Medicines and Healthcare products Regulatory Agency
Herbal or Homeopathic Registration
Electronic Application Form
Version 1.0

Login Page

User Name:

Password:

Login

If you are a member of more than one company group, please select which organisation you are completing this form on behalf of:

Confirm

i. Is this a replacement application form? ○Yes ◉No

The replacement will amend or update a currently pending submission when the original form is incorrect or incomplete or in response to MHRA review.

If yes, please give the MHRA Reference Number (Case Number):

Search

Case Number:

ii. If this application form is being submitted through the MHRA portal, will the associated documents be sent subsequently by post (e.g. CD ROM, DVD, paper etc)? ○Yes ◉No

If this is not a replacement form and documents are to be sent through post, please generate a ticket number for the application form.This ticket number will be used to correlate the form you submit through the MHRA portal with the associated documents submitted by post. Please include a copy of this form with the associated documents sent by post.

Generate Ticket Number

ADMINISTRATIVE DATA: REGISTRATION

Application Particulars

○ **Herbal Registration** ○ **Homeopathic Registration**

1. This Application Concerns: <Please select an application type>

1.1 Initial

Search

Registration Number:

1.1.1a Fee Type:

1.1.1b Supplementary Fees .

Please tick any of the following that apply.

☐ The medicinal product contains one or more vitamins or minerals from a new source. European Pharmacopoeia certificates of suitability cover all the vitamins or minerals

☐ The medicinal product contains one or more vitamins or minerals from a new source. European Pharmacopoeia certificates of suitability DO NOT cover all the vitamins or minerals.

☐ The medicinal product contains one or more new excipients.

☐ The medicinal product contains one or more TSE risk excipients from a new source.

☐ The medicinal product is a sterile medicinal product.

1.1.2 **Proposed Registration Holder:**

1.1.2.a Company Name:

1.1.2.b Company Address:

1.1.2.c Trading Style Name:

1.1.3 Product Name

1.2 **Renewal**

Search

Registration Number:

1.2.1 Fee Type:

1.2.1 **Licence Holder**

1.2.1.a Company Name:

1.2.1.b Company Address:

1.2.2 **Product Summary**

1.2.2.a Specific Product name:

1.2.2.b Active Substance List:

1.2.2.c ATC Code and Group:

1.2.2.d Route of Administration List:

Please go to Question 1.4 (page 4)

1.3 **Variations**

Search

Registration Number:

1.3.1 Fee Type

1.3.2 **Registration Holder:**

1.3.2.a Company Name:

1.3.2.b Company Address:

1.3.3 **Product Summary**

1.3.3.a Specific Product name:

1.3.3.b Active Substance List:

1.3.3.c ATC Code and Group:

1.3.3.d Route of Administration List:

Add Registration | Remove Registration | Update Registration

List of Parallel Imports

2. Registration Application Particulars

2.1 Pharmacotherapeutic Group

Search

2.1.a ATC Code:

2.1.b ATC Group:

2.1.c Please indicate if the application for the ATC Code is still pending: ◯Yes ◯No

2.2 Route of Administration

2.2.a Route of Administration:

Add Route Remove Route

Route of Administration List:

2.2 Container, Container Material, Closure and Administration Device(s)

2.2.a Container:

2.2.b Container Material:

Add Container Material | Remove Container Material

Container List:

2.2.c Closure:

2.2.d Closure Material:

Add Closure Material | Remove Closure Material

Closure List:

2.2.e Administration Device:

2.2.f Administration Device Material:

Add Device Material | Remove Device Material

Administration Device Material List:

2.2.g Pack Size:

Add Pack Size | Remove Pack Size

List of Pack Sizes:

Note: for mutual recognition procedures, all package sizes authorised in the Reference Member State should be listed

2.2.h Shelf Life (prior to opening):

2.2.i Shelf Life (after opening):

2.2.j Shelf Life (after reconsitution):

2.2.k Proposed Storage Condition(s):

Add Storage Condition | Remove Storage Condition

Proposed Storage Conditions List:

2.2.l Proposed Storage Condition(s) (after first opening):

Add Storage Condition | Remove Storage Condition

Proposed Storage Conditions (after first opening) List:

Add Pack | Remove Pack | Update Pack

List of Packs

2.3 Legal Status

2.3.1 Proposed dispensing / classification

(Classification under Article 1(19) od Directive 2001/83/EEC as amended)

If product **is** subject to medical prescription, please specify:

2.3.2 Classification:

(not all listed options are applicable in each member state. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only to those categories provided for in their national legislation)
** Note: for further information, please refer to Article 71 of Directive 2001/83/EC as amended*

If product is **not** subject to medical prescription, please specify:

