



Practical User Guide for Electronic Application Forms (eAF) for human and veterinary medicinal products in the EU

Version 1.7

July 2018

Remark to the reader

This document reflects the current state of knowledge and will be subject to future updates to take new information on-board. Therefore, it is important that comments are feed back to the eAF User Group by e-mail [EMA IT service desk \(https://servicedesk.ema.europa.eu\)](https://servicedesk.ema.europa.eu).

Screenshots in this document have been taken in most cases from the eAF version 1. 20. In some cases, the guidance will still use screenshots based on earlier versions. It would not be possible to match this guidance document with exactly one version of the eAF. However, very recent information about new functionalities or changes can be retrieved from the release notes at <http://esubmission.ema.europa.eu/eaf/index.html>.

Document History

Change Record

Version	Author(s)	Comments
1.0	eAF User Group	This document has been prepared by the sub-group on guidance and information of the eAF User Group in collaboration with CMDh and CMDv
	eAF User Group	First draft for revision, made the document in line with reported corrections, improved consistency with the Q&A on eAF and aligned with changes of the eAFs version 1.18
1.1	eAF User Group	Indicating acceptance of an image of a text snippet for EMA, additional advice for optimising the PDF file for eCTD purpose, minor editorial changes after review
1.2	eAF Sub-Group on Guidance	Update of the guidance to include new features of version 1.20 as well as to improve several sections based on user comments.
1.3	eAF Sub-Group on Guidance	Consolidation of review comments.
1.4.1	eAF Sub-Group on Guidance	Deleting the note in section 2.5.3 pointing to a workaround not meaningful.
1.4.2	eAF Sub-Group on Guidance	Update based on eAF v1.20.0.3 (Screenshots updated as necessary, advice on button “Add All” for member states in MAA hum/vet and REN), correction of link to EMA IT service desk
1.4.3	eAF Sub-Group on Guidance	Clean version for publication
1.6	EMA	Updated to reflect eAF v1.22.0.0
1.7	EMA / eAF Sub-Group on Guidance	Updated to reflect eAF v1.23.0.0 and the NtA changes triggering the updated version of the eAF.

Reviewers

Version	Name	Organisation
1.0	Representatives of NCA and EMA	eAF Full Group,
	Representatives of NCA and EMA	CMDh,
	Representatives of NCA and EMA	CMDv
1.1	Representatives of NCA and EMA	eAF Full Group,
1.2	Representatives of NCA and EMA	eAF Full Group, CMDh and CMDv, eSub CMB
1.7	Representatives of NCA and EMA	eAF Full Group, CMDh and CMDv, eSub CMB

Distribution

Version	Distributed to	Way of distribution
1.0	General public	Published on the EMA eSubmission website
1.1	General public	Published on the EMA eSubmission website
1.4	General public	Published on the EMA eSubmission website
1.5	General public	Published on the EMA eSubmission website
1.6	General public	Published on the EMA eSubmission website
1.7	General public	Published on the EMA eSubmission website

Coming into Operation

Version	Date in operation	Comment
1.0	July 2015	This guidance document should always be read in conjunction with the respective regulatory guidance documents on human and veterinary medicinal products. In parallel a Q&A document is available providing quick up-to-date additional information regarding usage of eAFs.
1.1	October 2015	This is an interim update. A next update will follow once the eAF version 1.19 is published.
1.4	June 2016	This is an interim update. Further updates are expected based on user feedback once version 1.20 is published.
1.5	October 2016	Updated version based on eAF v1.20.0.3
1.6	December 2017	Updated version based on eAF v1.22.0.0
1.7	July 2018	Updated version based on eAF v1.23.0.0

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On the following pages general technical information in regard to all electronic application forms is provided. Additional information related to the specific application forms is provided in separate sections.

PURPOSE AND GENERAL TECHNICAL RULES

Purpose of the document

It is mandatory to use the electronic application form as a part of your submission package for all (Human and Veterinary submissions in all Member States. The paper MS Word application forms are no longer provided by Notice to Applicants (NtA).

This document provides practical and technical support on the use of the Electronic Application Forms (eAF) for human and veterinary medicinal products separately and in addition to the regulatory USER GUIDE FOR THE ELECTRONIC APPLICATION FORM FOR A MARKETING AUTHORISATION which is available for human medicinal products at [CMDh](#) and for veterinary medicinal products at [CMDv](#). This document should be read in the context with the regulatory guidance referenced above.

Note: The reliable regulatory information must be taken from the (regulatory) USER GUIDES OF THE APPLICATION FORM only.

In addition, a Question & Answer document has been published at <http://esubmission.ema.europa.eu/eaf/index.html> and is intended to cover anticipated questions relating specifically to the electronic forms. In addition, field level help is also available in the eAF by moving the mouse pointer over each field of the electronic forms. These are called 'tooltips'.

Note: If you do not see the tooltips when you 'hover' the mouse over the fields in the forms please contact your IT support.

The release notes list new functionality provided when new versions of the forms become available. It is strongly recommended to always review the release notes when a new version of the forms becomes available.

You can also find information relating to the use of the forms in the release notes, for example some workaround solutions.

- If you encounter an issue with a specific field, please refer to the 'Known Issues' in the Release Notes for the specific form. These may be found on the [eAF pages](#) of the EMA's eSubmission website. New issues may be raised via [EMA IT service desk](#) (<https://servicedesk.ema.europa.eu>).
- If the information cannot be included in the form, please review any workaround solutions provided in the release notes or use an annex. If still not all information can be included, please contact [EMA IT service desk](#) (<https://servicedesk.ema.europa.eu>).

- In case of any further technical queries, please contact [EMA IT service desk](mailto:EMA.IT.service@ema.europa.eu) (<https://servicedesk.ema.europa.eu/>).

Referential Term Change Request processes

In case of a missing term – as a general rule – in order to complete an eAF, please use the RMS Change Request processes as outlined in the “Referentials Management Services (RMS) operating model” document. Please submit a request through the SPOR Portal - <http://spor.ema.europa.eu/rmswi/#/> providing as much supporting documentation as possible (e.g. name of the product concerned, SmPC, etc.). Please note you need to be registered with SPOR prior to submission of change requests: <https://register.ema.europa.eu/identityiq/login.jsf>. The user guide for managing referential and organisation data in eAF is available [here](#).

If you need to request a missing substance in order to complete an eAF, please submit a request for substance insertion with the corresponding SmPC to the EMA Service Desk portal - <https://servicedesk.ema.europa.eu/>.

Access to the forms and news on updates

The use of the electronic application form has become mandatory as of July 1st, 2015, for the centralised procedure and as of January 1st, 2016, for all MRP/DCP and national procedures. Technical details are accessible at <http://esubmission.ema.europa.eu/eaf/index.html>. You will also find there the most recent version of the respective form.

Updates to the electronic application forms are expected to reflect any updates agreed by the European Commission, in consultation with the competent authorities of the Member States and the European Medicines Agency (EMA).

Note: Regular updates will happen according to the release planning.

The simplest way to keep up to date with changes to eAF is to [subscribe to the eAF RSS feed](#).

Click the button  on the site itself. For more information about RSS feeds, see *The EMA's Guide to RSS*.

Requirements on Adobe Reader and IT security settings

When opening the eAF for the first time with Adobe Acrobat, Adobe Reader or with an Adobe related plug-in in the eCTD review tool, click “Allow content” when prompted, then click “Trust this document always”. To avoid any issues, it is recommended that you (re)install your chosen review tool after any Adobe software related updates.

Adobe is no longer supporting version 9 or below, therefore we strongly advise to upgrade Adobe Acrobat/Reader to the most recent version. The minimum specification to use eAF is Adobe Reader/Acrobat version 10 or above. (It is always recommended to use latest version). If you wish to continue using Adobe Acrobat 9 and eAFs are working fine with it then you can do so, however should there be any compatibility issues then Adobe won't be able to support EMA. Please keep yourself informed about the [Adobe supported versions](#).

Extensive testing has not been performed using Linux or Mac OS environments, however there are no known issues preventing the use as long as Adobe reader and internet connection are accessible.

Note: The built-in PDF viewer with Mozilla Firefox and Google Chrome do not support XFA - based PDF forms. Guidance to assist with resolving this issue can be found here:



Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document.

<http://helpx.adobe.com/livecycle/kb/xfa-forms-firefox-chrome.html>

In case you receive the message '*Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document.*' when opening the form the first time, click the 'Options' button and select 'Trust this document always'.

Note: If the IT policy of your local organisation forbids you from making changes to a security setting, it is recommended that you contact your local IT service desk and request that they allow access to the following URL: <http://eaf.ema.europa.eu/eaf/services/EutctService?wsdl>

IMPORTANT: This web services location, managed by the EMA, enables many of the forms' fields, searches and drop-down lists to be populated dynamically. Without access, the form **cannot** be completed.

Opening the form

It takes longer to open the eAFs than opening Word or other PDF documents. This is due to the forms being connected to web services and once the form is opened, lists are loaded from EUTCT & RMS and there are some build in 'business validation rules' in the forms which are making the forms 'heavy'. However, not all term lists are loaded initially.

The searchable fields will not work if there is no internet connection (such as Active substance, Excipients and ATC code). Other drop-down lists are loaded into the form when the form opens initially and this is one of the reasons that the form takes longer time to open.

The average response times for how long it takes to open a current version of the eAF depends on the form. The responses are also different for new forms that are being opened directly from the eAF website as opposed to those that have been filled in, locked and submitted by the MAA/MAH.

Navigation in the forms

You can jump between different sections of the forms by clicking your mouse on the bold blue section name. When you click to this text you are automatically taken to the Table of Contents section from where you can navigate to any other part of the form.

TABLE OF CONTENTS	
DECLARATION AND SIGNATURE	
1. TYPE OF APPLICATION	
1.1	This application concerns
1.2	Orphan medicinal product information
1.3	Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulations (EC) no 1234/2008, or any national legislation, where applicable
1.4	This application submitted in accordance with the following Article in Directive 2001/83/EC
1.5	Consideration of this application also requested under the following article in Directive 2001/83/EC or Regulation (EC) No 726/2004
1.6	Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')
2. MARKETING AUTHORISATION APPLICATION PARTICULARS	
2.1	Name(s) and ATC code
2.2	Strength, pharmaceutical form, route of administration, container and pack sizes

2. MARKETING AUTHORISATION APPLICATION PARTICULARS	
2.1 NAME(S) AND ATC CODE	
2.1.1	Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

Click to return to Table of Contents.

This functionality is limited in the locked forms where the table and contents and all the headers have been greyed out. The return to the Table of Contents will only work if the header is surrounded by dotted line.

TABLE OF CONTENTS

DECLARATION AND SIGNATURE

1. TYPE OF APPLICATION

1.1 This application concerns

1.2 Orphan medicinal product information

1.3 Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulations (EC) no 1234/2008, or any national legislation, where applicable

1.4 This application submitted in accordance with the following Article in Directive 2001/83/EC

1.5 Consideration of this application also requested under the following article in Directive 2001/83/EC or Regulation (EC) N° 726/2004

1.6 Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 Name(s) and ATC code

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

2.3 Legal status

2.4 Marketing authorisation holder / Contact persons / Country

2.5 Manufacturers

2.6 Qualitative and quantitative composition

3. SCIENTIFIC ADVICE

4. OTHER MARKETING AUTHORISATION APPLICATIONS

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

4.2 Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company group of companies OR which are "licensees").

4.3 For multiple/duplicate applications of the same medicinal product

4.4 Marketing authorisation applications for the same product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are "licensees"). Same qualitative and quantitative composition in active substance and having the same pharmaceutical form).

5. ANNEXED DOCUMENTS (where appropriate)

FORM VALIDATION

unlocked

TABLE OF CONTENTS

DECLARATION AND SIGNATURE

1. TYPE OF APPLICATION

1.1 This application concerns

1.2 Orphan medicinal product information

1.3 Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulations (EC) no 1234/2008, or any national legislation, where applicable

1.4 This application submitted in accordance with the following Article in Directive 2001/83/EC

1.5 Consideration of this application also requested under the following article in Directive 2001/83/EC or Regulation (EC) N° 726/2004

1.6 Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 Name(s) and ATC code

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

2.3 Legal status

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

locked

Click to advance to named section.

Dotted line indicates the link back

It is also possible to jump back to the respective sections of the form footnote references in the end of the document and back to the relevant section in the form by clicking the section that is surrounded by a dotted line. This functionality is disabled in locked forms.

In which Member States²?

Click to go to corresponding footnote.

² For centrally authorised products a list of EU Member States / Norway / Iceland where the product is on the market should be provided in a separate appendix

Integration of the forms into dossier

Only the final signed PDF created using the electronic forms should be submitted in the relevant part of the dossier. Indeed, the XML data can be extracted from the pdf file. This action will be performed by agencies when receiving the pdf form. Therefore, applicants should refrain from providing the XML data file separately.

It is underlined that the forms are secured in such manner that no change can be brought outside filling the field, i.e. no bookmarks or hyperlinks can be added, no merging with other files can be done, no comments can be brought in the pdf file. In addition, it is not allowed to add any attachments/hyperlinks to the document.

If the eAF.xml is stored in the CTD (eCTD or NeeS) sequence or VNeeS submission, an error during technical validation will be reported. It is of course strongly advised against printing out the form and scanning it in.

IMPORTANT: You must not use the attachment function within the forms to attach supporting documents. Whilst this feature is visible in the Reader/Acrobat window under a paper clip (📎), it should not be used. To avoid confusion, this functionality maybe removed as a future enhancement to the electronic forms.



IMPORTANT: You must not use the bookmarking functionality in PDF as this will affect the how the forms are locked and may lead to rejection by the receiving agencies.

