**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 |  |
| Emergency contact number (mobile) |  |
| Fax number |  |
| Email address |  |
| Confirm 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) |  |

**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 | Chemical  Biological  Herbal  Homoeopathic |
| Pharmaceutical form(s) |  |
| Proposed legal status | Prescription  Non-prescription |
| Is the advice solely connected with a future | Clinical Trials Authorisation (CTA)  Marketing Authorisation Application (MAA) |
| Or is advice on both CTA and MAA sought? |  |
| Regulatory procedure in the UK | Clinical Trial Authorisation  New Product Authorisation  Product maintenance and variation  Supply reclassification  Product advertising  Product and patient information  Medical device incorporating ancillary medicinal substance |
| Advice sought | Quality  Non-clinical  Clinical  Regulatory  Pharamacovigilance/Risk management plan  Paediatric development  National Institute of Biological Standards and Control |
| Please add any comments related to the advice sought.  (Please separately attach a draft of the proposed questions) |  |
| Preferred dates |  |
| Unavailable dates |  |
| Is this product currently under assessment in any other Member State? |  |
| Has CHMP scientific advice been sought on this development programme? |  |
| If ‘Yes’ please provide details and attach all advice received |  |
| Has previous MHRA scientific advice been sought on this development programme? |  |
| 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 a previous MAA been made for this product for this indication? |  |
| If so, please give the PL number or European Procedure number |  |
| Actual/Proposed procedure to be followed for this product (if known) |  |
| For a centralised product is the UK rapporteur or co-rapporteur? |  |