**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

 **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? |  |