Export of the XML data

The '**Export XML**' function allows users to extract the content of the electronic form in the XML (eXtensible Mark-up Language) file format. This is useful in a number of ways, including:

1. The XML output can be used in other IT systems (for example receiving regulators can use this data to populate their systems).
2. Previously exported XML outputs may be imported into a new version of the form, as long as the underlying .xsd (XML Schema Definition) has not changed in the interim.
3. The XML file is much smaller than the PDF file so may be considered more suitable for archiving.

To extract and view the XML the following steps are to be performed:

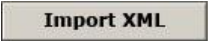
1. Navigate to the Form Validation page in the PDF, and then click  to create an XML file.
2. To export the full form xml (including the drop-down list cache in the envelope node of the schema), click 'No' when asked 'Would you like to export just the user entered form data?'.
3. To extract the user entered data only, click 'Yes' when asked 'Would you like to export just the user entered form data?'.
4. Save the file in your local file system and use your chosen XML file editor to view the data and its structure.

Note: You may also use the inbuilt export xml tool in Reader or Acrobat. The procedure to reach the inbuilt function varies in the different major software versions. The common procedure path for Reader 10 is: Extended>Export Data. The export can also be automated, but EMA does not provide a specific tool.

Import of the XML data

This function is intended to be mainly used by industry in order to recover and reuse data from a previous eAF into a new one.

It is also possible to **import XML** data in the correct format, if you have previously exported XML data (as long as the underlying .xsd (XML Schema Definition) has not changed in the interim):

1. Navigate to the Form Validation page in the PDF, and then click  to open the file system browser to find a previously created XML file.
2. Once the xml is imported, save, close then re-open the form whilst online to refresh the lists.

Note: You may also use the inbuilt import xml in Reader or Acrobat to import previously completed form data.

IMPORTANT: Performing this procedure, may overwrite the cached drop-down lists with an older version. To ensure this is remedied, save, close then re-open the form whilst online. This ensures the lists refresh, overwriting any out of date list content in the form cache.

Note: It is possible that there will be some information lost when you export and import data from an older version of eAF to a new version of eAF due to changes in the form and the underlying schema. However, if you export from unlocked version and import into new version you will be able to change content in the form.

When exporting from a 'locked version of the form' you can make changes in the actual xml only and import into new version.

Update of the XML data

Concerns that the content will not remain the same after a couple of months (and require a print due to modified terms from controlled terms lists) are not justified as the terms will have a version ID which will assure that the display remains the same.

In case of updates of the eAF it will be possible to extract the data from the existing version of the form and import the data into the revised version of the eAF. Most likely, manual correction may have to be done at least if data field types have been changed.

When any of the eAFs are opened via a computer that is connected to the internet, an automated version check is performed to inform the user if a more recent version of the eAF is available for download. Drop down terms are always updated when opening the form, but in case the

user did not close and open the form for longer time in the meantime there might be updated list available. So user can click on “Update lists” button update the list. You will find the button at

the far end of the form:

Update lists

Users can also follow these steps to manually check the version:

1. Right-click on the body of the form and select ‘Document Properties...’ or on the Acrobat menu bar select: File>Properties (PC keyboard shortcut= CTRL+D).
2. The ‘Document Properties’ dialog window appears. Click the ‘Custom’ tab to find version information.

Note: The NtA revision number of the form on the right hand side reflects the paper form on which the particular electronic form is based on. The version number of the eAF is displayed on the left hand side.

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL
Health systems, medical products and innovation

eAF Version Number: 1.23.0.0

Revision 13

Data fields and formats

In the form **square boxes** indicate that multiple choices are possible while **round boxes** indicate that one choice excludes the other possibilities.

Free text fields have been implemented in a number of sections of the forms where no controlled terminology is available. Improvement is ongoing on finding best solution to implement structured data fields throughout the form. In some sections free text fields provide additional options to describe e.g. roles of a manufacturer as long as no controlled terminologies are available.

Normally, free text fields in the forms allow only plain text. Only in the table for present and proposed information text in the variation form inclusion of **formatted text** will be possible (see [section 3 of VAR form](#)). Tracked-changes functionality is currently not available in interactive Acrobat forms.

The user interface indicates where text fields, data fields or entire sections can be duplicated or eliminated by just using 

For each type of pack give:

2.2.3.1 Package size

The eAFs are intelligent forms where a lot of business rules have been built in and some **sections** are only **displayed depending on previous selections**. It is not necessary or even possible to delete not required sections.

Once entered in the form, **information in fields** will remain visible when the corresponding fields are un-ticked. To reduce the risk of accidental data loss it was decided to ensure sections completed then hidden would persist. Data may only be deleted on a field by field basis by users. In some other cases, the values will be deleted when a different selection will be chosen, e.g. in the variations form when you switch between centralised and MR procedures.

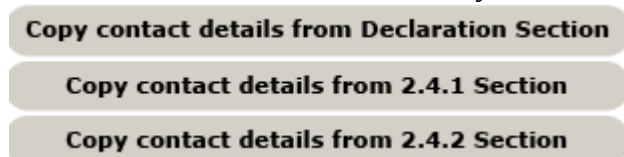
In **pop-up calendar fields**, it is possible to select future months and years when using the calendars within the form. With the calendar open, click the month/year then select the month/year option from the drop-down. Finally, click the day to close the calendar.

In the forms some **‘copy from xx’ buttons** are introduced to allow copying information from previous sections to reduce the need to re-enter data multiple times.

Please provide us your proposals for implementation of certain sections/fields, any usability issues of the forms or certain character sets that you would hope to be supported in any future implementation in order to meet your needs, via [EMA IT service desk](#).

Providing contact & address details

Contact & address details should be provided in the eAF in a harmonised way. Given there are a number of these sections required, the eAF provides users with the ability to reuse this data from one section to another, therefore reducing the number of repetitive data entry steps. This is supported by buttons for copying this data from e.g. section ‘Declaration and Signature’ into sections where same details may be relevant:



There are two ways offered to complete the data fields: You can complete address data line by line manually or select these details from the Organisation Management Service (OMS) by using an appropriate identifier (see over-next sub-section)

Manual completing address details

The data field labeled "Address " is to enter building name/number or street.

The data field labeled "City/Locality/Town/Village" field is to enter details on city/town /village etc.

The information how the address details should be filled in are provided in the tooltips when you hover on the corresponding field.

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct,
please visit the OMS page in the SPOR portal for more information:
<http://spor.ema.europa.eu/omswi/#/>

Find Organisation

Clear Address

Company name	Pharma Company Ltd.
Address	Mainstreet 23
City/Locality/Town/Village	Capitaltown
State	
County	
Postcode	EF 2391 G
Country	United Kingdom
Telephone	
E-mail	

Providing OMS organisation details to auto-populate address fields

In order to facilitate entry of the large number of required organisation and address details; the eAF is integrated with OMS data. This allows for users to search and select organisations from OMS records resulting in the auto-completion of the related address fields. This is intended to simplify data entry and reduce the number of repetitive manual data entry steps, in addition one of the first integrated system under the Agency SPOR program.

In all eAFs where there are organisation and address details required (with the exception of CROs & Billing Addresses), users will see the following: after pressing the button “Find Organisation”:

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct,
please visit the OMS page in the SPOR portal for more information:
<http://spor.ema.europa.eu/omswi/#/>

Find Address

Clear Address

LocID

OR

Organisation name

Country

Search

Address Results

Select

Select/Close

This allows users to search for OMS organisations by using either:

- A unique Organisation ID\Location ID (OrgID/LocID). This 9 digit unique ID is issued as part of the OMS registration process.
- Using a combination of both the organisation name and country

Once the user executes the search, the results are displayed in pipe delimited format with the following details:

- Language
- Company Name
- Address Line 1
- City
- Country

Note: the contents and structure is entirely dependent on the data present in OMS; given the early stage of OMS it is likely that not all data will be available as required. If data is missing or corrections are required; these need to be managed through the OMS change management process. Refer to the following link for further information:

<http://spor.ema.europa.eu/omswi/#/viewDocuments>

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct,
please visit the OMS page in the SPOR portal for more information:
<http://spor.ema.europa.eu/omswi/#/>

Find Address
Clear Address

LocID

OR

Organisation name Search

Country

Address Results

EN Incline Therapeutics Europe Limited 21 St. Thomas Street United Kingdom
EN Speciality European Pharma Limited 16 John Street United Kingdom
EN Vertex Pharmaceuticals (Europe) Limited Paddington Central Level 9 United Kingd
EN Celgene Europe Limited 1 Longwalk Road Stockley Park United Kingdom
EN Kowa Pharmaceutical Europe Company Limited 105 Wharfedale Road Wetherby U

Select Select/Close

Once the user has selected the OMS record – this will auto populate all address related fields with the exception of the Telephone, Fax & email. These details are held in OMS on the company level and the information required in the eAF is required for the procedure specific contact.

Company name	Incline Therapeutics Europe Limited
Address 1	21 St. Thomas Street
City/Locality/Town/Village	Bristol
Postcode	BS1 6JS
Country	United Kingdom
OrgID	ORG-100003216
LocID	LOC-100000283
Telephone	
Telefax	
E-mail	

There is also the possibility to enter previously selected OMS addresses without having to perform a search on each individual entry; thus further aiding entry of organisation address fields, this can be illustrated as follows:

Previously selected addresses
EN 21 St. Thomas Street Bristol United Kingdom

In case the service is temporarily not available or matching data are not available the following error messages will be displayed:

Warnung: JavaScript-Fenster - Web Service Issue

Web Services currently unavailable. Please see Q&A documentation.

OK

Warnung: JavaScript-Fenster -

Could not find any results for "LOC-123456789". Please enter the Organisation and address details manually

OK

You may proceed with completing the address data manually.

File Naming Convention

For human medicinal products the file name will be **common-form-var.pdf**. The variable part should be used as outlined in the file & folder naming convention of the updated eCTD validation criteria version 6.1. NeeS validation criteria version 4.1. In case you have to annex parts from the Classification Guideline for variations, this should become part of the ‘var’-section, e.g. **common-form-annex-classgl.pdf**

Recommended usage of the variable part of the file name in this section:

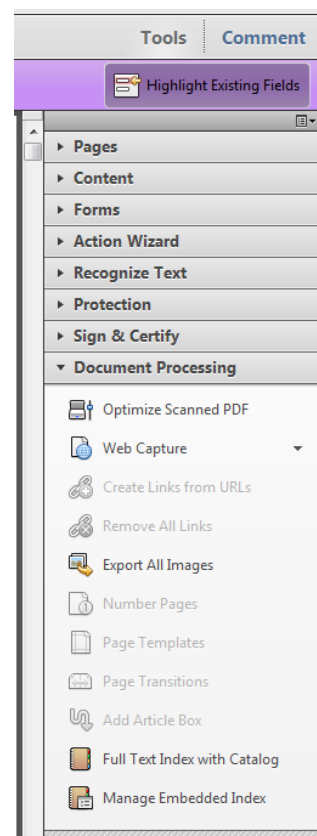
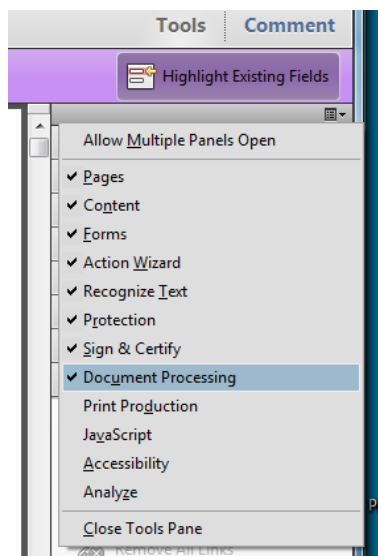
cc-form-eaf-var.pdf

cc-form-annex-var.pdf

In case of veterinary submissions please consult the respective [guidance](#).

Rendering the eAF PDF file for eCTD purpose

Be aware of the settings for optimising the PDF file in accordance with the eCTD specifications. Make sure, that the line “Document Processing” is ticked on (as highlighted below) to allow full text index with catalogues and managing embedded indexes.



Validating the form

You can choose to click the  button, which is on the last page of each of the eAFs as soon as you open the document. Once the forms are validated all mandatory fields are highlighted (in yellow or red). Validation can be executed as often as needed. The resulting list will provide links to the respective section where corrections or additional entries are needed. If you are providing a separate annex to the application form instead of entering the information directly in a particular mandatory field, enter a space, N/A (not applicable) or a full stop to bypass the current minimum validation requirements. If the field does not allow text/full stop ignore the validation error and note this in the application cover letter.

In certain cases, it might not be possible to fill in all 'mandatory' fields in the eAFs leaving some form validation errors. If the information required in such fields is provided via an annex for example or the fact that the information is not available is mentioned in the cover letter this doesn't normally cause any issues during content validation phase. However, if information required in the mandatory section is not filled in and no annex is provided a content validation issue might be triggered and the application cannot be processed.

The form validation is simply a feature that enables use of business rules and guides the MAA/MAH to fill in the form correctly to avoid content validation issues once the application has been submitted.

The validation errors are not visible in the form after it is locked and signed, however, the number of remaining errors will be shown in the validation screen of the locked form.

Validating the form before entering the data might affect the form performance by making data entry slightly slower – consider if you wish to validate the form, to highlight mandatory fields, before you start data entry.

Note: The validation rules are imposed to ensure that a good quality submission is facilitated for all concerned parties. The validation rules are not linked to eCTD, NeeS or VNeS validation rules and in some cases, for example when separate annex is used, it is acceptable to have 'validation error' in the form which does not lead to 'business validation issues'.

Applicants are encouraged to contact EMA technical help [EMA IT service desk](#) if currently implemented business rules should be reviewed and/or changed.

If you have any questions, comments or proposals for a best practice solution based on your requirements, please send these to [EMA IT service desk](#) for consideration.