2.3.3 Supply:

2.3.4 Promotion:

2.3.5 Other Information:

Contact and Company Details

2.4 Marketing Authorisation Holder / Contact Persons / Company

2.4.1 Proposed marketing authorisation holder legally responsible for placing the product on the market in the Community / each Member State:

Search

2.4.1.a Company Name:

2.4.1.b Company Address:

Search

2.4.1.c Contact Name at this Address
(centralised procedure only)

Attach proof of establishment of the applicant in the EEA (Annex6.3)

2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the Community/each Member State:

Search

2.4.2.a Company Name:

2.4.2.b Company Address:

Search

2.4.2.c Contact Name:

If different to 2.4.1 above, attach letter of authorisation (Annex6.4)

2.4.3 Person/Company authorised for communication between the Registration holder and the competent authorities after authorisation if different from the above in the Community / each Member State:

Search

2.4.3.a Company Name:

2.4.3.b Company Address:

Search

2.4.3.c Contact Name:

Attach C.V. of qualified person (Annex 6.5)

2.4.4 Qualified Person in the EEA for Pharmacovigilance:

Search	
2.4.4.a Company Name:	
2.4.4.b Company Address:	
Search	
2.4.4 c Contact Name:	

Attach C.V. of qualified person (Annex 6.4)

2.4.5 Scientific Service of the Registration Holder in the EEA *as referred to in Article 98 of Directive 2001/83/EC as amended (for MRP and national applications, the contact person in the country where the application is made):*

Search	
2.4.5.a Company Name:	
2.4.5.b Company Address:	
Search	
2.4.5 c Contact Name:	

2.5 Manufacturers

2.5.1 Authorised Manufacturer(s) (or Importer) responsible for batch release in the EEA *in accordance with Article 40 and 51 of Directive 2001/83/EC as amended (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):*

2.5.1.a Company Function

Search

2.5.1.b Company Name:

2.5.1.c Company Address:

2.5.1.d Manufacturing Authorisation Number:

2.5.1.e Trading Style:

Add Manufacturing Company | Remove Manufacturing Company | Update Manufacturing Company

List of Manufacturing Companies

2.5 Manufacturers

2.5.1.1 Site(s) in EEA or in countries with MRA/PECA in operation, where batch control/testing takes place *(if different from 2.5.1) as required by Article 51 of Directive 2001/83/EC as amended:*

2.5.1.2.a Company Function

Search

2.5.1.2.b Company Name:

2.5.1.2.c Company Address:

2.5.1.2.d Manufacturing Authorisation Number:

2.5.1.1.e Trading Style:

Add Site | Remove Site | Update Site

List of Sites

2.5.2 Manufacturer(s) of the Medicinal Product and Site(s) of Manufacture:

(Note: Including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product)

2.5.2.a Company Function:

Search

2.5.2.b Company Name:

2.5.2.c Company Address:

Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 6.8)

2.5.2.d Is the Manufacturing Site in the EEA?: ◯Yes ◯No

If yes (Manufacturing Site in the EEA) please specify:

2.5.2.e Manufacturing Authorisation Number:

Attach manufacturing authorisations required under Article 40 of Directive 2001/83/EC as amended (Annex 6.6)

2.5.2.f Name of Qualified Person

If no (Manufacturing Site outside the EEA) please specify:

Where MRA/PECA is in operation, attach equivalent of manufacturing authorisation (Annex 6.6)

2.5.2.g Has the site been inspected for GMP Compliance by an EEA Authority or by an Authority of countries where MRA/PECA is in operation?: ◯Yes ◯No

If yes, please provide in Annex 6.9 for each site a statement from the competent authority which carried out the inspection, including:

- *last GMP inspection date*
- *name of competent authority which carried out the inspection*
- *the type of inspection (pre/post-authorisation/special/re-inspection)*
- *category of products and activities inspected*

2.5.2.h Outcome of the GMP inspection: ◯Compliant ◯ Non-compliant

Add Manufacturer | Remove Manufacturer | Update Manufacturer

List of Manufacturers

2.5.3 Manufacturer(s) of the Active Substance(s):

Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Brokers or suppliers details alone are not acceptable

2.5.3.a Company Function:

Search

2.5.3.b Substance:

Search

2.5.3.c Company Name:

2.5.3.d Company Address:

2.5.3.e Brief Description of Manufacturing Steps Performed by

2.5.3.f Manufacturing Authorisation Number:

2.5.3.g Has a Ph.Eur. Certificate of suitability been issued for the active substance(s)? ○Yes ○No

If yes, please specify:

2.5.3.h Certificate Holder:

2.5.3.i Reference Number:

