

**The applicant’s <Multidisciplinary>/<Quality>/<Clinical>/<Non-Clinical>/<Module 1> response**

**Responses to the questions raised by the MHRA**

<Product name(s)>

<(Active Substance)>

<PL> <PLGB> <PLNI>

Applicant:

The tables below (Timetable and MHRA assessors) are completed by the MHRA; the tables should not be deleted by the applicant.

Timetable:

|  |  |
| --- | --- |
| Start of procedure |  |
| <1st><2nd> Request for further information |  |
| Applicant’s Response Received |  |
| Report Date |  |

MHRA Assessors:

|  |  |  |
| --- | --- | --- |
| Quality | Name: |  |
| Email: |  |
| Non-Clinical | Name: |  |
| Email: |  |
| Clinical | Name: |  |
| Email: |  |
| Clinical Pharmacology | Name: |  |
| Email: |  |
| Statistics | Name: |  |
| Email: |  |
| Risk management plan | Name: |  |
| Email: |  |

CONTENTS

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[1. Assessment of responses to the <1st><2nd>RFI 3](#_Toc125039634)

[2. Additional remarks from the applicant: 8](#_Toc125039635)

1. Responses to the Questions raised in the <1st><2nd>RFI

The applicant should prepare the responses to the MHRA questions as they have been introduced in the Request for Further Information (RFI) or the Commission on Human Medicines (CHM) Letter, by adding them, exactly as they have been written, into this response template.

All sections (i.e. the questions, the applicant’s response, and the assessor’s comment box) should be replicated as many times as the number of questions under each relevant heading.

ASMF related questions (even if included in the list of questions) should be answered separately from this response template.

The response document should be provided both in pdf format in Module 1 and in current Word (docx) format in the working documents folder, with a confirmation on the cover letter that both versions are identical.

The applicant should provide the product information (SmPC, PL, labelling text) in separate clean and track-changed documents as per current MHRA guidance.

The applicant should use this template for each response prepared throughout the procedure.

**MAJOR OBJECTIONS**

If no major objections were raised in the list of questions, the contents under this heading can be deleted and the following text added instead:

<None>

**<QUALITY>**

**<Drug substance (related to additional data provided by applicant only)>**

### Question X

The applicant should pre-fill the MHRA questions as they have been provided, i.e. verbatim. Numbering of the questions should match the list of questions in the RFI /CHM Letter.

#### The applicant’s response

The applicant should pre-fill their responses for each question, not simply referring to annexes. Annexes may be referenced where large data packages, new data, space consuming tables or pictures are required to support the responses. Annexes should be easily identifiable in the response.

The applicant is reminded to introduce the additional data into the relevant CTD sections as necessary, to update the dossier.

|  |
| --- |
| **Assessor’s comment:**  This section is completed by the MHRA; the fields should not be deleted by the applicant.  **Point Resolved/Partly Resolved/Not Resolved** |

**<Drug product>**

### Question X

#### The applicant’s responses

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<NON-CLINICAL>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<CLINICAL>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Risk management plan>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<MODULE 1>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**OTHER CONCERNS**

**<QUALITY>**

**<Drug substance (related to additional data provided by applicant only)>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Drug product>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<NON-CLINICAL>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<CLINICAL>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Risk management plan>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<MODULE 1>**

**<Application-related comments>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Summary of Product Characteristics>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Package leaflet>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<User consultation>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

**<Labels>**

### Question X

#### The applicant’s response

|  |
| --- |
| **Assessor’s comment:**  **Point Resolved/Partly Resolved/Not Resolved** |

1. Additional remarks from the applicant:

Other changes proposed by the Applicant (unrelated to the list of questions) should be listed here. Please note that these changes should be minimised and the response submission should not be seen as an opportunity to update the dossier with any major new information.