Signature

In regard to the requirements of signing the application form, EMA and national competent authorities may have different legal obligations. The respective websites need to be consulted. Additional information will be provided by [CMDh](#) and [CMDv](#).

Up to now the effect of inserting an image (normally this will be an image of a relevant signature. In addition, an image of a text snippet stating that this form was signed by the person authorized by the applying company can be used as well, (e.g. stating “This form was approved/authorized following company policies by [Mr. Nick Name; Head of Reg. Affairs] with authorization to sign. The signature is in file.”) The image is to lock the application form to avoid any further data manipulation. This image will not work as a digital advanced or qualified electronic signature nor can replace requirements of wet signed forms.

Brief instructions how to insert an image are contained within the tooltip for all signature fields within the eAFs. In order to ensure that the image is displayed accurately, the size should follow below recommendations:

Unit of Measurement	Width	Height
centimetres	12.70	2.54
Inches	5	1
pixels	1500	300

For guidance on how best to create a high quality scanned signature image file, the following search ‘string’ (within Google, for example) returns good results: Create scanned signature image.

Note: Digital signatures (as opposed to scanned signatures) are not currently within the scope of this project.

Important note: The inclusion of the signature (image) will lock the form and will prevent further data entry. Therefore, the inclusion of that image should be the very last step completing the form. It is strongly recommended to save an un-locked version of the form and to execute the validation of the form prior to including the signature image. However, export of the xml file and re-import into a new eAF pdf file will work as well (see also [section below](#)).

There is no need to use qualified signatures for eAFs submitted to the EMA for Centralised Procedure applications. The eAF does not change the wet signature requirements at the NCAs. Please check the national requirements for wet signatures to avoid validation issues.

In DCP/MRP an AF signed by multiple responsible persons is needed for communication with specific Authorities (could be initial submission or renewal or variation). Ideally provide a single contact point. For those NCAs that require multiple contact persons include a separate annex with the contact details.

Saving the form

The filename format for human submissions is the same as for the paper form and is detailed in the latest version of the [EU Module 1 Specification EU Module 1 Specification](#) (Appendix 2: Directory / File Structure for Module 1 (Sequential Number 9)). Also for veterinary submissions the requirements for filenames do not change with introduction of the eAF.

The eAF form (.pdf) itself contains the xml data. This document should be included within the CTD structure in folder 1.2. In the VNeS dossier structure the correct location is in folder “1a-admin-info”. Do not include the raw xml extraction separately (see [here](#) for more details).

It is strongly recommended to save the form before locking the form. You might need to use the unlocked version to update the application form in case of business validation issues when updated application form is requested. In addition, you can re-use the file for e.g. a new variation of the same product. As an alternative and independent from locking the form, you are also able to export the XML data and import them in an empty form and correct or modify the data then.

Note: If the form has been locked with a signature image, this image will be exported and imported back. The eAF will remain locked.

To save the form, press  at the far end of the form or press Ctrl + S - progress is saved to the downloaded location. Note that if you have not saved it to a specific location, this action opens the 'Save As' dialogue to prompt saving in a particular folder other than the default location. Make a note of where the document is saved to easily pick up where you left off. When you have completed the eAF, you may save it in your desired location.

Note: When a signature file is attached to the eAF it will be locked and no further changes are possible (with the exception of the additional signatory section, where only this section is locked).

MAA FORM (human)

On the following pages technical information in regard to the human marketing authorization application form is provided. Additional information related to the veterinary form as well as related to the variation and renewal form will be provided in a separate section thereafter.

ADMINISTRATIVE DATA

DECLARATION and SIGNATURE

A screenshot is provided to illustrate some principles in this section.

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required. For centralised procedures a combined application form is acceptable (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form:

Strength:

Units

Active Substance

Search

OK

Clear

Cancel

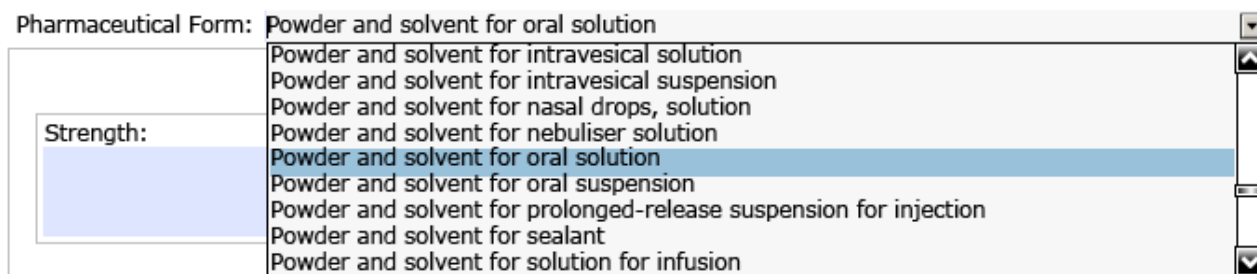
Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Product (Invented) name

The form allows providing just one product name. In the text field 250 characters are possible to be used. In case of different names and marketing authorisation holders in the concerned member states a separate list needs to be appended to the application form in Annex 5.19. However, for MAA for MRP/DCP there should be one common application form for each form or strength but for all member states involved.

Pharmaceutical form

The pharmaceutical form should be described as in the current version of standard terms from the Ph. Eur. provided by the [EDQM](#) as also displayed via [SPOR RMS controlled vocabulary list](#). Only the full term should be mentioned (not the short term).



The screenshot shows a web form with a label 'Pharmaceutical Form:' followed by a dropdown menu. The dropdown is open, displaying a list of pharmaceutical forms. The first option, 'Powder and solvent for oral solution', is highlighted in blue. To the left of the dropdown, there is a label 'Strength:' followed by a text input field.

Pharmaceutical Form:
Powder and solvent for oral solution
Powder and solvent for intravesical solution
Powder and solvent for intravesical suspension
Powder and solvent for nasal drops, solution
Powder and solvent for nebuliser solution
Powder and solvent for oral solution
Powder and solvent for oral suspension
Powder and solvent for prolonged-release suspension for injection
Powder and solvent for sealant
Powder and solvent for solution for infusion

Dropdown field to select, ("Click arrow button")

The dropdown includes the pharmaceutical forms described in the Standard terms published in the European Pharmacopoeia that provides standardised nomenclatures and quality standards for medicinal substances and products (<https://www.edqm.eu/en/standard-terms-590.html>)

The information should be in accordance with the one in Section 2.1.2.

Keying in the first character the term is beginning with will display the list at that position in the alphabetical order. You may use the mouse or the down arrow button to navigate to the correct term. Pressing 'enter' button or click the left mouse button will select the term.

In case the correct term is not available a most appropriate alternative should be selected. Usually, new pharmaceutical form terms can be required in advance by the agency responsible to run the procedure of the new marketing authorization application.

Strength(s)

The strength(s) will be entered in a structured way. Regulatory requirements should be considered relating to the rules on naming of combination products. The units of measurement will be selected from a controlled list according to standard terms as provided by EDQM (For selection the term name its first character is being used to display the list). The active ingredient data fields need to be duplicated as necessary.

Product (invented) name		Ibucafego 200 mg /20 mg orodispersible tablets	
-------------------------	--	--	--

Pharmaceutical form(s): Orodispersible tablet

Strength:

200

Units

mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Full name of the active substance(s) (including salt or hydrate, if applicable):

IBUPROFEN D,L-LYSINATE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

Strength:

20

Units

mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Full name of the active substance(s) (including salt or hydrate, if applicable):

CAFFEINE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

Active Substance(s)

Dropdown field to select, (“Click arrow button”) (The dropdown includes a dictionary)

Full name of the active substance(s) (including salt or hydrate, if applicable):
IBUPROFEN D,L-LYSINATE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Full name of the active substance(s) (including salt or hydrate, if applicable):

IBUPROFEN D,L-LYSINATE

Caffeine
CAFFEINE
IBUPROFEN D,L-LYSINATE

Search
Select

OK Clear Cancel

Type in minimum of three characters from the name of the active substance name and click search. If you enter more characters you will receive more accurate results. Scroll through the list or use the arrow-down-button of the keyboard and select the correct name and confirm selection by pressing the button **Select**

Full name of the active substance(s) (including salt or hydrate, if applicable):

IBUPROFEN D,L-LYSINATE

OK Clear Cancel

The selected substance name will be displayed. A further click on the “OK” button will close the interactive section.

For corrections the button “Add Active Substances” need to be activated and opens the dialogue again.

Full name of the active substance(s) (including salt or hydrate, if applicable):
IBUPROFEN D,L-LYSINATE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

To select another active substance, you have to the button .add a new substance section and open the dialogue by pressing the button “Add Active Substances”. . This procedure needs to be repeated for every additional active substance.

The screenshot above displays the case of two active substances.

Once the list is complete, use “Populate data” button **Populate data in sections 2.1.2, 2.2.1 and 2.6.1** to copy to all other similar sections.

Note: These other similar sections cannot be filled if this first one is not completely populated.

Note: Workaround solution for entering formatted text using rtf format in Word or Outlook and copy pasting the edited text to eAF does not work in the Initial MAA form when the details in sections 2.1.2, 2.2.1 and 2.6.1 are populated from ‘Declaration’ section. If you require special characters in these sections, please add an annex and mention this on the cover letter.

When selecting the "Populate data in sections 2.1.2, 2.2.1 and 2.6.1" button - the form will copy data into each respective section with the exception of the Active Substance field in section 2.2.1 only. Users will need to manually enter and select an active substance for this field.

Base/Active moiety

Users may also provide the base/active moiety details of the active substance. This should only be added in this section if different to the active substance, serving to specify the strength of the pharmaceutical preparation and if the substance is included in the product as a salt or hydrate:

Full name of the active substance(s) (including salt or hydrate, if applicable)		+
IBUPROFEN (LYSINE)		▼
Base/active moiety of the active substance(s) (if different from above)		–
IBUPROFEN		▼
Substance type : (e.g. chemical substance, recombinant biological substance)		Chemicals ▼

The class (type) of the substance should be selected from the proposed catalog.

Applicant

The applicant address details should be selected from SPOR OMS organization dictionary as outlined in section [Providing OMS details](#).

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Find Organisation

Clear Address

LocID

OR

Organisation name

Country

Search

Address Results

EN|Laboratorios Abelló S.A.|Calle Josefa Valcarcel 38|Madrid|Spain

ES|Laboratorios Abelló S.A.|Calle Josefa Valcarcel 38|Madrid|Spain

Select

Select/Close

One of the address lines presented can be selected and its selection need to be confirmed by pressing

Select

Select/Close

LocID

OR

Organisation name

Country

Search

Address Results

EN|Laboratorios Abelló S.A.|Calle Josefa Valcarcel 38|Madrid|Spain

ES|Laboratorios Abelló S.A.|Calle Josefa Valcarcel 38|Madrid|Spain

Select

Select/Close

All available details will be retrieved from OMS:

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Applicant	Laboratorios Abelló S.A.
Address	Calle Josefa Valcarcel 38
City/Locality/Town/Village	Madrid
County	Madrid
Postcode	28027
Country	Spain
OrgID	ORG-100000941
LocID	LOC-100000230
Telephone	
E-mail	

The personal details like telephone and e-mail address are not available in OMS and need to be added as appropriate.

Person confirming that fees will be or have been paid, on behalf of the Applicant

The following fields need to be completed in accordance to the letter of authorization as detailed in the USER GUIDANCE which is available for human medicinal products at [CMDh](#) and for veterinary medicinal products at [CMDv.CMDv](#). However, the company address details can be copied from the previous section

1. TYPE OF APPLICATION

Below screenshots will describe the options to complete the form according to the planned procedure. Selecting one of the round boxes will add further lines as appropriate for the respective procedure. Changing of the selection will hide the lines but addition different ones according to the other procedure selected.

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

- ☒ 1.1.1 A CENTRALISED PROCEDURE
(according to Regulation (EC) No 726/2004)
- ☐ 1.1.2 A MUTUAL RECOGNITION PROCEDURE
(according to Article 28(2) of Directive 2001/83/EC)
- ☐ 1.1.3 A DECENTRALISED PROCEDURE
(according to Article 28(3) of Directives 2001/83/EC)
- ☐ 1.1.4 A NATIONAL PROCEDURE

1.1. This application concerns

In this case the centralised procedure is selected as an example how the section will be expanded depending from the selected procedure type.

This example is for human products specifically, for details of the veterinary products application form, please follow the [link](#).

☒ 1.1.1 A CENTRALISED PROCEDURE

(according to Regulation (EC) No 726/2004)

☒ « Mandatory scope » (Article 3(1) of Regulation (EC) No 726/2004)

☒ Annex (1) (Biotech medicinal product)

☒ Annex (1a) (Advanced Therapy Medicinal Product)

☐ Gene therapy medicinal product

☐ Somatic cell therapy medicinal product

☐ Tissue engineered product

The CAT-Rapporteur is only assigned in case of Combined Advanced Therapy Medicinal Products. In other cases, the selection of rapporteurs will be adjusted as appropriate.

