**MHRA - Request for Pre-submission Advice for IRP Applications**

This form should be used to request a pre-submission advice for IRP with the MHRA.

Please complete this form and email with your proposed questions and any other attachments to [presubmission@mhra.gov.uk](mailto:presubmission@mhra.gov.uk).

Upon receiving this form and accompanying document with specific questions, our team will assess the most appropriate form of advice to offer, available tools are written advice, virtual pre-submission meeting or formal Scientific Advice. The Agency will then inform on next steps.

**About you**

|  |  |
| --- | --- |
| Company name |  |
| Contact name |  |
| Email address |  |

**About the product(s)**

|  |  |
| --- | --- |
| Name of the active substance(s) |  |
| Proposed indication(s) |  |
| Type of product | Chemical  ATMP  Biosimilar  Other Biological |
| Is the Active Ingredient licensed in the UK? | Yes  No |
| Pharmaceutical form(s) |  |
| Proposed legal status | Prescription  Non-prescription |
| **If you wish to discuss multiple products, please give full information below** | |
|  | |

**Your Submission plans**

|  |  |
| --- | --- |
| Who are your proposed Reference Regulator/s? |  |
| Is the product approved in additional regions? |  |
| Date of approval in Reference regulator/s? |  |
| Does your product include or require an administration/medical device or an in vitro diagnostic (IVD)?  If yes, please provide details. |  |
| Has previous MHRA scientific advice or authorisation been sought on this product? |  |
| Key Regulatory procedure in the UK on which advice is sought | Marketing Authorisation application  Type II New therapeutic indication  Other type II variation  Line Extension (please note the original PL below)  Product and patient information |
| Please list the key objectives for the advice sought and provide any additional comments relevant to the request.  (Please separately attach a draft of the proposed questions) |  |

**[Please ensure that you provide a separate document listing any specific questions you have for our team and send to** [**presubmission@mhra.gov.uk**](mailto:presubmission@mhra.gov.uk)**]**