*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).

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| **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.*  |

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| **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 **🞏**
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| **5. Notified Body**Declaration and signature:Name:      Address:      Country:      E-mail address:      Telephone no.:      Fax no.:       |

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| 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 |

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| **7. Manufacturer of the medical device** Name:      Address:      Country:      E-mail address:      Telephone no.:      Fax no.:       |

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| **8. Description of the medical device with** **ancillary active substance(s)****Description of the medical device** <Text>**Administration route**\*<Text>

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| **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 of:

🗖 The next batch/print

🗖 Date: …………………………………………..

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| Fee paid*Please specify the fee type in line with national regulations\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| Main signatory\* Name in printSecond signatory  Name in print | Position DatePosition Date |

\* Signature of the Main signatory is mandatory  |