2.5.3.j Date of Last Update: *(dd-mm-yyyy)*

Provide copy in Annex 6.10

2.5.3.k Is a Master File to be used for the active substance(s) reference/original?: ○Yes ○No

If yes, please specify:

2.5.3.l Reference Number for EMEA/ Competent Authority:

2.5.3.m Date of Submission: *(dd-mm-yyyy)*

2.5.3.n Date of Last Update: *(dd-mm-yyyy)*

Attach letter of access for Community/Member State authorities where the application is made (see European DMF procedure for active ingredients) (Annex 6.10)
Attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC as amended (Annex 6.11)

2.5.3.o Has an EMEA certificate for a Vaccine Antigen Master File (VAMF) been issued or submitted *in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?* ◯Yes ◯No

If yes, please specify:

2.5.3.p Name of the VAMF Certificate Holder / VAMF Applicant:

2.5.3.q Reference Number of Application / Certificate:

2.5.3.r Date of Submission (if pending): *(dd-mm-yyyy)*

2.5.3.s Date of Approval or last update (if approved): *(dd-mm-yyyy)*

Provide copy in Annex 6.20

2.5.3.t Has the Active Ingredient Manufacturer been inspected by an EEA Country?: ◯Yes ◯No

If yes:

The following information should be provided in Annex 6.9 for each site:
- *last inspection date by an EEA country*
- *name of competent authority which carried out the inspection*
- *type of inspection (pre/post-authorisation/special/re-inspection)*
- *categories of ingredient and activities inspected*

2.5.3.u Please specify the outcome of the Inspection: ◯Positive ◯Negative

2.5.3.v Any materials of Animal and/or Human Origin contained or used in the Manufacturing Process of the Substance? ◯Yes ◯No

Add Manufacturer | Remove Manufacturer | Update Manufacturer

List of Manufacturers

2.6 Qualitative and Quantitative Composition

2.6.1 Qualitative and Quantitative Composition of the Active Substance(s) and Excipient(s)

2.6.1.a **Active Substances OR Homeopathic Stocks**

Search

2.6.1.c Substance:

2.6.1.d Quantity:

2.6.1.e Reference/Monograph Standard:

2.6.1.f Overage Quantity:

Add Active Substance | Remove Active Substance | Update Active Substance

List of Active Substances

2.6.1.g **Excipients*:**

Search

2.6.1.h Substance:

2.6.1.i Quantity:

2.6.1.j Reference/Monograph

2.6.1.k Modifier:

2.6.1.l Overage Quantity:

Add Excipient | Remove Excipient | Update Excipient

List of Excipients

*Note: *only one name for each substance should be given in the following order of priority: INN**, Ph.Eur., National Pharmacopoeia, common name, scientifica name*
***the active substance should be declared by its recomended INN, accompanied by its salt or hydrate relevant (for further details consult the Guideline on the SmPC)*

2.6.2 List of materials or animal and/or human origin contained or used in the manufacturing process of the medicinal product

2.6.2.a Are there any materials of Animal and/or Human Origin contained or used in the Manufacturing Process of the Medicinal Product?: ◯Yes ◯No

Search

2.6.2.b Substance:

2.6.2.c Function:

Note: Active substance, Excipient- including starting materials used in the manufacture of the active substance/excipient Reagent/culture medium - including those used in preparation of master and working cell banks

2.6.2.d Animal Origin Susceptible to TSE**?: ◯Yes ◯No

2.6.2.e Certificate of Suitability for TSE**?: ◯Yes ◯No

*Note: ** as defined in section 2 (scope) of the CPMP Note for Guidance*

2.6.2.f Certificate Number:

2.6.2.g Other Animal Origin: ◯Yes ◯No

2.6.2.h Human origin: ◯Yes ◯No

If a Ph.Eur. Certificate of suitability for TSE is available according to Resolution AP/CSP (99)4 of the Council of Europe attach it in Annex 6.12

Add Substance | Remove Substance | Update Substance

List of Substances

2.6.3 Genetically Modified Organisms

2.6.3.a Does the Medicinal Product contain or consist of Genetically Modified Organisms GMOs)? ◯Yes ◯No

If yes, please specify:

2.6.3.b Does the product comply with Council Directive 90/220/EEC? ◯Yes ◯No

Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 6.12)

3. Registrations to which cross reference is made

Search

MHRA Registration Number:

Add Registration | Remove Registration

List of Registrations

4. OTHER REGISTRATION APPLICATIONS

For National applications only, please complete the following in accordance with Article 8(j)-(l) of Directive 2001/83/EC as amended

