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 |

1. **About the request for advice**

|  |  |  |
| --- | --- | --- |
|  | Reason for seeking NSA | Recommended by HPRA  Initiated by applicant |
|  | 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  Nonclinical  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.) |  |
|  | Format requested | Swift (no meeting)  Standard (meeting) |
|  | 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 and regulatory 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 and regulatory advice from Ireland or other Member State(s) |  |
|  | Any relevant RMS assessment reports if a previous MAA was made |  |

|  |  |  |
| --- | --- | --- |
| 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)