*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 of:

🗖 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 |