Applications for the same Registration in the EEA

4.1 Are there Applications for the same* Registration in the EEA?: ○ Yes ○ No

*Note: * "same product" means from applicants belonging to the same mother company or group of companies OR which are "licences". (Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form)*
Note: refer to Comission Communication 98/C229/03

4.2 If yes, please specify the status of the application:

Registration Pending:

4.2.1.a Country:

4.2.1.b Date of Submission: *(dd-mm-yyyy)*

Registration Authorised:

4.2.2.a Country:

4.2.2.b Date of Submission: *(dd-mm-yyyy)*

4.2.2.c Trade Name:

4.2.2.d Authorisation Number:

4.2.2.e Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same registration in other Member States *(for national applications, Art. 17 or 18 of Directive 2001/83/EC as amended may apply)*? ○ Yes ○ No

4.2.2.f If yes, please elaborate:

Product Refused:

4.2.3.a Country:

4.2.3.b Date of Submission: *(dd-mm-yyyy)*

Product Withdrawn (by applicant before application):

4.2.4.a Country:

4.2.4.b Date of Withdrawal: *(dd-mm-yyyy)*

4.2.4.c Trade Name:

4.2.4.d Reason for Withdrawal:

Product Withdrawn (by applicant after application):

4.2.4.e Country:

4.2.4.f Date of Withdrawal: *(dd-mm-yyyy)*

4.2.4.g Authorisation Number:

4.2.4.h Trade Name:

4.2.4.i Reason for Withdrawal:

Product Suspended / Revoked (by competent authority):

4.2.5.a Country:

4.2.5.b Date of Suspension: *(dd-mm-yyyy)*

4.2.5.c Reason for Suspension/Revocation:

4.2.5.d Trade Name:

4.3 Multiple Applications of the same Registration

4.3.a Name of Other Product:

4.3.b Date of Application: *(dd-mm-yyyy)*

Search

4.3.c Applicant Company Name:

4.3.d Details of Differences:

Attach copy of correspondence with the European Commission for centralised procedures only (Annex 6.16)

Add Product | Remove Product | Update Product

List of Products

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- ☐ **5.1** Proof of Payment
- ☐ **5.2** Proof of establishment of the applicant in the EEA
- ☐ **5.3** Letter of authorisation for communication on behalf of the applicant/MAH
- ☐ **5.4** Curriculum Vitae of the Qualified Person for Pharmacovigilance
- ☐ **5.5** Marketing Authorisation required under Article 40 of Directive 2001/83/EC as amended (or equivalent, outside of the of the EEA where MRA/PECA is in operation)
- ☐ **5.6** Justification for more than one manufacturer responsible for batch release in the EEA
- ☐ **5.7** Flow-chart indicating the different sites involved in the manufacturing process of the medicinal product (including sites involved in sampling and testing for batch release of products manufactured in third countries)
- ☐ **5.8** Statement from the compotent authority which carried out the inspection of the manufacturing site(s)
- ☐ **5.9** Letter(s) of access to Drug Master File(s) or copy of Ph.Eur. Certificate(s) of suitability
- ☐ **5.10** Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/83/EC
- ☐ **5.11** Ph.Eur.Certificate(s) of suitability for TSE
- ☐ **5.12** Written consent(s) of the competent authorities regarding GMO release in the environment
- ☐ **5.13** List of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to applicants, volume 2A, chapter 7)

6. ADDITIONAL DATA REQUIREMENTS

6.1 **Indications:**

Search

Indication:

Add Indication | Remove Indication

List of Indications

6.2 **Contra-indications:**

Search

Contra-indication:

Add Contra-Indication | Remove Contra-Indication

List of Contra-indications

6.3 **Side Effects:**

Search

Side Effect:

Add Side Effect | Remove Side Effect

List of Side Effects

7. Variations

7.1 **Reason for Variation:**

7.2.a **PRESENT***	7.2.b **PROPOSED***

Note: Specify the precise and proposed wording or specification*
For SPC, labelling and package leaflet/insert changes, underline or highlight the changed words presented in the table above and provide as a separate Annex
For SPC changes, please provide updated fragments using the MHRA SPC templates. Do not submit a complete new version - only the changed sections.

Declaration and Signature

It is hereby confirmed that all existing data which are relevant to the registration of the medicinal product have been supplied in the dossier, as appropriate.

It is hereby confirmed that fees will be paid/have been paid according to National Community rules:

Name of Person Signing on Behalf of the Applicant

a. Name:

b. Company Name:

c. Person's Function:

d. Date of signature: *(dd-mm-yyyy)*

Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 6.4

Note: if fees have been paid, attach proof of payment in Annex 6.1 - see information on fee payments in the Notice to Applicants, Volume 2A, chapter 7.

Comments