



15 September 2020

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

Version 1.8.

Note to readers

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

Screenshots in this document have been, in most cases taken using eAF version 1.24. In some cases, this guidance will still use screenshots based on earlier versions. It is not possible to match this guidance document with one exact version of the eAF. However, information about new functionalities or changes are in the up to date 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.
1.7.1	eAF Sub-Group on Guidance	Including clarification on section 2.5.4
1.8	EMA	Updated to reflect eAF v1.24.0.0 (mainly variation form)

Reviewers

Version	Name	Organisation
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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	Method 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
1.7.1	General public	Published on the EMA eSubmission website
1.7.2	General public	Published on the EMA eSubmission website
1.8	General public	Published on the EMA eSubmisison website

Entering operation

Version	Date	Comments
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

Version	Date	Comments
1.7.1.	August 2018	Updated version based on version 1.7
1.7.2.	September 2018	Updates based on minor comments
1.8	September 2020	Updates based on eAF v1.24.0.0

Contents

Note to readers	2
Document History	3
Change Record.....	3
Reviewers	3
Distribution.....	4
Entering operation	4
Contents	6
Purpose and general technical rules	10
Purpose of this document	10
Referential term change request processes	10
Access to the forms and news on updates	11
Adobe Reader requirements and IT security settings	11
Opening the form	12
Navigating the forms	12
Integration of the forms into dossier	13
Export of XML data	14
Import of the XML data	14
Update of the XML data	15
Data fields and formats	15
Providing OMS organisation details to auto-populate address fields.....	17
File Naming Convention.....	20
Signature	21
Saving the form	22
MAA FORM (human)	22
Administrative Data	23
Declaration and Signature	23
Product (Invented) name	23
Pharmaceutical form	23
Strength(s).....	24
Active Substance(s)	26
Base/Active moiety	27
Applicant.....	27
Person confirming fees will be/ have been paid, on behalf of the Applicant.....	29
1. Type of application	29
1.1. This application concerns	30
1.1.1. A Centralised Procedure	31
1.1.2. A Mutual Recognition Procedure	31
1.1.3. A Decentralised Procedure.....	32
1.1.4. A National Procedure	32
1.2. Orphan Medicinal Product Information (human only)	32

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?	33
1.4. This application is submitted in accordance with the following article in Directive 2001/83/EC as amended	33
1.5. Consideration of this application requested under the following article of Directive 2001/83/EC or Regulation (EC) No 726/2004	33
1.6. Requirements according to Regulation (EC) N° 1901/2006 ('Paediatric Regulation') ...	33

2. Marketing Authorisation Application34

2.1. Names(s) and ATC code.....	34
2.1.1. Proposed (invented) name of the medicinal product in the European Union / Member State/Iceland/Lichtenstein/ Norway	34
2.1.2. Active substance(s)	34
2.1.3. Pharmacotherapeutic group	36
2.2. Strength, pharmaceutical form, route of administration, container and pack sizes	36
2.2.1. Strength and pharmaceutical form (use current list of standard terms – European Pharmacopoeia)	36
2.2.2. Route(s) of administration (current list standard terms - European Pharmacopoeia)	37
2.2.3. Container, closure and administration device(s)	38
2.2.4. Medical Devices	39
2.3. Legal status	39
2.4. Marketing authorisation holder / contact persons / company.....	40
2.4.1. Proposed responsible marketing authorisation holder/person	40
2.4.2. Person/company authorised for communication on behalf of the applicant during the procedure.....	42
2.4.3. Person/company authorised for communication	43
2.4.4. Summary of the applicant pharmacovigilance system	43
2.5. Manufacturers	43
2.5.1. Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA43	
2.5.2. Manufacturer(s) of the medicinal product and site(s) of manufacture.....	45
2.5.3. . Manufacturer(s) of the active substance(s) and site(s) of manufacture	48
2.5.4. Contract companies used for clinical trial(s) (including bioavailability and bioequivalence studies) included in the application or used for the validation of blood product manufacturing processes.	50
2.6. Quantitative and Qualitative Composition.....	51
2.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)	51
2.6.2. List of materials of animal and/or human origin contained/ used in the manufacturing process of the medicinal product?.....	54
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?.....	54
2.6.4. Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?	54

3. Scientific advice54

3.1. Was there formal scientific advice(s) given by EMA for this medicinal product?	54
3.2. Was there scientific advice(s) given by Member State(s) for this medicinal product?...	54

