**MHRA - Request for Pre-Submission advice form**

This form should be used to request a Pre-Submission advice with the MHRA.

Please complete this form and email with your proposed questions and any other attachments to PreSubmission@mhra.gov.uk

**Upon receipt of this request, the team will assess the type of advice required. This could be in the form of regulatory advice, a pre-submission meeting or directions to relevant MHRA guidance.**

 **About you**

|  |  |
| --- | --- |
| Company name |  |
| Contact name |  |
| Telephone number |  |
| Email address |  |

**About the product**

|  |  |
| --- | --- |
| Name of the active substance (if meeting is not product specific please write ‘Broader Scope meeting’) |  |
| Proposed indication(s) |  |
| Proposed submission date |  |
| Type of product and proposed application | [ ]  New active substance (chemical)[ ]  Established active substance (chemical)[ ]  New active substance (biological)[ ]  Established active substance (biological)[ ]  Line Extension[ ]  Type II variation |
| Pharmaceutical form(s) |  |
| Proposed legal status | [ ]  Prescription[ ]  Non-prescription |

**Your development plans**

|  |  |
| --- | --- |
| Which route are you looking to follow?  | [ ]  National Procedure[ ]  Rolling Review Procedure[ ]  International Recognition Procedure[ ]  Project Orbis[ ]  Access Consortium |
| Does your product include or require an administration/medical device or an in vitro diagnostic (IVD)? If yes, please provide details. |  |
| Do you hold an IP designation for this product? |  |
| Have you obtained MHRA scientific advice on this product? |  |

Please return your completed form along with additional information and any specific you questions you have at this time to presubmission@mhra.gov.uk at-least 3 months prior to submission.