), the benefit/risk profile included, have been included in the dossier, as required*.

It is also hereby confirmed that the fee has been paid according to Rules and regulations of the National Agency for Medicines and Medical Devices**
On behalf of the Notified Body:

……..
Signature

……..
Name and Surname*

……
Position

Place Date (year, month, day)

*****Please attach the authorisation issued by the Notified Body for the Contact Person in charge of communication with the National Agency for Medicines and Medical Devices/ signatory right granted by the Notified Body (annex 1.2)
****** Please attach the proof of fee payment (annex 1.3).

5. Manufacturer of the medical device

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

6. Manufacturer(s)

Authorised manufacturer(s) (or importer) in charge of batch release in the EEA as per Article 748 and 760 of Law no. 95/2006, Title XVII – The Medicinal Product, as amended:

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

Manufacturing Authorisation number:
☐ Please attach the copy of the Manufacturing Authorisation(s) (annex 1.4)
or
☐ Please specify the EudraGMP reference number of the Manufacturing Authorisation:

If available:
☐ Please attach the latest GMP Certificate (annex 1.6)
or
☐ Please specify the EudraGMP Certificate reference number: <Number>

Manufacturer(s) of the ancillary active substance(s) and manufacturing site(s)
NOTE:
Please include all manufacturing sites involved in the manufacturing process of the ancillary active substance, including quality in-process testing sites/control. Information on importer(s) and distributor(s) only are not acceptable.

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

Brief description of the technologic process at the manufacturing site:
☐ Please attach the flow chart, indicating the activities and their succession performed at the various manufacturing sites involved, testing places included (annex 1.5).

☐ For each ancillary active substance, please attach a declaration of the Qualified Person relating to ancillary active substance manufacturing in line with GMP Rules for starting materials (annex 1.9).

- The manufacturing site has been inspected for verification of GMP compliance by a competent authority in the EEA or an authority signatory of a mutual recognition agreement or a different community agreement, according to the provisions of the respective agreement.

❍ Nu ❍ Yes

If Yes, please include the following in annex 1.6:
☐ a declaration no older than 3 years from an inspecting competent authority
or
if available
☐ please attach the latest GMP Certificate (annex 1.6)
or
☐ please specify the EudraGMP Certificate reference number: <Number>

- The manufacturing site has been inspected for verification of compliance with GMP Rules by any other competent authority (including those in countries signatory of a mutual recognition agreement or a different community agreement but not on the territory of the manufacturing site).

❍ No ❍ Yes

☐ If Yes, please include brief data in annex 1.6 (and, if available, a GMP Certificate or a declaration)

• The European Pharmacopeia has issued a *Certification* of Suitability for the ancillary active substance(s)

❍ No ❍ Yes ☐ Please attach a copy of the Certificate in annex 1.7.

If Yes, please specify:

- name of the substance:

- name of the manufacturer:
- reference number:
- date of the latest verification (yyyy-mm-dd):

• There is a Active Substance Master File (ASMF) for the ancillary active substance(s)

❍ No ❍ Yes

If Yes, please specify:
- name of the ASMF holder:
- name of the manufacturer, if different from the above:
- ASMF EU reference number, if available:

- ASMF national reference number, if applicable and only when the ASMF EU reference number is not available:

- number of the ASMF version:

- date of submission (yyyy-mm-dd):
- date of the latest verification (yyyy-mm-dd):

☐ Please attach an access letter for the community competent authority/national competent authority of the Member State where the application has been submitted (see European ASMF procedure for active substances) (annex 1.7).