The product is also a

☒ Combined Advanced Therapy Medicinal Product

☐ Annex (3) (New active substance for mandatory indications)

☐ Annex (4) (Orphan designated medicinal product)

☐ « Optional scope » (Article 3(2) of Regulation (EC) No 726/2004)

☐ Annex 3(2)(a) (New active substance)

☐ Annex 3(2)(b) (Significant innovation or interest of patients at EU level)

☐ « Generic of a Centrally Authorised Medicinal Product »

☐ « Marketing Authorisation including paediatric indication »
(Article 28 of Regulation (EC) No 1901/2006)

☐ « Paediatric Use Marketing Authorisation (PUMA) »
(Article 31 of Regulation (EC) No 1901/2006)

Date of acceptance/confirmation by CHMP:

EMA Product number:

In case of Advanced Therapy Medicinal Products

☒ CAT Rapporteur	Title	
	First name	
	Surname	
☒ CAT Co-rapporteur	Title	
	First name	
	Surname	
☒ CHMP Co-ordinator	Title	
	First name	
	Surname	
☒ CHMP Co-coordinator	Title	
	First name	
	Surname	
☒ PRAC Rapporteur	Title	
	First name	
	Surname	

The second example is on veterinary products only:

☒ 1.1.1 A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)

☐ "Mandatory scope" (Article 3(1))

☐ "Optional scope" (Article 3(2))

☐ "Generic of a centrally authorised veterinary medicinal product" (Article 3(3))

☒ CVMP Rapporteur

Title

First name

Surname

☒ CVMP Co-rapporteur

Title

First name

Surname

1.1.1. A Centralised Procedure

For extension applications as indicated in section 1.3, if the corresponding original eligibility basis is obsolete (no longer exists), only ‘Centralised Procedure’ should be indicated, leaving the eligibility basis tick boxes blank. The eAF does not support this very rare case of differentiation as details of the CHMP acceptance are required due to validation rules. (A workaround might be explained in the Q&A document if necessary.)

1.1.2. A Mutual Recognition Procedure

For a mutual recognition procedure, the Reference Member State and details of that national authorisation need to be added. Concerned Member States can be added line by line or all in one go. Key in the first character of the Member State name. You may go down the drop down list using the down arrow button. Press the ‘plus’-button for a next line or the ‘return’-button to confirm the selection.

☒ 1.1.2 A MUTUAL RECOGNITION PROCEDURE
(according to Article 28(2) of Directive 2001/83/EC)

Reference Member State

Germany

Date of authorisation

2015-09-15

Marketing authorisation number

12345.00.00

(* a copy of the authorisation should be provided - see section 4.2)

Procedure number:

DE/H/1234/001/MR

☒ First use

☐ Repeat use (Please also complete section 4.2)

Add All

Remove All

Concerned Member State (specify)

Croatia

+

–

Concerned Member State (specify)

Finland

+

–

Concerned Member State (specify)

Greece

+

–

Concerned Member State (specify)

United Kingdom

+

–

Proposed/Agreed common renewal date

2020-08-15

In case of Repeat -use Procedure the list will indicated as first wave. A second wave will be added by “+”.at the right upper corner.

1.1.2 A MUTUAL RECOGNITION PROCEDURE
(according to Article 28(2) of Directive 2001/83/EC)

Reference Member State: **Germany**

Date of authorisation: **2017-10-03**

Marketing authorisation number: **12345.00.00**

(* a copy of the authorisation should be provided - see section 4.2)

Procedure number: **DE/H/0345/001/DC**

☐ First use ☒ Repeat use (Please also complete section 4.2)

Wave 1

Concerned Member State (specify)	Austria		
Concerned Member State (specify)	Belgium		
Concerned Member State (specify)	Bulgaria		
Concerned Member State (specify)	Croatia		
Concerned Member State (specify)	Cyprus		
Concerned Member State (specify)	Czech Republic		
Concerned Member State (specify)	Denmark		
Concerned Member State (specify)	Estonia		
Concerned Member State (specify)	Finland		
Concerned Member State (specify)	France		
Concerned Member State (specify)	Germany		
Concerned Member State (specify)	Greece		
Concerned Member State (specify)	Romania		
Concerned Member State (specify)	United Kingdom		
Proposed/Agreed common renewal date	2019-03-15		

Wave 2

Concerned Member State (specify)	Latvia		
Proposed/Agreed common renewal date	2019-03-15		

1.1.3. A Decentralised Procedure

There is no specific technical information to be considered.

1.1.4. A National Procedure

There is no specific technical information to be considered.

1.2.Orphan Medicinal Product Information (human only)

If your product is an orphan medicinal product, provide the below details. The display of these data fields will only happen in case you tick the radio button “yes”.

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

☒ Yes ☐ No

Orphan designation procedure number:

☐ Pending
☐ Orphan Designation Granted
☐ Orphan Designation Refused
☐ Orphan Designation Withdrawn

1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY

Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?

☒ Yes ☐ No

Please specify the EU Orphan Designation Number:

Has any of the designated orphan medicinal product(s) been granted a marketing authorisation in the EU?

☒ Yes ☐ No

Please specify:

Therapeutic indication(s)

Product (invented) name

Pharmaceutical form(s)

Strength(s)	Units	Name of the marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation

Is the medicinal product, subject of this application, considered as "similar" to any of the authorised orphan medicinal product(s)? (as defined in Article 3 of commission regulation (EC) no 847/2000)

☐ Yes(modules 1.7.1 and 1.7.2 to be completed) ☐ No(module 1.7.1 to be completed)

1.3.Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) no 1234/2008, or any national legislation, where applicable?

There is no specific technical information to be considered.

1.4.This application is submitted in accordance with the following article in Directive 2001/83/EC as amended

There is no specific technical information to be considered.

1.5.Consideration of this application requested under the following article of Directive 2001/83/EC or Regulation (EC) No 726/2004

There is no specific technical information to be considered.

1.6.Requirements according to Regulation (EC) N° 1901/2006 ('Paediatric Regulation')

There is no specific technical information to be considered.

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. NAME(S) AND ATC CODE

2.1.1. Proposed (invented) name of the medicinal product in the European Union / Member State/Iceland/Lichtenstein/ Norway

The information is identical to the one in section “Declaration and signature” and has to be populated automatically (see Section 1.1.1).

If the box is ticked like this an Annex 5.19 need to be provided.

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

Ibucafego 200 mg / 20 mg Tablets

(Value populated from the “Declaration” section.)

☒ If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in [\(Annex 5.19\)](#)

This field appears only in case of MRP or DCP selected in section 1.2 or 1.3. The annex is not integrated into the form but the required list should be added as a separate PDF file to the submission.

Attachments to the form should be included as per the currently approved processes. Annexes to the application form should always be included in section 1.2 of EU Module 1.

2.1.2. Active substance(s)

The declaration of the active substance will be populated automatically if the button in section 1 has been pressed.

Also changes you may want to apply need to be executed in section 1 first and will then populate this section correctly.

DECLARATION AND SIGNATURE

Product (invented) name **Ibucafego 200 mg / 20 mg orodispersible tablet**

Pharmaceutical form(s): **Orodispersible tablet**

Correct substance name or strength in section "Declaration and Signature" to be displayed in this section 2.1.2 correctly.

Strength: **200** Units: **mg**

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Full name of the active substance(s) (including salt or hydrate, if applicable):
IBUPROFEN (LYSINE)

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

Strength: **20** Units: **mg**

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Full name of the active substance(s) (including salt or hydrate, if applicable):
CAFFEINE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Section 2.1.2 being populated with above mentioned details: Ibucafego 200 mg / 20mg

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

Ibucafego 200 mg / 20 mg orodispersible tablet

(Value populated from the "Declaration" section.)

If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in [\(Annex 5.19\)](#)

2.1.2 Active substance(s)

*Note: * active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field:*

Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.*

(The value of the active substances field has been populated from "Declaration" section.)

Full name of the active substance(s) (including salt or hydrate, if applicable)	
IBUPROFEN (LYSINE)	+
Base/active moiety of the active substance(s) (if different from above)	–
IBUPROFEN	
CAFFEINE	
Base/active moiety of the active substance(s) (if different from above)	–

Substance type : (e.g. chemical substance, recombinant biological substance) **Chemical substance**

2.1.3. Pharmacotherapeutic group

The most complete code corresponding to the claimed therapeutic use of the product should be given. Please use current ATC codes. Consequently, this section should be duplicated where needed. To display the list, at least three characters need to be inserted. The list starts with the next available code based on your entry.

The two fields “ATC Code” and “Group” are linked and should be both completed.

The screenshot shows a form titled "2.1.3 Pharmacotherapeutic group (Please use current ATC code)". It contains two main input fields: "ATC code" and "Group". The "ATC code" field has a dropdown menu that is open, displaying a list of codes: N05, N05 (PSYCHOLEPTICS), N05A (ANTIPSYCHOTICS), N05AA (Phenothiazines with aliphatic side-chain), N05AA01 (chlorpromazine), N05AA02 (levomepromazine), N05AA03 (promazine), and N05AA04 (acenpromazine). A red box highlights the "ATC code" field with the text "Select for ATC Code field from the lowest level." A blue box highlights the "Group" field with the text "Select for Group field from the third or fourth level description." A "Select" button is located next to the dropdown menu. Below the "Group" field, there is a note: "If no ATC code has been assigned, please indicate if an application for ATC code has been made".

Note: The group text field is limited. You may have to shorten the text appropriately. It is advised to know the ATC code in advance as the search tool does not allow displaying the whole details of each code.

2.2. STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

2.2.1. Strength and pharmaceutical form (use current list of standard terms – European Pharmacopeia)

If the values of the “Pharmaceutical form, Strength and Active Substance field have been populated from ‘Declaration’ section” it will not be possible to edit the following data fields. If you need to correct an error, you have to go back to ‘Declaration’ section.

Search and select the active substance(s) in the 'Declaration' section of the form and populate the sections in the form where active substance is required by using 'Populate data in section 2.2.1 and 2.6.1 button.

2.2 STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)

(The values of the following fields have been populated from "Declaration" section.)

Pharmaceutical Form: Orodispersible tablet

Strength: 200

Units: mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Active substance(s) (as used for expression of strength*)

IBUPROFEN

Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety

Add Active Substance(s) or Base/active moiety

Strength: 20

Units: mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Active substance(s) (as used for expression of strength*)

CAFFEINE

Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety

Add Active Substance(s) or Base/active moiety

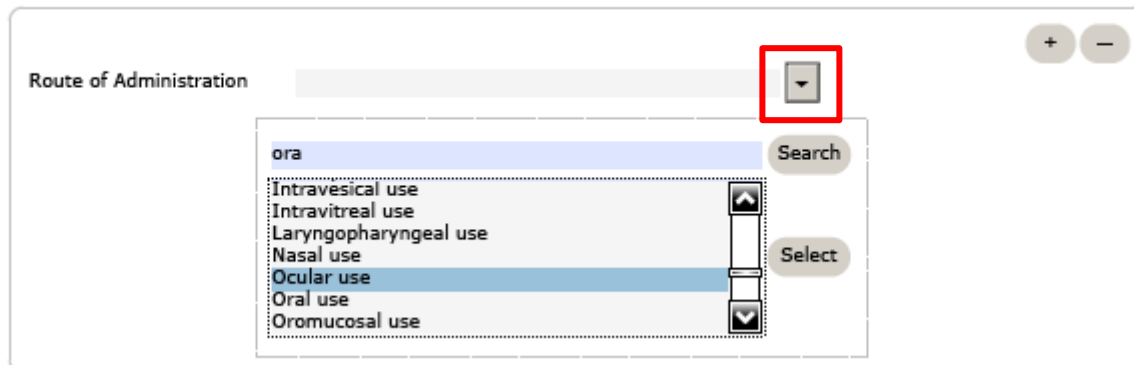
If a salt/ester/maleate/monohydrate etc. form is required, this can be added via the corresponding [base/active moiety field](#) as detailed in **Base/Active moiety** section.

In case you want to continue with the MAA veterinary form you should follow the [link](#).

2.2.2. Route(s) of administration (use current list of standard terms - European Pharmacopoeia)

Dropdown field to select (“Click arrow button”) opens the search menuue.

2.2.2 Route(s) of administration (use current list of standard terms - European Pharmacopoeia)



The screenshot shows a form field labeled 'Route of Administration'. To the right of the text input is a dropdown arrow button, which is highlighted with a red rectangle. Below the input field, a search menu is displayed. It contains a search bar with the text 'ora', a list of standard terms: 'Intravesical use', 'Intravitreal use', 'Laryngopharyngeal use', 'Nasal use', 'Ocular use', 'Oral use', and 'Oromucosal use'. To the right of the list are two buttons: 'Search' and 'Select'. The 'Ocular use' item is highlighted in blue. At the top right of the form, there are two buttons: a plus sign (+) and a minus sign (-).

The dropdown includes the current list of standard terms included in the “List of Standard Terms for pharmaceutical dosage forms, routes of administration and containers” published by the [EDQM](#) / [RMS](#)

The routes field is repeatable, where needed, with +/- buttons:  

2.2.3. Container, closure and administration device(s)

including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

You have to provide details for each of the pack sizes planned to be marketed. The package sizes fields are repeatable, where needed, with +/- buttons:  

The material is a free text field, but it is advisable to use known standard abbreviations for chemical names, such PVC, HDPE, etc.

2.2.3 Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

+ -

For each type of pack give:

2.2.3.1 Package Size 1 2 x 12 tablets + -

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

Description
2 HDPE-blister/alu foil closurex12 tablets

+ -

For each container give:

+ -

Container	Blister	▼
Material	HDPE	
Closure	Child-resistant closure	▼
Administration Device		▼

+ -

2.2.3.2 Proposed shelf life 3 Years ▼

2.2.3.3 Proposed shelf life (after first opening container) ▼

2.2.3.4 Proposed shelf life (after reconstitution or dilution) ▼

2.2.3.5 Proposed storage conditions

Do not store above 30°C

+ -

2.2.3.5 Proposed storage conditions

Keep the container in the outer carton

+ -

2.2.3.6 Proposed storage conditions after first opening

+ -

Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites) (Annex 5.17)

These are numeric fields, where ‘.’ as a decimal separator needs to be used.

2.2.4. Medical Devices

The medical product incorporates, as an integral part, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC

There is no specific technical information to be considered.