4. Other marketing authorisation applications	54
5. Annexed documents (where appropriate)	54
MAA FORM (veterinary)	55
Administrative data	55
Declaration and signature.....	55
1. Type of application	56
1.1. This application concerns	56
1.1.1. A Centralised Procedure	56
1.1.2. A Mutual Recognition Procedure	56
1.1.3. A Decentralised Procedure.....	56
1.1.4. A National Procedure	57
1.2. Is this an application for a change to your 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?	57
1.3. This application is submitted in accordance with the following articles in Directive 2001/82/EC	57
1.4. MRL status (only for food-producing species).....	57
1.5. Consideration of this application is also requested under the following article in Directive 2001/82/EC or Regulation (EC) No 726/2004	59
2. Marketing authorisation application particulars	59
2.1. Name(s) and ATC vet code and target species	59
2.1.1. Proposed (invented) name of the veterinary medicinal product in the European Union / Member State/Iceland/Lichtenstein/ Norway.....	59
2.1.2. Active substance(s).....	59
2.1.3. Pharmacotherapeutic group (Please use current ATC vet code)	60
2.1.4. Target species	60
2.2. Strength, pharmaceutical form, route of administration, container and pack sizes	60
2.2.1. Strength and pharmaceutical form (use current list of standard terms – European Pharmacopeia)	60
2.2.2. Route(s) of administration (use current list of standard terms - European Pharmacopoeia)	60
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)	61
2.3. Legal status	62
2.4. Marketing authorisation holder / contact persons / company.....	62
2.5. Manufacturers	62
2.6. Quantitative and qualitative composition	62
2.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)	62
2.6.2. List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?.....	62
2.6.3. Does the veterinary medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?	62
3. Scientific advice	62
3.1. Was there formal scientific advice(s) given by CVMP for this veterinary medicinal product?	62
3.2. Was a scientific recommendation(s) given by Member State(s) for this veterinary medicinal product?	62

4. Other marketing authorisation applications	62
5. Annexed documents (where appropriate)	62
VARIATION FORM	63
1. Application for variation to a marketing authorisation	63
2. Products concerned by this application	65
3. Types(s) of changes (s)	66
Present and proposed section – text fields	69
Present and proposed section – address details	70
4.a Type IB and Type II variations – new indications – orphan medicinal product information	71
4.b Type IB and Type II variations – Paediatric Requirements	72
4.c Type II variations – Extended data exclusivity/market protection	73
Annexed documents (where appropriate)	74
Declaration of the applicant	74
Signature	74
RENEWAL FROM	75
1. Application form for renewal of a marketing authorisation	75
2. Approved manufacturers	77
3. Quantitative and qualitative composition in terms of the active substance(s) and the excipient(s)	80
4. Documents appended to this application	81
Declaration and Signature	82

Purpose and general technical rules

The following pages provide general technical information regarding to all four PDF format electronic application forms. Additional information related to the specific application forms is provided in separate sections.

Purpose of this document

As part of a submission package, it is mandatory for all (Human and Veterinary) submissions in EU Member States to use the electronic application form. 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 (eAFs) for human and veterinary medicinal products, 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: Reliable regulatory information must be taken from the (regulatory) user guides of the application form only.

A question and answer document is available at <http://esubmission.ema.europa.eu/eaf/index.html> to cover anticipated questions relating specifically to the electronic forms.

Field level help or tool tips are also available in the eAF by moving the mouse pointer over each field of the electronic forms.

Note: If the tooltips are not visible when you hover over the fields in the forms please contact your IT support.

The release notes list any new functionality when new versions of the forms become available. It is strongly recommended to review the release notes each time a new version of the forms is available.

Information is also available 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 `section in the release notes for the specific form [here](#) on the eSubmission website. Raise any new issues with the [EMA Service Desk](#).

If the information cannot be included in the form, please review any workaround solutions provided in the release notes, or use an annex. In case of any further technical queries, please contact the [EMA Service Desk](#)

Referential term change request processes

In case of a missing term and as a general rule, in order to complete an eAF, use the RMS Change Request processes as outlined in the Referential Management Services (RMS) operating model document. Please submit a request using the SPOR Portal: <http://spor.ema.europa.eu/rmswi/#/>

Provide 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>. The latest versions of the respective forms can also be found there.

