Request for National Scientific and Regulatory Advice

When completing this form, reference should be made, where appropriate, to the HPRA Guide for National Scientific and Regulatory Advice and to the accompanying documentation as requested in section c). If there is not enough space in the boxes provided, please attach any relevant documentation to this form.

1. **Administrative information**

|  |  |  |
| --- | --- | --- |
|  | Date of formal request |  |
|  | Organisation seeking advice | Name |  |
| Address |  |
|  | Applicant’s contact details | Contact person |  |
| Telephone |  |
| Emergency contact (mobile) |  |
| Fax number |  |
| Email address |  |
|  | Contact details for invoicing (if different from above) | Name |  |
| Address |  |
| Email address |  |

1. **About the product**

|  |  |  |
| --- | --- | --- |
|  | Name of the active substance (If advice is not product-specific, please write ‘general advice’.) |  |
|  | Proposed indication(s) |  |
|  | ATC code (if known) |  |
|  | Type of product | [ ]  Chemical[ ]  Biological[ ]  Herbal[ ]  Homeopathic |
|  | Pharmaceutical form(s) |  |
|  | Proposed legal status | [ ]  Prescription[ ]  Non-prescription |
|  | Is the advice solely connected with a future | [ ]  Clinical Trials Authorisation (CTA)[ ]  Marketing Authorisation Application (MAA)[ ]  Other:  |
|  | Regulatory procedure in Ireland | [ ]  Clinical trials authorisation[ ]  New product authorisation[ ]  Product maintenance and variation[ ]  Supply reclassification[ ]  Product advertising[ ]  Product and patient information[ ]  Other:  |
|  | Advice sought | [ ]  Quality[ ]  Swift (no meeting)[ ]  Pre-clinical[ ]  Clinical[ ]  Statistics[ ]  Pharmacokinetics (excluding modelling)[ ]  Regulatory[ ]  List of questions [[1]](#footnote-1) |
|  | Please add any comments related to the advice sought (Please attach a draft of the proposed questions separately.) |  |
|  | Preferred dates for meeting (Final documentation must be submitted 30 days before the meeting.) |  |
|  | Unavailable dates |  |
|  | Is this product currently under assessment in any other Member State? If yes, please name the State(s). | [ ]  Yes[ ]  No |
|  | Has CHMP scientific advice been sought on this development programme? | [ ]  Yes[ ]  No |
|  | If ‘Yes’, please provide details and attach all advice received. |  |
|  | Has national scientific advice from Ireland or other Member States been sought previously on this development programme? | [ ]  Yes[ ]  No |
|  | If ‘Yes’, please provide details and attach all advice received. |  |
|  | Has a previous MAA been made for this product for this indication? | [ ]  Yes[ ]  No |
|  | If ‘Yes’, please give the PA number or European procedure number and detail the type of procedure (MR, DCP or centralised).Provide any relevant RMS assessment reports. | **<PA or EU procedure number>****<type of procedure>** |

1. **Documentation to be attached and page reference**

|  |  |
| --- | --- |
|  |  Page(s) range |

|  |  |  |
| --- | --- | --- |
|  | List of questions and brief overview (For each question raised, the applicant should state their position and provide a written summary.) |  |
|  | CHMP scientific advice |  |
|  | National scientific advice from Ireland or other Member State(s) |  |
|  | Any relevant RMS assessment reports if a previous MAA was made |  |

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| --- |
| 1. **Signed for and on behalf of <company name>**
 |
| I, (please print full name in block capital letters)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Certify that the information and documentation submitted with this application is correct in detail and all the information requested has been supplied. |
| **Signed**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Date**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |
| Position:  |  |
|  |
| **Please send the completed form and accompanying documentation by email to scientificadvice@hpra.ie.** |

1. A concrete and precise list of questions must be provided together with the request for advice. The list of questions is necessary for the validation of the request. Only questions which have been put forward in the list are subject to the advice procedure. See the Guide for National Scientific and Regulatory Advice for more details. [↑](#footnote-ref-1)