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.