2.3. LEGAL STATUS

The dispensing status will apply to all Member States the product is authorised to be marketed. For convenience all Member States selected according to section 1.1 can be added or removed by pushing the respective button **Add Selected** or **Remove All**.

2.3 LEGAL STATUS

2.3.1 Proposed dispensing/classification

(Classification under Article 1(19) of Directive 2001/83/EC)

☐ Subject to medical prescription (Complete 2.3.2)

☒ Not subject to medical prescription (Complete 2.3.3 & 2.3.4)

The screenshot shows a user interface for selecting member states. At the top, there are two buttons: 'Add All' and 'Add Selected' (highlighted with a red box). To the right of 'Add Selected' is a 'Remove All' button. Above these buttons is a text box that says 'Click to create selected member states.' Below the buttons is a list of member states, each with a dropdown menu and '+' and '-' buttons. The list includes: European Union/Member State Croatia, European Union/Member State Finland, European Union/Member State Greece, European Union/Member State United Kingdom, and European Union/Member State Germany. A tooltip on the left states: 'The button "Add All" should not be used as in that case the RMS will not be added.'

European Union/Member State	Member State	+	-
	Croatia		
	Finland		
	Greece		
	United Kingdom		
	Germany		

The adjustment of the list can easily be achieved by deleting single Member States pressing .

2.4. MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

There are two options you have to select from: Centralised Procedure and National Procedures in section 1.1. It is not possible to change the selection in this section. Address details can be copied from the Declaration section by pressing the button

Copy contact details from Declaration Section

or

Copy address from above address details

or

Copy contact details from 2.4.1 Section

as appropriate.

2.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS

2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS

☐ Centralised procedure ☒ National procedure including mutual recognition/decentralised procedure

+ -

Copy contact details from Declaration Section

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Find Organisation
Clear Address

Company name	BonnPharma
Address	Kurt-Georg-Kiesinger-Allee 3
City/Locality/Town/Village	Bonn
State	
County	
Postcode	53121
Country	Germany
Telephone	0049 228 99 3079999
Telefax	
E-mail	Bill.miller@bonnpharma.de

☐ Attach proof of establishment of the applicant/MAH in the EEA (Annex 5.3)

Has SME status been assigned by the EMA?

☒ Yes ☐ No

EMA-SME Number

Date of expiry

☐ Attach copy of the "Qualification of SME Status" (Annex 5.7)

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

+ -

☐ Yes (for fees paid, attach proof of payment in) (Annex 5.1)

☐ No

Copy address from above address details

+ -

For Member State(s) Germany

Billing address (when relevant)

Company name BonnPharma

VAT number

In the second case the address details will be assigned to the respective Member State. To ease data entry a button to insert contact details from Declaration section has been added. To add the Member States also selected in that section press the button “Add Selected”.

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State

☐ Centralised procedure ☒ National procedure including mutual recognition/decentralised procedure

+ –

Copy contact details from Declaration Section

Add Selected
Remove All
?

Member State + –

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omsui/#/>

Find Organisation
Clear Address

Company name + –

For MRP/DCP/National procedure; The Member State field allows to multiple Member States to have the same marketing authorisation holder contact person or alternatively to show that one or more Member States have different marketing authorisation holder contact persons.

Note: This field is not mandatory when it is not filled then it will be assumed that all relevant member states have the same marketing authorisation holder contact person.

For details how to fill in the address in a correct format please follow the [link](#).

In addition, details of the proof of payment can be entered regardless of the procedure.

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

+ –

☐ Yes (for fees paid, attach proof of payment in) (Annex 5.1)

☒ No

+ –

Copy address from above address details

For Member State + –

Billing address (when relevant)

VAT number 123-XYZ-2018

Company name BonnPharma

Address Kurt-Georg-Kiesinger-Allee 3

City/Locality/Town/Village Bonn

State

County

Postcode 53121

Country Germany

Telephone 0049 228 99 307 9999

E-mail Bill.miller@bfarm.de

Purchase order(PO) number

If the fees have not been paid in advance and an invoice is going to be sent out you should select 'No' and indicate the billing address (even if it has not yet been relevant to pay a fee as it will be invoiced later).

For Centralised Procedure; either select 'EU' from the term list or leave the Member state field empty.

2.4.2. Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/

No specific technical guidance is necessary.

2.4.3. Person/company authorised for communication

No specific technical guidance is necessary.

2.4.4. Summary of the applicant pharmacovigilance system

For the section 2.4.4 Summary of the pharmacovigilance system, in a community procedure with more than 1 MAH the section "Qualified Person in EEA for Pharmacovigilance" can be multiplied for more than one QPPV. Also the location of the Pharmacovigilance system master file can be multiplied independently. If the location is the same for all Member States, the Member states need to be added in the first box. If this is not the case, the entire section need to be copied. In this case section 2.4.4 needs to be repeated as different PV master files will be maintained. For each system the QPPV may be identical.

2.5. MANUFACTURERS

Note: All manufacturing and control sites mentioned throughout the whole dossier must be consistent regarding their names, detailed addresses and activities.

In this section the address fields offer a possibility to enter two addresses if the administrative address differs from the manufacturing site:

2.5.1. Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA

Subsections are defined to describe different roles:

- Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision)
- Official batch release for Blood products and Vaccines
- Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)
- Contact person in the EEA for product defects and recalls
- Batch control Testing arrangements

On top of the sub-section a free text field is included so that those applicants who have multiple manufacturers doing batch releases can include details of e.g. which packaging the manufacturer is responsible for. This is an optional field that can be left empty if it is not needed.

The screenshots below illustrate the principle of the two options which are offered for all address fields in section 2.5 in case the administrative address and the manufacturing facility address is identical or different:

Option # 1:- When the administrative address and manufacture address are the same:

Optional free text field describes the role of the manufacturer.

Do you have a separate admin and manufacturer address? ☐ Yes ☒ No

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Find Organisation

Clear Address

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

E-mail

Manufacturing Authorisation number

Attach copy of manufacturing authorisation(s) (Annex 5.6)

The fields related to telephone, e-mail can be duplicated in order to indicate more than one number in case the administrative and operating addresses differ:

Option # 2:- When the administrative address and manufacture address are different:

For additional Authorised Manufacturers the data fields can be repeated, where required, with +/- buttons: 

So, fields should be duplicated for each manufacturer.

Any manufacturer responsible for batch release in the EEA should be listed under section 2.5.1 of the application form. Since this is the only section where this information should be provided, the need for a drop-down menu has not been identified. If the site responsible for batch release in the EEA is also involved in batch control testing activities, the name and address of such site should be repeated in section 2.5.1.2.

+ -

Do you have a separate admin and manufacturer address? ☒ Yes ☐ No

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omsui/#/>

Find Organisation

Clear Address

Company name	
Admin Office Address	
City/Locality/Town/Village	
Admin Office State	
Admin Office County	
Postcode	
Admin Office Country	
Admin Office Telephone	
Admin Office E-mail	

+ -

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omsui/#/>

Find Organisation

Clear Address

Company name	
Manufacturing Facility Address	
City/Locality/Town/Village	
Manufacturing Facility State	
Manufacturing Facility County	
Postcode	
Manufacturing Facility Country	
Manufacturing Facility Telephone	
E-mail	

Repeat this sub-section as many as manufacturing facilities must be entered.

Manufacturing Authorisation number

Attach copy of manufacturing authorisation(s) (Annex 5.6)

Or

Enter EudraGDMP document reference number

If available

Attach latest GMP certificate (Annex 5.9)

2.5.2. Manufacturer(s) of the medicinal product and site(s) of manufacture

The free text field is included so that a description of the partial product (e.g. vial with solvent, vial with powder, solvent etc. can be included if necessary to indicate which part of the product a specific manufacturer produces. This field is optional and can be left empty

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, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)

Copy contact details from 2.5.1.a

+ -

Address details can be copied from section 2.5.1.a if identical or if more convenient to make minor corrections afterwards.

For sites in the EEA, the manufacturing authorisation number should always be provided. In addition, either a copy of the authorisation (“tick box”) or the EudraGMDP reference number should be provided. If neither the copy nor the EudraGMDP number are provided a validation error will be displayed.

☒ Site(s) is in the EEA: ☐ Site(s) is outside the EEA:

+ -

Manufacturing authorisation number

☐ Attach copy of manufacturing authorisation(s) (Annex 5.6)

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person

(if not mentioned in manufacturing authorisation)

Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.

In case the site is outside the EEA additional information must be provided:

☐ Site(s) is in the EEA:
 ☒ Site(s) is outside the EEA:

+ -

if available,

D-U-N-S number⁷

☐ Attach document equivalent of manufacturing authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC (Annex 5.6)

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of the agreement?

☐ Yes
 ☐ No

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

☐ Yes
 ☐ No

⁷ The Data Universal Numbering System (D-U-N-S) is a system developed by Dun & Bradstreet (D&B) which assigns a unique digit numeric identifier to a single business entity. It is used in this case to facilitate the identification of manufacturing sites outside of EEA

In case the company address or just the address details of manufacturing sites needs to be multiplied, the address or the address details of the manufacturing site can be duplicated maintaining the one address of the administrative site:

Regarding section 2.5.2 (Manufacturer of the medicinal product) and 2.5.3 (Manufacturer of the active substance) the manufacturer names, addresses and in case manufacturing sites need to be stated (and repeated) in each section separately. To avoid duplication of data entry, the buttons are offered:

Copy contact details from 2.5.1.a

Copy contact details from 2.5.1.a

Copy contact details from Declaration

Do you have admin address and manufacturer address? ☒ Yes ☐ No

Company name

Admin Office Address 1

Admin Office Address 2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax

Admin Office E-mail

+ -

Company name

Manufacturing Facility Address 1

Manufacturing Facility Address 2

Postcode

Manufacturing Facility Country

Manufacturing Facility Telephone

Manufacturing Facility Telefax

Manufacturing Facility E-mail

+ -

Company name

Manufacturing Facility Address 1

Manufacturing Facility Address 2

Postcode

Manufacturing Facility Country

Manufacturing Facility Telephone

Manufacturing Facility Telefax

Manufacturing Facility E-mail

The reasoning from a regulatory point of view reads as follows: Release testing of the finished product is part of Quality testing. This activity is only linked to sites performing Batch Control testing arrangements in relation to the Batch Release of the product as per

requirements of Article 51 of Directive 2001/83/EC. As such a site may perform both release testing under 2.5.1.2 and “normal” QC-FP activities under 2.5.2 which are not linked to the batch release. In this case, the site(s) will be listed twice i.e. under each section. However, if the site only performs one or the other quality control testing only, the site(s) will then need to be listed in the relevant section depending on the QC-FP activity. Testing arrangements in relation to the Batch Release of the product. Sometimes, sites perform both kinds of testing activities however only sites located in the EEA or where an MRA or ACAA arrangement is in place can be listed in 2.5.1.2. Third country sites (USA and any other country outside the EEA/MRA/ACAA) cannot perform this activity and should therefore not be listed under 2.5.1.2. These sites are only authorised to perform QC-FP activities not related to the Batch Release.

However, only the tests carried out for the products that the application is concerned should be listed here. Therefore, you should not mention all possibilities as is stated in Manufacture License for company (if possible to find them there).

2.5.3. Manufacturer(s) of the active substance(s) and site(s) of manufacture

All manufacturing sites involved the manufacturing process of each source of active substance. For each site provide the relevant information.

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant. For each site provide the relevant information.

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

Active Substance

Copy contact details from Declaration Section

Copy contact details from 2.5.1.a

Do you have a separate admin and manufacturer address? ☐ Yes ☒ No

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omsx/#/>

Find Organisation

Clear Address

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

E-mail

The active substance is selected from previously selected list (Section 2.1). The values of Active Substance field have been populated from "Declaration" section.

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

☐ Attach flow-chart indicating the sequence and activities of the different sites involved manufacturing process, including batch control sites (Annex 5.8)

☐ For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and guidelines on good manufacturing practice for starting materials (Annex 5.22)

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

☐ Yes ☐ No

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

☐ Yes ☐ No

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

☐ Yes ☐ No

Is a Active Substance Master File to be used for the active substance(s)

☐ Yes ☐ No

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

☐ Yes ☐ No

Brief description of manufacturing steps performed by manufacturing site: For all manufacturing sites a brief description of their duties need to be included.

Dropdown field to select between the manufacturing steps performed. ("Click arrow button")

The dictionary for processing of medicinal products and for manufacturing steps are linked to the guidance document included in the eAF itself next to this field where more information can be sought from.

Brief description of manufacturing steps performed by manufacturing site:

Manufacture of active substance

Manufacture of active substance intermediate

Packaging of active substance

Preparation of Working Cell Bank

Quality Control Testing - Biological

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - non-sterility

Quality Control Testing - Microbiological - sterility

These are the Interpretation Documents for MIAs and GMP certificates. These are part of the 'Compilation of Union Procedures on Inspections and Exchange of Information', which is published on the EMA external website (see pages 144-173)¹. E.g. the role 'Manufacture of the finished product' or "Manufacturing of the VMP" are covered by the term 'Processing of medicinal product'

The contents of the controlled vocabulary are coming directly EUTCT (for substances only) as well as RMS (for all other lists) and the terms have been decided by the European inspectors from documents issued from Inspection.

Additional information in regard to inspections, suitability of Pharm. Eur. Certificates or information on ASMF can be entered if the respective box 'yes' is ticked.