☐ Please attach a copy of the written confirmation by the active substance manufacturer on medical device manufacturer's notification of changes in the manufacturing process or specifications, as per Law **no.** 95/2006, Title XVII – The Medicinal Product, as amended (annex 1.8)

7. Pharmacotherapeutic classification *(please use current ATC code)*

ATC Code: **Pharmacotherapeutic classification:** <Text>

If no ATC code has been assigned, please specify whether an application has been submitted in that respect: ☐

8. Description of the medical device with ancillary active substance(s)

Description of the medical device

<Text>

Intended purpose of the ancillary medicinal substance as incorporated into the device with scientific explanation that the action of the medicinal substance is only ancillary to that of the device

☐ Please attach the Report of the Notified Body on the usefulness of ancillary active substance(s) incorporation (annex 1.1)

<Text>

Administration route*

<Text>

Ancillary active substance(s)	**Quantity**	**Unit**	**Reference/ Monograph standards (e.g., European Pharmacopeia**
<Text>			
<Text>			
<Text>			

Packaging components, including description of material*

<Text>

Pack size

<Text>

Proposed shelf-life (unopened)

<Text>

Proposed shelf-life (in use)

<Text>

Recommended storage conditions

<Text>

*Please use Romanian Standard Terms in line with European Standard Terms

List of materials of animal origin contained or used in the ancillary active substance(s) manufacturing process

NONE: ☐

Name	**Position*** **AS** **OI**	**TSE susceptible material of animal origin**	**Other animal origin**
1.	☐ ☐	☐ Yes** ☐ No	☐
2.	☐ ☐	☐ Yes** ☐ No	☐
3.	☐ ☐	☐ Yes** ☐ No	☐

*AS = ancillary active substance(s), OI = other ingredient (including starting material used in ancillary active substance(s) manufacturing)

** Please attach a copy of the Ph. Eur. Certificate of Suitability as per Resolution AP/CSP (99) 4 of the Council of Europe, if available (annex 1.10)

9. Attachments (where appropriate)

☐ 1.1 Report of the Notified Body on the usefulness of ancillary active substance(s) incorporation
☐ 1.2 Letter of authorisation for communication with the National Agency for Medicines and Medical Devices on behalf of the notified body
☐ 1.3 Proof of fee payment
☐ 1.4. Manufacturing Authorisation(s) required as per Article 748 of Law no**.** 95/2006, Title XVII – The Medicinal Product, as amended (or the equivalent thereof outside the EEA, where a mutual recognition agreement or other community agreement applies); any supporting document in line with Article 702 (4) n) of Law no. 95/2006.
☐ 1.5 Flow chart indicating the different sites involved in the manufacturing process of the ancillary medicinal active substance(s) as incorporated into the device.
☐ 1.6 GMP Certificate(s) or other GMP declarations of compliance; if applicable, a summary of other GMP inspections performed.
☐1.7 Letter of access to Active Substance Master Files or copy of Ph. Eur. Certificate(s) of Suitability
☐ 1.8 Copy of written confirmation from the manufacturer of the ancillary medicinal substance to inform the applicant in case of modification of the manufacturing process or specifications according to Order of the Minister of Health no. 906/2006 for approval of analytical pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products, as amended (transposing annex I to Directive 2001/83/EC)
☐ 1.9 For each ancillary active substance, declaration from the manufacturer's Qualified Person responsible for batch release in the EEA to ancillary active substance(s) manufacturing in line with GMP Rules. Alternatively, such declarations may also be signed by a Qualified Person on behalf of all Qualified Persons involved (on condition this is clearly stated).
☐ 1.10 TSE Certificate of Suitability granted by the European Pharmacopeia.

ANNEX 2
to Scientific Council Decision no. 24/11.10.2013

DOCUMENTATION TO BE SUBMITTED BY THE NOTIFIED BODY TO THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

Section 1

- Application form
- General information on the medical device
  - General description of the medical device
  - Scientific explanation that the action of the medicinal substance is only ancillary to that of the device, as per Scientific Council Decision no. 23/11.10.2013 on approval of National Agency for Medicines and Medical Devices handling of requests by a Notified Body for scientific opinion on the quality and safety of an ancillary medicinal substance incorporated as an integral part into a medical device
- Signed declarations and Curriculum Vitae of Qualified experts.
- Notified Body report on usefulness of the ancillary medicinal substance incorporated as an integral part into a medical device.
- Labelling

Section 2

Module 2.3: Quality Overall Summary (relevant individual documents) concerning the ancillary active substance itself, in line with e-CTD format as set out in "Notice to Applicants", Volume 2B;

- Critical appraisal summaries (or expert reports) on the quality, non-clinical and clinical data of the medicinal substance as incorporated into the medical device, according to. 2b), 3) and 4) of subsection C3 of the Annex to SCD no. 23/11.10.2013.

