Briefing Document for National Scientific and Regulatory Advice

This briefing document should provide an overview and a list of questions, with sufficient detail to enable the HPRA to provide a written response (if seeking swift advice) or to prepare for the meeting (for standard advice).

For the overview, please provide information on the medicinal product and development programme. Any other relevant information can be provided in section 1.3 ‘additional information’. Any supportive documents, which cannot be included in this document, should be listed in section 4 ‘attachments’ and included as attachments when submitting your email application. For the list of questions, you must state your question and provide your position on the matter.

The HPRA may request additional information, if sufficient information is not provided. The finalised briefing document must be submitted within seven days of acceptance of a request for swift advice, or 30 days before the meeting for standard advice. This briefing document, plus any supportive documents and the completed application form, should be submitted via email to [scientificadvice@hpra.ie](mailto:scientificadvice@hpra.ie).

1. background information submitted by the applicant
   1. Background information on the disease to be treated

<Background information on disease>

* 1. Background information on the product

<Background information on product, the development programme overview and/or marketing>

<Background information on the reference product if applicable, see Notice to Applicants Volume 2a Chapter 1, reference product available in IE, global marketing authorisation as defined in Article 6(1) of Directive 2001/83/EC, data exclusivity, etc.>

* 1. Additional information

<Additional information>

1. Questions from the applicant
   1. Questions on quality development

**Question <n> Copy this section for each question**

<Question>

**Applicant’s position**

<Applicant's position>

* 1. Questions on toxico-pharmacological development

**Question <n> Copy this section for each question**

<Question>

**Applicant’s position**

<Applicant's position>

* 1. Questions on clinical development

**Question <n> Copy this section for each question**

<Question>

**Applicant’s position**

<Applicant's position>

* 1. Questions on regulatory development

**Question <n> Copy this section for each question**

<Question>

**Applicant’s position**

<Applicant's position>

1. Other comments not directly related to the questions

<Other comments if relevant>

1. attachments
2. <List supportive documents to be included as email attachements, if any>