**MHRA - Request for scientific advice form**

This form should be used to request a scientific advice meeting with the MHRA.

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

**About you**

|  |  |
| --- | --- |
| Company name |  |
| Contact name |  |
| Contact address |  |
| Telephone number |  |
| Email address |  |
| Contact name for invoicing (if different from above) |  |
| Contact address for invoicing (if different from above) |  |
| Contact email for invoicing (if different from above) |  |
| SME fee waiver request | Yes  No |
| If Yes, is MHRA payment easement confirmation attached | Yes  No |

**About the product**

|  |  |
| --- | --- |
| Name of the active substance (if advice is not product specific please write ‘Broader Scope advice’) |  |
| Proposed indication(s) |  |
| ATC code (if known) |  |
| Type of product | New active substance (chemical)  Established active substance (chemical)  New active substance (biological)  Established active substance (biological)  Herbal  Homoeopathic |
| Pharmaceutical form(s) |  |
| Proposed legal status | Prescription  Non-prescription |

**Your development plans**

|  |  |
| --- | --- |
| Is the advice connected with a future | Clinical Trial Authorisation (CTA) application for a specific study(ies)  Marketing Authorisation Application (MAA)  General development advice including both CTA and MAA elements |
| Does your product include or require an administration/medical device or an in vitro diagnostic (IVD)?  If yes, please provide details. |  |
| Key Regulatory procedure in the UK on which advice is sought | Clinical Trial Authorisation  New Product Authorisation  New therapeutic indication  Product maintenance and variation  Sale and Supply reclassification  Product advertising  Product and patient information  Medical device incorporating ancillary medicinal substance |
| Specific Advice sought (this will guide which MHRA experts will give advice | Quality  Non-clinical  Clinical  Regulatory  Devices  Statistics  Pharmacovigilance/Risk management plan  Paediatric development  Orphan product designation  National Institute of Biological Standards and Control |
| 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) |  |

**Your preferences for a meeting/written only advice**

|  |  |
| --- | --- |
| Preferred meeting dates |  |
| Unavailable meeting dates |  |
| Do you wish to request written only scientific advice without a meeting? (note this may be declined, usual fees apply) |  |
| If requesting written only scientific advice please provide an estimated date of briefing document submission. |  |

**Other procedures related to product**

|  |  |
| --- | --- |
| Is this product currently under assessment in any EU Member State? |  |
| Has previous MHRA scientific advice been sought on this development programme? |  |
| If ‘Yes’ please provide details and attach all advice received |  |
| Has scientific advice been sought on this development programme from other agencies? |  |
| If ‘Yes’ please provide details and attach all advice received |  |
| Has advice been sought from the MHRA Innovation Office on this development programme? |  |
| If ‘Yes’ please provide the reference number if known |  |
| Has an Innovative Licensing and Access Pathway (ILAP) Innovation Passport designation been sought |  |
| If ‘Yes’ please provide the reference number if known |  |
| Has a Promising Innovative Medicine (PIM) designation been sought? |  |
| If ‘Yes’ please provide the reference number if known |  |
| Are you considering engaging with the ILAP? |  |
| Has a previous MAA or variation application been made for this product for this indication? |  |
| If so, please give the PL number or European Procedure number |  |
| Actual/Proposed regulatory procedure to be followed for this product (if known) |  |