Section 3

Module 3: For the ancillary medicinal substance itself, relevant information, submitted in one of the three following acceptable formats:

• Relevant parts of Module 3 of e-CTD format in "Notice to Applicants" Volume 2B;

• Active Substance Master File (ASMF), organised as outlined in Module 3.2.S of E-CTD format in "Notice to Applicants" Volume 2B;

• European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP), if available.

Quality documentation, in accordance with the titles and requirements of subsection C.3, 2b) of the annex to SCD no. 23/11.10.2013, for the ancillary medicinal substance as incorporated in the medical device.

Section 4

Non-clinical documentation in accordance with the titles and requirements of subsection C.3, 3) of the annex to SCD no. 23/11.10.2013, for the ancillary medicinal substance as incorporated in the medical device.

Section 5

Clinical documentation in accordance with the titles and requirements of subsection 4) of the annex to SCD no. 23/11.10.2013, for the ancillary medicinal substance as incorporated in the medical device.

ANNEX 3
to SCD no. 24/11.10.2013

APPLICATION FORM
SUPPLEMENTARY CONSULTATION FOR SCIENTIFIC OPINION

An individual application form is to be submitted for each medical device incorporating one or several ancillary active substance(s).

1. Name of the medical device	**2. Number of initial scientific opinion**

3. Name of the ancillary active substance(s)*

**one name only, in the following order of preference: rINN, Ph.Eur. name, Romanian Pharmacopoeia name, Common Name, scientific name.*

4. Status of assessment of the ancillary active substance(s)
(please tick as appropriate)

- First assessment ☐
- Second assessment, with new manufacturer ☐
- Second assessment, with the same manufacturer ☐

5. Notified Body

Declaration and signature:

Name:

Address:

Country:

E-mail address:

Telephone no.:

Fax no.:

6. Name and address of the Contact Person*:

Name and address of the Contact Person:

Telephone no.:

Fax no. (optional):

E-mail address:

* Please attach the authorisation issued by the Notified Body for the Contact Person in charge of communication with the National Agency for Medicines and Medical Devices/ signatory right Granted by the Notified Body

7. Manufacturer of the medical device

Name:

Address:

Country:

E-mail address:

Telephone no.:

Fax no.:

8. Description of the medical device with ancillary active substance(s)

Description of the medical device

<Text>

Administration route*

<Text>

Ancillary active substance(s)	Quantity	Unit
<Text>		
<Text>		
<Text>		

Packaging components, including description of material*

<Text>

Pack size

<Text>

*Please use Romanian Standard Terms in line with European Standard Terms

9. Changes proposed in this application

The change concerns the following section of the Dossier (please check all sections concerned)

☐ Quality
☐ Non-clinical
☐ Clinical
☐ Other

Exact purpose and context of change

<Text>

Current*	**Proposed***
<Text>	<Text>

Support documentation

* Please provide the exact current and proposed situation of the text or specification, including the number(s) of the dossier section, as detailed as appropriate.

Applicant's declaration:

This is an application for supplementary consultation concerning change of terms of the initial scientific opinion, according to specified proposals. I hereby declare that (please check as appropriate)

☐ There are no other changes in addition to those specified in this application (except for changes envisaged in other parallel applications);

☐ Changes do not concern the usefulness of the ancillary active substance incorporated as an integral part into a medical device, as originally verified by the notified body;

☐ All conditions set out for the change in question have been met (where appropriate);

☐ The assessment fee has been paid;

☐ The change(s) is/are to be implemented as

☐ The next batch/print

☐ Date: ……..

Fee paid *Please specify the fee type in line with national regulations*_____	
Main signatory*	Position
Name in print	Date
Second signatory	Position
Name in print	Date

* Signature of the Main signatory is mandatory