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

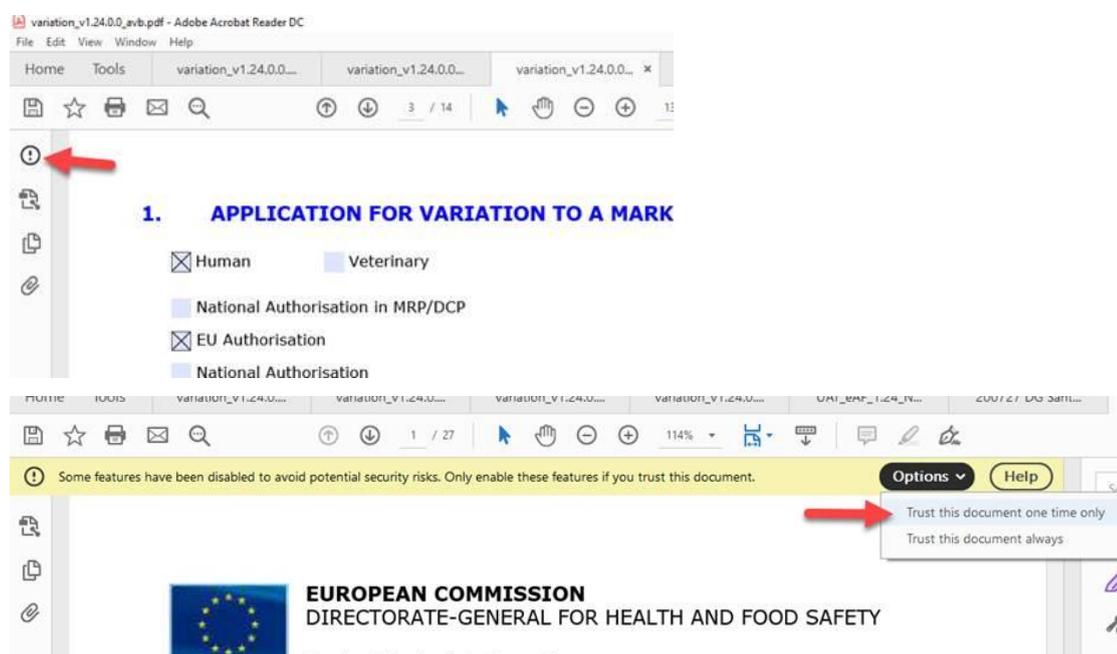
Note: Regular updates occur according to release planning.

The simplest way to keep up to date with changes to eAF is to subscribe to the eAF RSS feed.

For more information about RSS feeds, see [The EMA's Guide to RSS](#).

Adobe Reader requirements and IT security settings

When opening the eAF for the first time with Adobe Reader™, **click** the exclamation mark at the top of the left hand side menu bar and once a yellow bar opens across the top of the form, then **click Trust this document one time only or Trust this document always**. It has been noted that for some users the Trust this document one time only option works better.



Adobe™ no longer supports version 9 or earlier, so we strongly advise to upgrade Adobe Reader™ to the latest version. Please keep updated about Adobe™ supported versions.

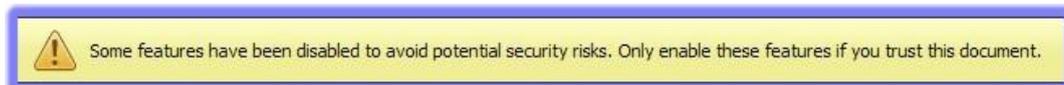
The minimum specification to use eAF is Adobe Reader™ version 10 or above. If you wish to continue using Adobe Acrobat 9 and eAFs are working fine with it then do so, however should there be any compatibility issues then Adobe is unable to support the EMA.

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 an 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](#).

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

If you receive this error message when opening the form the first time **click Options** and **click Trust this document** always.



Note: If the IT policy of your local organisation prohibits you from making changes to a security setting, 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: The 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. Please note that 'Trusting' the forms is an essential step to access the drop-down lists. Some issues have been reported when multiple PDF documents are open at the same time and some of the documents have been signed with Adobe Sign. This can prevent the eAFs from working and if you experience this issue, please close the document containing the Adobe Sign signature. Please note that the eAFs must not be signed using Adobe Sign or any other digital signature tool.

Opening the form

The eAF forms are connected to a web services and this means they can take longer to open than conventional documents. When a form is opened, lists are loaded from EUTCT and RMS and some have complex built in 'business validation rules' which can make the forms heavy.

Drop-down lists are also loaded into the form and when initially opened 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.