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

☒ Yes ☐ No

Please

Attach latest GMP certificate in [\(Annex 5.9\)](#)

Or

EudraGMP certificate reference number

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

☒ Yes ☐ No

If yes, please provide summary information in [\(Annex 5.9\)](#) (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

☒ Yes ☐ No

Name of the CEP holder

Name of the manufacturer if different from the above

CEP number

Date of last update

Provide copy in [\(Annex 5.10\)](#)

Is a Active Substance Master File to be used for the active substance(s)

☒ Yes ☐ No

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

Attach letter of access for European Union/Member State authorities where the application is made (see "European ASMF procedure for active ingredients") [\(Annex 5.10\)](#)

Attach copy of 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 2001/82/EC [\(Annex 5.11\)](#)

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

☒ Yes ☐ No

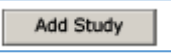
Active Substance

Name of the VAMF Certificate Holder / VAMF Applicant

Reference number of Application / Certificate

Date of submission (if pending)

2.5.4. Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes.

For each contract company, state where analytical tests are performed and where clinical data are collected and open data fields by pressing the button: 

In case multiple studies have been performed by just one contract company all study titles can be keyed in by repeating the first section.

Company details are grouped and details of the tasks related to the study can be provided. In case multiple contract companies have been involved the address fields and details of the tasks are repeatable with +/- buttons inside. .



The form is divided into two main sections. The top section is for adding a study, with a title field, protocol code, and EudraCT number. The bottom section is for adding company details, with fields for company name, address, postcode, country, telephone, telefax, and email. Both sections have repeatable buttons (+/-) and buttons to add or delete the entry.

Study Section:

- Title of study:**
- Protocol code:**
- EudraCT number:**

Company Section:

- Company name:**
- Address 1:**
- Address 2:**
- Postcode:**
- Country:**
- Telephone:**
- Telefax:**
- E-mail:**
- Duty performed according to contract:**

2.6. QUANTITATIVE AND QUALITATIVE COMPOSITION

2.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

The chosen active substance(s) is/are automatically displayed in section 2.6.1 on the 'Name of active substance field(s)'. You are able to add additional information on the active substance as well as all excipients in a separate list.

To interpret the composition correctly the reference of counting must be stated in the first line. All quantities of substances are referring to a defined quantity of the specified pharmaceutical form, e.g. 1 (unit) of tablets or 100 (ml) of a solution.

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

A note should be given as to which quantity the composition refers (e.g. 1 capsule)

Pharmaceutical Form Tablet 1 U

(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)

Strength 200 Units mg

List the active substance(s) separately from the excipient(s)

Free text field for additional description or qualifying

Name of active substance	Quantity / Unit	Reference / Monograph Standard
IBUPROFEN (LYSINE)	equal to 200 mg	Ph.Eur.

Free text field for additional description or qualifying

Name of Excipient	Quantity / Unit	Reference / Monograph Standard
LACTOSE 72 MESH	equal to 321 mg	Ph.Eur.

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Press this button to duplicate the section for an additional strength (CP only)

In centralised procedures multiple strengths can be included into one application form. For this purpose, the below frame of strength need to be duplicated. In case of national procedures, only one strength per pharmaceutical form can be mentioned in one MAA form.

In the preceding free text field, you should add a qualifying like 'calculated as'. This text field will also serve for an additional explanation to separate the filling of a capsule from the capsule shell or clustering all ingredients of the printing ink.

Name of active substance	Quantity / Unit	Reference / Monograph Standard
IBUPROFEN (LYSINE)	approximately equal to	
calculated as	equal to	
	less than	
	less than or equal to	
	more than	
	more than or equal to	
	quantity sufficient	
	range	

The quantity is constructed of an operator, a value, and the unit of measurement: . A reference may be added, e.g. Pharm.Eur.

If you select 'range' as the quantity operator, the value field will be split into lower and upper value:

Quantity / Unit
range
From:
To:

The quantity operator 'quantity sufficient' means adding enough of an ingredient to achieve a specific final volume or total weight. This term has been discussed extensively in the past and it was agreed that 'quantity sufficient' was introduced as quantity operator in the eAFs and will now allow to describe the limits precisely.

To express for example: "to five grams of NaCl add enough (quantity sufficient qs) water to make 100 ml"

Ingredient = water

Quantity operator = "quantity sufficient";

Value =100

Unit = "mL"

Name of active substance	Quantity / Unit
	approximately equal to
	equal to
	equivalent to
	less than
	less than or equal to
	more than
	more than or equal to
	quantity sufficient
	range

If you have selected multiple active substances in the 'Declaration' section, these will be automatically displayed.

Delete any unnecessary fields displaying incorrect terms if relevant using button.

Process steps in case of a missing substance name/term

If you need to request a missing substance in order to complete an eAF, please submit a request for substance insertion with the corresponding SmPC at the EMA Service Desk portal - <https://servicedesk.ema.europa.eu/>.

If you need to request a new term (e.g. pharmaceutical form or unit of measurement) or a request for an update of an already existing term in order to complete the eAF, please submit a request through the SPOR Portal - <http://spor.ema.europa.eu/rmswi/#/> providing as much supporting documentation as possible (e.g. name of the product concerned, SmPC, etc.). Please note you need to be registered with SPOR prior to submission of change requests: <https://register.ema.europa.eu/identityiq/login.jsf>. The user guide for managing referential and organisation data in eAF is available [here](#).

A provisional term may be added to the list within 5 working days; however, please note that there is a possibility that the term might not be approved in future. More information on how to request additional terms in eAF can be found [in the 'RMS Web User Manual' document available at <http://spor.ema.europa.eu/rmswi/#/viewDocuments>](#).

In case of declaration of overages you have to complete this separate section:

Details of any overages should not be included in the formulation columns but stated below:

Active Substance	Overage	+
		-
For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002		

Excipient	Overage	+
		-
For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002		

You have to press the “+” button first. You can then select from the pull down menu the substance as included in the composition and add the overage value. Use the full stop to indicate decimal numeric values.

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

There is no specific technical information to be considered.

2.6.3. Is an EMEA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

There is no specific technical information to be considered.

2.6.4. Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

There is no specific technical information to be considered.

3. SCIENTIFIC ADVICE

3.1. Was there formal scientific advice(s) given by EMA for this medicinal product?

There is no specific technical information to be considered.

3.2. Was there scientific advice(s) given by Member State(s) for this medicinal product?

These sections may be replicated where needed.

4. OTHER MARKETING AUTHORISATION APPLICATIONS

There is no specific technical information to be considered.

5. ANNEXED DOCUMENTS (where appropriate)

There is no specific technical information to be considered.

MAA FORM (veterinary)

On the following pages technical information in regard to the veterinary marketing authorization application form is provided. To avoid duplication of information reference is provided to the human MAA form as appropriate. Information related to the variation and renewal form will be provided in a separate section thereafter.

ADMINISTRATIVE DATA

For details on this section please refer to the identical section of the MAA form for human medicinal products via this [link](#).

DECLARATION and SIGNATURE

DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form(s):

Strength: Units:

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety

Full name of the active substance(s), (including salt or hydrate, if applicable)

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Applicant

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

E-mail

A screenshot is provided to illustrate some principles in this section which are entirely the same as for human medicinal products.

1. TYPE OF APPLICATION

Below screenshots will describe the options to complete the form according to the planned procedure. Selecting one of the round boxes will add further lines as appropriate for the respective procedure. Changing of the selection will hide the lines but addition different ones according to the other procedure selected.

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

- ☐ 1.1.1 A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)
- ☐ 1.1.2 A MUTUAL RECOGNITION PROCEDURE (according to Article 32(2) of Directives 2001/82/EC)
- ☐ 1.1.3 A DECENTRALISED PROCEDURE (according to Article 32(3) of Directive 2001/82/EC)
- ☐ 1.1.4 A NATIONAL PROCEDURE

1.1. This application concerns

In this case the centralised procedure is selected as an example how the section will be expanded depending from the selected procedure type.

This example is for veterinary products specifically, for details of the human products application form, please follow the [link](#).

☒ 1.1.1 **A CENTRALISED PROCEDURE** (according to Regulation (EC) No 726/2004)

- ☐ "Mandatory scope" (Article 3(1))
- ☐ "Optional scope" (Article 3(2))
- ☐ "Generic of a centrally authorised veterinary medicinal product" (Article 3(3))

☒ CVMP Rapporteur	Title	
	First name	
	Surname	
☒ CVMP Co-rapporteur	Title	
	First name	
	Surname	

1.1.1. A Centralised Procedure

There is no specific technical information to be considered.

1.1.2. A Mutual Recognition Procedure

There is no specific technical information to be considered.

1.1.3. A Decentralised Procedure

There is no specific technical information to be considered.

1.1.4. A National Procedure

There is no specific technical information to be considered.

1.2. Is this an application for a change to your existing marketing authorisation leading to an extension as referred to in Annex II of Regulations (EC) NO 1084/2003 or 1085/2003, or any national legislation, where applicable?

There is no specific technical information to be considered.

1.3. This application is submitted in accordance with the following articles in Directive 2001/82/EC

There is no specific technical information to be considered.

1.4. MRL status (only for food-producing species)

1.4 MRL STATUS (ONLY FOR FOOD-PRODUCING SPECIES) ☒

When the veterinary medical product is intended for use in food-producing animals, please provide the following information as available at the time of submission of the application¹

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

substance(s)

Marker residue

Other Provisions

Therapeutic classification

Animal species

MRL

Target Tissues

Application for a Maximum Residue Limit has been made to the EMA

☐ Yes

☐ Not applicable

¹All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.

Animal species

All food producing species except poultry

All mammalian food producing species

All other food producing species

All ruminants

Bees

Bovine

Caprine

Chicken

Deer, including reindeer

MRL

Target Tissues

2 microgram/litre

Milk

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

+

–

substance(s)

+

–

BENZYLPENICILLIN SODIUM

▼

+

–

Marker residue

Other Provisions

For bovine milk only

▼

+

–

Therapeutic classification

Animal species

Bovine

▼

+

–

MRL

2 microgram/litre

Target Tissues

Milk

▼

+

–

+

–

substance(s)

+

–

Species

▼

+

–

Remarks

The form requires that excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification is given. If this is the case, the tick box “not applicable” can be selected, and the justification should be provided in the “remarks” field.

In case an MRL application has been submitted to EMA and the procedure is still pending the tick box “Yes” should be selected and details on the application including submission date should be provided in the following section:

Application for a Maximum Residue Limit has been made to the EMA

☒ Yes

substance(s)

Date of Submission

Species

Remarks

1.5. Consideration of this application is also requested under the following article in Directive 2001/82/EC or Regulation (EC) No 726/2004

There is no specific technical information to be considered.

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. NAME(S) AND ATC VET CODE AND TARGET SPECIES

2.1.1. Proposed (invented) name of the veterinary medicinal product in the European Union / Member State/Iceland/Lichtenstein/ Norway

The information is identical to the one in section “Declaration and signature” and will be populated automatically (see Section 1.1.1).

If the box is ticked like this an Annex 5.18 need to be provided.

2.1	NAME(S), ATC VET CODE AND TARGET SPECIES
2.1.1	Proposed (invented) name of the veterinary medicinal product in the European Union / Member State / Iceland / Liechtenstein / Norway
	Wonderpil Extractum
	(Value populated from the "Declaration" section.)
☒	If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in Annex 5.18

This field appears only in case of MRP or DCP selected in section 1.2 or 1.3. The annex is not integrated into the form but the required list should be added as a separate PDF file to the submission.

2.1.2. Name of the active substance(s)

The declaration of the active substance will be populated automatically if the button in section 1 has been pressed.

2.1.3. Pharmacotherapeutic group (Please use current ATC vet code)

2.1.4. Target species

The most complete code corresponding to the claimed therapeutic use of the product should be given. Consequently, this section should be duplicated where needed.

The two fields “ATC Code” (the specific vet terms should be selected) and “Group” are linked and should be both completed. It is recommended to key in the third or fourth level description.

2.1.3 Pharmacotherapeutic group (Please use current ATC vet code) & 2.1.4 Target Species

+ -

Target species Bovine, including buffalo + -

Target species Beef cattle + -

ATC code ▼

QJ01C

QJ01C (BETA-LACTAM ANTIBACTERIALS, PENICILLIN)

QJ01CA (Penicillins with extended spectrum)

QJ01CA01 (ampicillin)

QJ01CA02 (pivampicillin)

QJ01CA03 (carbenicillin)

QJ01CA04 (amoxicillin)

QJ01CA05 (carindacillin)

Select

Group Penicillins with extended spec

☐ If no ATC vet code has been assigned, please indicate if an application for the ATC vet Code has been made

Note: It may happen that the description of the third or fourth level of the ATC vet code is too long to be included completely.

2.2. STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

2.2.1. Strength and pharmaceutical form (use current list of standard terms – European Pharmacopoeia)

For details refer to the human products application form, please follow the [link](#).

2.2.2. Route(s) of administration (use current list of standard terms - European Pharmacopoeia)

2.2.2 Route(s) of administration (click 'find' to use the current list of standard terms - European Pharmacopoeia)

+ -

Route of Administration Intradermal use ▼

Target species Bovine, including buffalo ▼

Dropdown field to select (“Click arrow button”)

The dropdown includes the current list of standard terms included in the “List of Standard Terms for pharmaceutical dosage forms, routes of administration and containers” published by the [EDQM](#) / [RMS](#).

The routes field is repeatable, where needed, with +/- buttons:

+ -

Complete the section by selecting the target species again.

2.2.3. Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

2.2.3 Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

For each type of pack give:

Package Size 1 + -

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

Description:

For each container give:

+ -

Container

Material

Closure

Administration Device

2.2.3.2 Proposed shelf life

2.2.3.3 Proposed shelf life (after first opening container)

2.2.3.4 Proposed shelf life (after reconstitution or dilution)

2.2.3.5 Proposed storage conditions + -

2.2.3.6 Proposed storage conditions after first opening + -

Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDv websites) ([Annex 5.17](#))

You have to provide details for each of the pack sizes planned to be marketed. The package sizes fields are repeatable, where needed, with +/- buttons: + - as indicated in the figure above.

