**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](mailto: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](mailto:presubmission@mhra.gov.uk) at-least 3 months prior to submission.