Note: The searchable fields will not work if there is no internet connection (such as Active substance, Excipients and ATC code).

Navigating 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.

2. MARKETING AUTHORISATION APPL

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the Eur
Norway:

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 lead extension as referred to in Annex I of Regulations (EC) no 1234/national legislation, where applicable

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

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

1.6 Requirements according to Regulation (EC) No 1901/2006 ("Paed

2. MARKETING AUTHORISATION APPLICATION PARTICU

2.1 Name(s) and ATC code

2.2 Strength, pharmaceutical form, route of administration, containe



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 Directiv 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 Regul

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 Name(s) and ATC code

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

2.3 Legal status

2.4 Marketing authorisation holder / Contact persons / Co

2.5 Manufacturers

2.6 Qualitative and quantitative composition

3. SCIENTIFIC ADVICE

4. OTHER MARKETING AUTHORISATION APPLIC

4.1 For National/MRP/DCP applications, please complete the following in accord 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 th 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. applicants belonging to the same mother company or group of companies OR which are "licensees". Same qualitative and quantitative composition in active subs 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 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/...

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 sam pharmaceutical form from applicants belonging to the same mother company or 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)

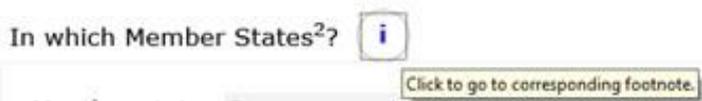
FORM VALIDATION

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.



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. 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 eCTD sequence or VNeS 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. Unfortunately this functionality cannot be removed as it is inherent to adobe forms.

Important: Do not use the bookmarking functionality in PDF as this affects on how the forms are locked and may lead to rejection by receiving agencies.

Export of 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 do the following:

1. Navigate to the Form Validation page in the PDF, and then click **Export XML** 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 although the EMA does not provide a specific tool.

Import of the XML data

This function 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 click **Import XML** 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 built in 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 resolved, save, close and re-open the form whilst online. This will refresh the lists and overwrite any outdated list content in the form cache.

Note: It is possible that some information will be lost when you export and import data from an older version of eAF to a new version due to changes in the form, and 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 only make changes in the actual xml and import into the 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.

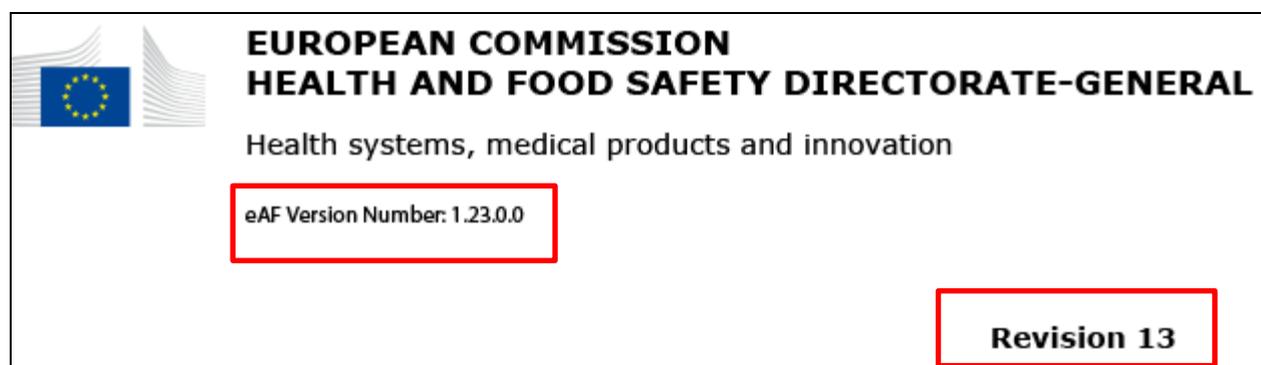
In case of updates of the eAF it will be possible to extract the data from the existing version of the form and import the data into the revised version. Most likely, manual correction may have to be done at least if data field types have been changed.

When any eAFs are opened when connected to the internet, an automatic version check is done to notify the user if a new version of the eAF is available for download. Drop down terms are always updated when opening the form. **Click** the **Update lists** button to update the list.

To manually check the version of eAF, do the following:

1. Right-click on the body of the form and select Document Properties or on the Acrobat menu bar click: File>Properties (PC keyboard shortcut= CTRL+D).
2. The Document Properties dialog window is displayed. **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.