In this figure the coloured fields indicate the mandatory section to be filled at a minimum. The colour appears after pressing the validate form button at the end of the form.

The term list on Container, Closure and Administration Device will become more complete over time. Therefore, check carefully in advance whether the term you will use is provided. Otherwise require the term asap at mdms@ema.europa.eu.

The material is a free text field, but it is advisable to use known standard abbreviations for chemical names, such PVC, HDPE, etc.

2.3. LEGAL STATUS

There is no specific technical information to be considered.

2.4. MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

For details refer to the human products application form, please follow the [link](#).

2.5. MANUFACTURERS

For details refer to the human products application form, please follow the [link](#).

2.6. QUANTITATIVE AND QUALITATIVE COMPOSITION

2.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

For details refer to the human products application form, please follow the [link](#).

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

There is no specific technical information to be considered.

2.6.3. Does the veterinary medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

There is no specific technical information to be considered.

3. SCIENTIFIC ADVICE

3.1. Was there formal scientific advice(s) given by CVMP for this veterinary medicinal product?

There is no specific technical information to be considered.

3.2. Was a scientific recommendation(s) given by Member State(s) for this veterinary medicinal product?

These sections may be replicated where needed.

4. OTHER MARKETING AUTHORISATION APPLICATIONS

There is no specific technical information to be considered.

5. ANNEXED DOCUMENTS (where appropriate)

There is no specific technical information to be considered.

VARIATION FORM

On the following pages technical information in regard to the variation form is provided.

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

☒ Human ☐ Veterinary

☒ National Authorisation in MRP/DCP

☐ EU Authorisation

☐ National Authorisation

Variation procedure number(s)¹ 

[Click here to populate variation number in section 2](#)

DE/H/2020/BB1-002/II/G/022

+

-

Reference Member State / Reference Authority for worksharing Germany 

Concerned Member State(s)

Add All

Remove All

Austria  + -

Estonia  + -

Finland  + -

Type of Application (tick all applicable options)

☐ Single variation

☒ Grouping of variations

☐ Including a line extension³ 

☒ Worksharing

☐ Type IA_{IN}

☐ Type IA

☐ Type IB unforeseen² 

☐ Type IB

☒ Type II

☐ Type II Art. 29⁴ 

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☐ Indication

☐ Paediatric requirements

☐ Safety

☐ Quality

☐ Annual variation for human influenza vaccines

☐ Non-food producing target species

☐ Other

Details of the procedure number and involved Member States depend from the type of procedure. In case of variations to a national authorisation in MRP/DCP select the Reference Member State. In the list below all Member States or the EMA can be selected except the same Member States as already selected in the role of RMS. You may add

member states line by line or use the ‘Add all’-button **Add All** to add all member states in one go. You can remove all by pressing the ‘Remove all’-button **Remove All**. It is also possible to remove single member states line by line. The most time effective way of working depends from the number of member states.

The type of variation must be selected next. In case of variations other than IA/IA_{IN} additional information about the scope of the variation should be indicated.

In case of purely nationally authorized products involved in a worksharing procedure, the Reference Authority will be included instead of the RMS.

Type of Application (tick all applicable options)

☐ Single variation ☒ Type IA_{IN}

☒ Grouping of variations ☐ Type IA

☐ Including a line extension³ ☐ Type IB unforeseen²

☒ Worksharing ☐ Type IB

☐ Type II

☐ Type II Art. 29⁴

Type of Application (tick all applicable options)

☒ Single variation ☐ Type IA_{IN}

☐ Grouping of variations ☐ Type IA

☐ Worksharing ☐ Type IB unforeseen²

☐ Type IB

☒ Type II

☐ Type II Art. 29⁴

Additional information on the scope is requested.

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☐ Indication

☒ Paediatric requirements

☒ Safety

☐ Following Urgent Safety Restriction

☐ Quality

☐ Annual variation for human influenza vaccines

☐ Non-food producing target species

☐ Other

The selection of the MA Holder address will be supported by the SPOR Organisation Management Service as outlined in Section [Providing contact & address details](#).

2. PRODUCTS CONCERNED BY THIS APPLICATION

The variation form allows to include all forms and strengths. Again, the signatures should be provided by the MAH. If different national companies are involved it is recommended to add power of attorney as required by member states appropriately.

The products involved in the variation need to be named. To allow all possibilities to be keyed in in a structured manner, this section has completely been revised. The principles of that construct are explained in the figure below:

The diagram illustrates the structure of the variation form with the following components and callouts:

- Variation No.:** A text field. Callout: "The Variation number will be optional for NP, and will be mandatory for MRP/DCP".
- Active Substance:** A text field with a dropdown arrow. Callout: "The active substances will be mandatory for 'Single Variation' only. It will be optional where 'Grouping of Variations' and/or 'Worksharing' have been selected."
- Member State(s):** A dropdown menu. Callout: "Adds a blank row/removes a row."
- MA Number(s):** A text field with a +/- button. Callout: "• +/- Button allow for multiple MA Numbers to be added within a row to address authorisations based on pack sizes. • Free Text field. • This is a mandatory field."
- Invented Name:** A dropdown menu. Callout: "• Free Text Field. • Pull down for selecting one of the previous entries. • This is a mandatory Field."
- MA Holder Name(s):** A dropdown menu. Callout: "• Free Text field. • Pull down for selecting one of the previous entries. • This is a mandatory Field."
- Pharmaceutical Form:** A dropdown menu. Callout: "• This is a controlled list. • User will be able to select from drop down list. • This is a mandatory field."
- Strength:** A dropdown menu. Callout: "• Free text field. • Pull down to select a previous entries. • This is a mandatory field."
- Unit:** A dropdown menu. Callout: "• This is a controlled list. • User to select from drop down list. • This is a mandatory field."
- Clone Button:** A button with a plus/minus icon. Callout: "The Clone Button can be used to replicate the current line onto a new row, as if the + button has been pressed., but also the content will be replicated."

The sample displays how several products with different authorisation numbers different product names or different MAH names etc. can be added. In case the strength details are too complex, a footnote can be added to describe the strengths in more detail:

2. PRODUCTS CONCERNED BY THIS APPLICATION? (?)

☒ Form and Strength information is provided in footnote

Variation Number	DE/H/0212/001/1A/098	Clone
Active Substance	IBUPROFEN (LYSINE)	
Member State	Germany	Clone
MA Number(s)	Invented Name	MA Holder Name
1234.00.00	Advil	Company
1234.00.01	Advil forte	Company
Member State	Austria	Clone
MA Number(s)	Invented Name	MA Holder Name
PVK 1234	Advil	Company
PVK 1235	Advil forte	Company
Member State	Netherlands	Clone
MA Number(s)	Invented Name	MA Holder Name
RVG 120034	Advil	Company
RVG 120035	Advil forte	Company
Footnote This describes all employed strenghts		

3. TYPE(S) of CHANGE(S)

You have to confirm that all relevant pages from the Guideline will be added as well as the relevant documentation by ticking the check box:

☒ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked.

The classification Guideline table should be added as a separate document provided in the same location as the application form, clearly identifiable as [Classification Guideline](#). File name could be **common-form-annex-classgl.pdf**. It is important not to attach the annexes into the eAF itself, this will prevent proper locking of the forms

As a next step you have to select the changes you want to submit: The full list of variation items according to EU Commission Guidelines will be presented by pressing

Show All Types

Once you have made your selection you can close the list /collapse the list to show only the selected items by pressing **Show Only Selected / Collapse All** at the end of the list.

You may control the selection and adjust it. To correct the list the button “Refresh Selected” can be pressed.

Show All Types		Refresh Selected	
Variation	Selected		
B.I.a z)	1		
A.7	1		
A.4	1		

List of selected items

		Procedure type		
☒ A.4	Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)	☒ IA	☐ IB*	Implement. Date: + -
*If one of the conditions is not met and the change is not specifically listed as Type II.				
☒ A.7	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	☒ IA	☐ IB*	Implement. Date: + -
*If one of the conditions is not met and the change is not specifically listed as Type II.				
*Note: Where notice has been given by the authorities of the intention to perform an inspection, the deletion of the relevant site shall be notified immediately.				
B.I.a	Change in manufacture of the active substance	Procedure type		
☒ z)	Other variation	☒ IA	☐ IB ☐ II	Art. 5 Implement. Date: + -

Show All Types
Refresh Selected

Variation	Selected
B.I.a z)	1

Variation	Description	Procedure type	Implement. Date:
☐ A.4	Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)	☒ IA ☐ IB ^a	
^aIf one of the conditions is not met and the change is not specifically listed as Type II.			
☐ A.7	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	☒ IA ☐ IB ^a	
^aIf one of the conditions is not met and the change is not specifically listed as Type II. *Note: Where notice has been given by the authorities of the intention to perform an inspection, the deletion of the relevant site shall be notified immediately.			

B.I.a	Change in manufacture of the active substance	Procedure type	Implement. Date:
☒ z)	Other variation	☒ IA ☐ IB ☐ II	Art. 5

Show All Types
Refresh Selected

Variation	Selected
B.I.a z)	1

B.I.a	Change in manufacture of the active substance	Procedure type	Implement. Date:
☒ z)	Other variation	☒ IA ☐ IB ☐ II	Art. 5

Depending from the items you have to complete the following table to describe the present and proposed wording in the PL or SmPC or any brief description of the changes or DUNS number of involved manufacturer or ASMF reference number. Due to the anticipated complexity this is not needed in case of worksharing or grouping procedures affecting more than one product.

It is mandatory to select at least one scope from the list.

Present and proposed section – text fields

Scope B.I.c.3 a)		PRESENT ^{9,10}	PROPOSED ^{9,10}
Text		<i>Slope of degradation 0.2</i>	<i>Slope of degradation 0.3</i>
Image			

Scope D.20 a)		PRESENT ^{9,10}	PROPOSED ^{9,10}
Text			
Image			

D-U-N-S number ¹¹		D-U-N-S number ¹¹	
EU or National ASMF reference number ¹²		EU or National ASMF reference number ¹²	

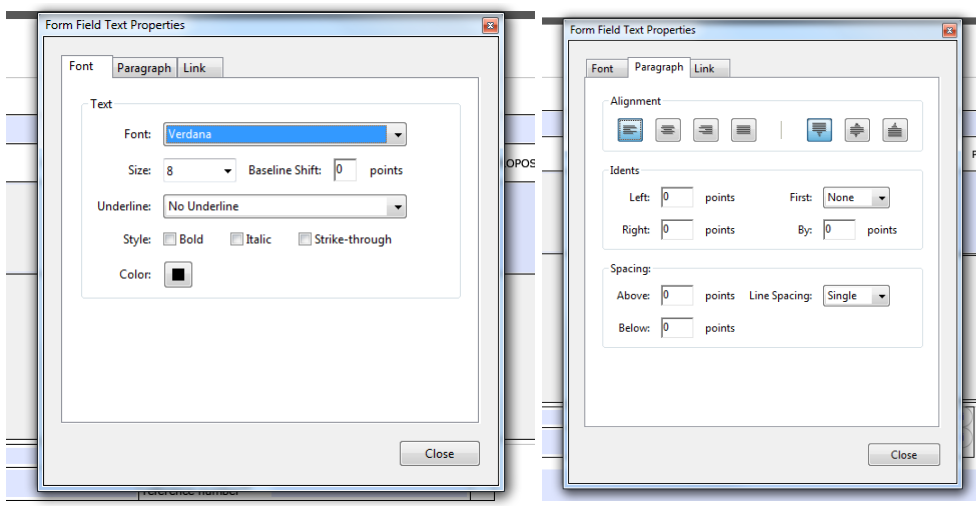
OTHER APPLICATIONS¹³

It is possible to include **formatted text**, but only in the present and proposed text fields of this form. All other free text fields in the forms allow only plain text. A track-changes functionality is currently not available in interactive Acrobat forms.

The formatting can be changed based on the following rules:

Click to insert details regarding present product information in the free text field. You can change the presentation of the text. To underline, set italic or set bold, select the words and use following key combinations: CTRL+U, CTRL+I, CTRL+B on Windows and CMD+U, CMD+I, CMD+B on Mac.

Using the right mouse button, you can select “Text style” providing the same options:
If selecting “Hyperlink” at the pop-up provides more options to directly format the text or paragraph:



Alternatively, rich text (formatted) can be used by editing the text in Word or Outlook in rtf format and copy pasting the formatted text in to the present and proposed fields.

C.I.6 a)	
PRESENT ^{9,10}	PROPOSED ^{9,10}
This is the old version.	This is also a test for formatting text in a different way

Complex table as part of the present and proposed section in the variation eAF cannot be included. Where a table is needed in the present and proposed section of the eAF you are able to include the information in separate annex included in folder 1.2 of the eCTD structure for Human applications or in the “1a-admin-info” folder of the VNeS structure for Veterinary applications. The annex should be attached as a separate PDF document, clearly named (for example ‘ema-form-annex-presentandproposed’) in the folder 1.2 or folder “1a-admin-info” for VNeS submissions.

Text such as 'See Annex Present and Proposed' should be entered into the mandatory present and proposed fields of the eAF.

To include an image (always one image per cell) you will click with the left mouse button into the cell. You can then select from your file share an image as appropriate. The image cannot be enlarged. If the size needs to be adjusted, please provide the image as an annex.

In addition, it is not possible within one section of the present/proposed table to alternate text fields and image fields. You will need to repeat the scope section entirely.

Present and proposed section – address details

The section now allows the usage of OMS entry as detailed in Providing OMS organisation details to auto-populate address fields.

