

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
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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 <Text>
- The next batch/print
- Date:

Fee paid

Please specify the fee type in line with national regulations _____

Main signatory*

Name in print

Second signatory

Name in print

Position

Date

Position

Date

* Signature of the Main signatory is mandatory