Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Guide to Cover Letter & Supplementary Information

This form has been designed as an aid to determine the additional information required in the Cover Letters and Application Forms of initial and variation applications.

IMPORTANT: Answer all of the questions below fully (ensuring that you scroll down to the bottom of the document) to determine the correct information required for your application. Failure to submit the appropriate information in the cover letter and the dossier may result in the Application being invalidated.

APPLICATION TYPE

- (●) Initial Marketing Authorisation Application
- ( ) Herbal and Homeopathic Medicines
- ( ) Variation Application

APPLICATION TERRITORY:

United Kingdom (PL)

APPLICATION ROUTE:

Please select…

VARIATION TYPE

APPLICATION LEGAL BASIS

Please select…

ORPHAN MEDICINAL PRODUCTS DESIGNATION

For Type IB Medicinal Products, if the following applies:

4a New Indications – orphan medicinal product information Are you applying for orphan designation for this medicinal product?	No
4b Paediatric Requirements Has any medicinal product been designated as an orphan medicinal product (in Great Britain and/or EU) for a condition relating to the indication proposed in this application?	No
4c Extended data exclusivity/market protection	

Results Reset Form