PRESENT ^{9,10}		PROPOSED ^{9,10}		
Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omsui/#/.		Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omsui/#/.		?
Find Organisation		Find Organisation		
Clear Address		Clear Address		
Company name		Company name		
Address		Address		
City/Locality/ Town/Village		City/Locality/ Town/Village		
State		State		
County		County		
Postcode		Postcode		
Country		Country		
OrgID		OrgID		
LocID		LocID		
Telephone		Telephone		
E-mail		E-mail		

Depending on the role of the company of which the address need to be included, it may happen that OMS cannot provide details. It is assumed that in those cases – more likely in the present part of that section – the details need to be completed manually. Although due to the early stage of productive OMS usage not every address might be available, it is highly recommended to use OMS for any new address to be inserted in the proposed section.

4a Type II variations – new indications – orphan medicinal product information

This section will only appear if variation type II has been selected. The section can be flagged out, if not applicable

4.a Type II variations - new indications - orphan medicinal product information
(For human medicinal products only; mark this section N/A if the variation does not relate to a new indication)
☐ Select flag if not applicable; section will not be displayed.

Has orphan designation been applied for, for this new indication?
☒ Yes ☐ No

Orphan designation procedure number:

☐ Pending
☐ Orphan Designation Granted
☐ Orphan Designation Refused
☐ Orphan Designation Withdrawn

Information relating to orphan market exclusivity
Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the new indication proposed in this variation application?
☒ Yes ☐ No

Please specify the EU Orphan Designation Number(s):

Has any of the designated Orphan medicinal product(s) been granted a marketing authorisation in the EU?
☐ Yes ☐ No

4b Type II variations – Paediatric Requirements

This section will only appear if variation type II has been selected. The section can be flagged out, if not applicable

4.b Type II variations - Paediatric requirements

(For human medicinal products only; section to be completed only for variations concerning a new indication or for variations related to PIP implementation)

(Note: The notion of 'global marketing authorisation' as stated in Article 6(1)2nd subparagraph of Directive 2001/83/EC, as amended, should be taken into account for products belonging to the same¹⁴ marketing authorisation holder)

☐ Select flag if not applicable; section will not be displayed.

☒ Article 8 of Paediatric Regulation applies to this variation application since.

☒ This application relates to a new indication for an authorised medicinal product which:

☐ is protected by a supplementary protection certificate under Regulation (EC) No 469/2009.

☒ is protected by a patent which qualifies for the granting of the supplementary protection certificate.

☐ This application relates to a previous/ongoing/parallel procedure which triggered Article 8 requirement.

☐ Article 8 of the paediatric regulation does not apply to this application, since.

☐ This application relates to a new indication for a paediatric use marketing authorisation (PUMA).

☒ This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation

☐ This application relates to paediatric studies included in a paediatric investigation plan

This application includes:

☐ PIP Decision Number ¹⁵		+	-	i
☐ Product-Specific Waiver Decision Number ¹⁶		+	-	i
Class Waiver Decision Number		+	-	

(Note: a copy of the PIP/Product-Specific Waiver decision including the paediatric Committee (PDCO) opinion and the Summary Report, is to be included in Module 1.10)

Has this application been subject to PIP compliance verification?

☒ Yes ☐ No

Please specify

The compliance document reference

+

-

(Note: If available, a copy of the PDCO compliance report with, where applicable, the PDCO opinion or the document issued by the national competent authority is to be included in Module 1.10)

☒ Please provide the overview table of PIP results in Module 1.10

4c Type II variations – Extended data exclusivity/market protection

This section will only appear if variation type II has been selected. The section can be flagged out, if not applicable

4.c Type II variations - Extended data exclusivity/market protection:

☐ Select flag if not applicable; section will not be displayed.

Consideration of this application is also requested under the following article in directive 2001/83/EC or regulation (EC) No 726/2004:

☒ Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004 (one year of market protection for a new indication)

☐ Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)

☐ Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)

(Note: The report justifying the claim for extended data exclusivity/market protection is to be provided in Module 1.5.3)

ANNEXED DOCUMENTS (WHERE APPROPRIATE)

ANNEXED DOCUMENTS (WHERE APPROPRIATE)

The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:

☒ Summary of product characteristics

☐ Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation¹⁷

☐ Labelling

☒ Package leaflet

☐ Mock-ups¹⁸

☐ Specimens¹⁸

DECLARATION OF THE APPLICANT

SIGNATURE

This section need to be completed in the same way as in other forms. You may refer to the respective [section](#) above.

RENEWAL FORM

On the following pages technical information in regard to the renewal form is provided.

1. APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION

This form is applicable to both domains and you have to make a selection at first (indicated with arrows in the figure below):

1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION

The screenshot shows the 'APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION' form. At the top, there are two radio buttons: 'HUMAN' and 'VETERINARY'. Below them are three radio buttons: 'National authorisation in MRP/DCP', 'EU authorisation', and 'National authorisation only'. A red box highlights the question 'Is the product currently marketed?' with 'Yes' and 'No' radio buttons. A blue box highlights the 'Add All' button. A blue box highlights the 'Member state' dropdown menu. A blue box highlights the 'Pharmaceutical form(s)' dropdown menu. A blue box highlights the 'Strength(s)' and 'Units' fields. A blue box highlights the 'Active Substance' field. A blue box highlights the 'OK', 'Clear', and 'Cancel' buttons. A blue box highlights the 'Click here to populate data in section 3' link. Annotations with arrows point to the 'HUMAN' and 'VETERINARY' radio buttons, stating 'All member states can be included in one go.'; the '+' button next to the 'Member state' dropdown, stating '+ for an additional invented name'; the '+' button next to the 'Pharmaceutical form(s)' dropdown, stating '+ for an additional pharmaceutical product'; and the '?' icon next to the 'Pharmaceutical form(s)' dropdown.

A **renewal** form must be provided for each form and strength of a medicinal product (except for Centrally Authorised products where renewal always covers the whole product with all its forms and strengths). Nevertheless, the product name per member state may differ. In case of combined packages and different composition of pharmaceutical products need to be addressed, several options to copy data fields are provided.

Another difference to the previous form is the indication whether the product is marketed or not (squared box), but all other details need to be completed as known from the MAA form or the variation form.

Again you have the option to populate the product details in section "Qualitative and quantitative composition" (section 3.)

Further product characteristics have to be provided:

The screenshot shows a form with three main sections. The top section contains a dropdown for 'ATC code' and a text input for 'Group'. Below these is a checkbox labeled 'If no ATC code has been assigned, please indicate if an application for ATC code has been made'. The middle section has a dropdown for 'Route of Administration' and a checkbox. The bottom section has a dropdown for 'Member state' and a text input for 'MA Number'. Each section has expand/collapse (+/-) buttons and an information (i) icon.

In case of selecting "Veterinary" this section will be adapted to add the target species and it is expected that the ATC vet code and respective group are chosen (although not explicitly mentioned):

The screenshot shows a form adapted for Veterinary use. It includes a dropdown for 'Target Species', a dropdown for 'ATC code', and a text input for 'Group'. Below these is a checkbox labeled 'If no ATC code has been assigned, please indicate if an application for ATC code has been made'. The form has expand/collapse (+/-) buttons and an information (i) icon.

Name and address of the Marketing Authorisation Holder will be handled in the same way as in other forms. Details provided [here](#).

Name and address of MA holder

+ -

Add All Add Selected Remove All ?

Member state	Finland	+	-
Member state	France	+	-
Member state	Greece	+	-
Member state	Hungary	+	-
Member state	Germany	+	-

Company Name	BfArM-Pharma
Address 1	Kurt-Georg-Kiesinger-Strasse 3
Address 2	Bonn
	(name of: city, town, village, etc)
Postcode	53175
Country	Germany
Telephone	+492282079999
Telefax	
E-mail	bill.miller@bfarm.de

Again buttons are added to allow replication of data:

Name and address of contact person⁴

+ -

Add All Add Selected Remove All ?

Copy contact details from previous Section

Member State	Germany	+	-
--------------	---------	---	---

Title	
First name	Bill
Surname	Miller
Company Name	BfArM-Pharma
Address 1	Kurt-Georg-Kiesinger-Strasse 3
Address 2	Bonn
	(name of: city, town, village, etc)
Postcode	53175
Country	Germany
Telephone	+492282079999
Telefax	
E-mail	bill.miller@bfarm.de

2. APPROVED MANUFACTURERS

2. APPROVED MANUFACTURERS

Details of the role of the manufacturer can be described in the free text field on top.

Authorised manufacturer(s) (or importer) responsible for **batch release** in the EEA (in accordance with Articles 40 and 51 of Directive 2001/83/EC, as amended, or Articles 44 and 55 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Decision)

+ -

Company Role: Batch release

Do you have a separate admin and manufacturer address? ☒ Yes ☐ No

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Find Organisation

Clear Address

Company name	BfArM-Pharma
Admin Office Address	Kurt-Georg-Kiesinger Allee 3
City/Locality/Town/Village	Bonn
Admin Office State	
Admin Office County	
Postcode	53121
Admin Office Country	Germany
Admin Office Telephone	0049 228 99 307 9999
Admin Office E-mail	Bill.miller@bfarm.de

+ -

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/omswi/#/>

Find Organisation

Clear Address

Company name	BfArM-Pharma Testing Site
Manufacturing Facility Address	Hans-Mueller-Platz 1
City/Locality/Town/Village	Bonn
Manufacturing Facility State	
Manufacturing Facility County	
Postcode	53121
Manufacturing Facility Country	Germany
Manufacturing Facility Telephone	0049 228 99 307 8888
Manufacturer Facility E-mail	bob.scholz@bfarm.de

The free text field (see the square box) can be used to indicate the 'role' of the manufacturer for applications with multiple active substances, excipients and manufacturers. For example, this field can be used to indicate the manufacturer of the 'Drug product' and manufacturer of the 'solvent' or the batch release of the product. This field should be left empty if it is not needed.

For blood products and vaccines:
State laboratory or laboratory designated for official **batch release**, as accordance with Articles 111(1), 113, 114 (1)-(2) and 115 of Directive 2001/83/EC as amended.

+ -

Copy address details from 'batch release'

Laboratory Name

Do you have admin address and manufacturer address? ☐ Yes ☐ No

Company name

Admin Office Address 1

Admin Office Address 2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax

Admin Office E-mail

+ -

Company name

Manufacturing Facility Address 1

Manufacturing Facility Address 2

Postcode

Manufacturing Facility Country

Manufacturing Facility Telephone

Manufacturing Facility Telefax

Manufacturing Facility E-mail

Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where **batch control/testing** takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above

Copy address details from 'batch release'

Do you have a separate admin and manufacturer address? ☐ Yes ☒ No

+ -

Company name

Address 1

Address 2
(name of: city, town, village, etc)

Postcode

Country

Telephone

Telefax

E-mail

In the various address fields you will find buttons to copy the address details as appropriate.

If Ph. Eur certificate has been issued, further details can be provided in this section

Brief description of functions performed by manufacturers of the active substance(s)

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

☒ Yes

☐ No

Name of the CEP holder

Name of the manufacturer if different from the above

CEP number

Date of last update

Is a Active Substance Master File to be used for the active substance(s)

☒ Yes

☐ No

If yes, please provide the following information

Name and contact details of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of last update

3. QUANTITATIVE AND QUALITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)

The details are the same as for [2.6.1 MAA human](#).

This section will be concluded with a tabular listing of changes of the product information texts. This table can be provided as a separate document attached to the application form as well. Per section or subsection of the SmPC or PL you should use a separate line item by item to be changed.

PRESENT PRODUCT INFORMATION TEXT	PROPOSED PRODUCT INFORMATION TEXT	
		+ -
		+ -
		+ -

In case you want to use formatted text elements please follow the tips provided [here](#).

4. DOCUMENTS APPENDED TO THIS APPLICATION

In cases where a renewal is being made for either a Human or Veterinary medicinal product following the nationally authorised procedure (National authorisation in MRP/DCP or National authorisation only), users can elect to have a shortened renewal procedure and provide the appropriate justification as illustrated below:

4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY	
Product subject to shortened renewal	☒
Shortened Procedure Reason	

For the remaining Module 1 section depending from your selections you have to complete the list of documents you will attach.

Module 1	
☐	1.0 Cover letter
☐	1.1 Comprehensive table of content (not applicable for centrally authorised medicinal products)
☐	1.2 Renewal Application Form with the following annexes:
☐	A list of all authorised product presentations for which renewal is sought in tabular format
	Details on contact persons:
☐	• Qualified person in the EEA for Pharmacovigilance
☐	• Contact person in the EEA with overall responsibility for product defects and recalls
☐	• Contact person for scientific service in the EEA in charge of information about the medicinal product
☐	Chronological list of all post-authorisation submissions since grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR and PSUR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change.
☐	Chronological list of conditions and Specific Obligations (for centrally authorised products) submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved (where applicable)
☐	Revised list of all remaining conditions and any Specific Obligations (for centrally authorised products) (where applicable)
☐	A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the EudraGMP database will suffice, once this is available
☐	For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome
☐	A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU ⁵

DECLARATION and SIGNATURE

This section need to be completed in the same way as in other forms. You may refer to the respective [section](#) above.

DECLARATION AND SIGNATURE

I hereby make application for the above Marketing Authorisation to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 23 of Directive 2001/83/EC or Article 27 (1) of Directive 2001/82/EC or Article 16 or Article 41(1) of Regulation (EC) No 726/2004. The product conforms with current CHMP/CVMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authority.

☒ Proof of payment (when relevant)

+

−

Have all relevant fees been prepaid to competent authorities?

☒ Yes (for fees paid, attach proof of payment in Annex)

☐ No

Add All

Remove All

For Member State(s)

+

−

Please specify fee category under National rules

Title

First name

Surname

Status (Job Title)

Date

Signatory

Additional Signatory

+