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 where 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 using "+" or "-" buttons.

A screenshot of a form interface. At the top right, there are two circular buttons: a plus sign (+) and a minus sign (-). Below them, the text "For each type of pack give:" is displayed. Underneath, there is a light blue rectangular field containing the text "2.2.3.1 Package size". To the right of this field are two more circular buttons: a plus sign (+) and a minus sign (-).

eAFs are intelligent forms with built in business rules. Some sections are only displayed depending on previous selections. It is not necessary/possible to delete sections which are not required.

Once information is entered, the fields remain visible when un-ticking corresponding fields. To reduce the risk of accidental data loss completed sections when completed, are hidden. Data can only be deleted on a field by field basis by users. In some other cases, the values will be deleted when a different selection is chosen in the variations form when you switch between centralised and MR procedures.

The pop-up calendar fields allow you to select future months, and years within the form. With the calendar open, click the month/year and select the month/year option from the drop-down menu. Finally, click the day to close the calendar.

In some forms there are **copy from xx/populate from xx and clone** buttons to allow copying/duplicating information from previous sections to remove the need to re-enter data multiple times.

Please provide any proposals for implementation of certain sections/fields, any usability issues of the forms or certain character sets that you would like to see in any future implementation in order to meet your needs.

Providing contact & address details

Provide contact and address in a consistent 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. This reduces the need to repeat entry steps. See the example below:

Copy contact details from Declaration Section

Copy contact details from 2.4.1 Section

Copy contact details from 2.4.2 Section

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). Use of OMS is strongly recommended and it should be noted that mandatory use of OMS in the eAFs is being discussed.

Manual completing address details

Information how the address details must be entered in are provided in the tooltips when you hover over the corresponding field. The address details should only be entered manually exceptionally. The OMS data should always be used where possible.

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; eAF is integrated with OMS data. This allows users to search and select organisations from OMS records resulting in the auto-completion of the related address fields. This is to simplify data entry and reduce the number of repetitive manual data entry steps. The eAF OMS integration is one of the first integrated systems 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 **clicking 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 search is executed, 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 Wharfside Road|Widnes|United Kingdom

Select Select/Close

Once the OMS record has been selected all address related fields will be populated with the exception of the telephone and 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.

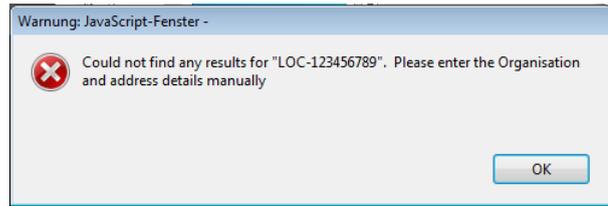
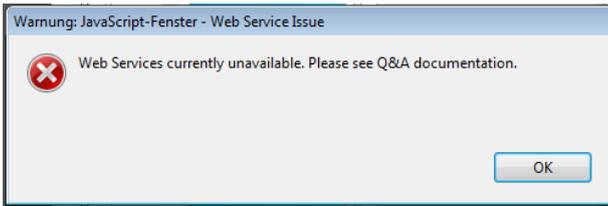
Company name	Incline Therapeutics Europe Limited
Address 1	21 St. Thomas Street
City/Locality/Town/Village	Bristol
Postcode	BS1 6JS
Country	United Kingdom
OrgID	ORG-100003216
LocID	LOC-100000283
Telephone	
Telefax	
E-mail	

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

Previously selected addresses

- EN|21 St. Thomas Street|Bristol|United Kingdom

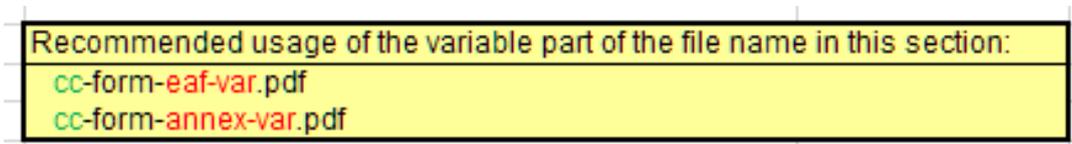
If the service is temporarily unavailable or matching data is not available the following error messages is displayed:



In case such as this, please save and closed the form and reopen. If this does not help, please raise a ticket with the EMA service desk. In urgent cases, you may proceed and complete the address data manually.

File Naming Convention

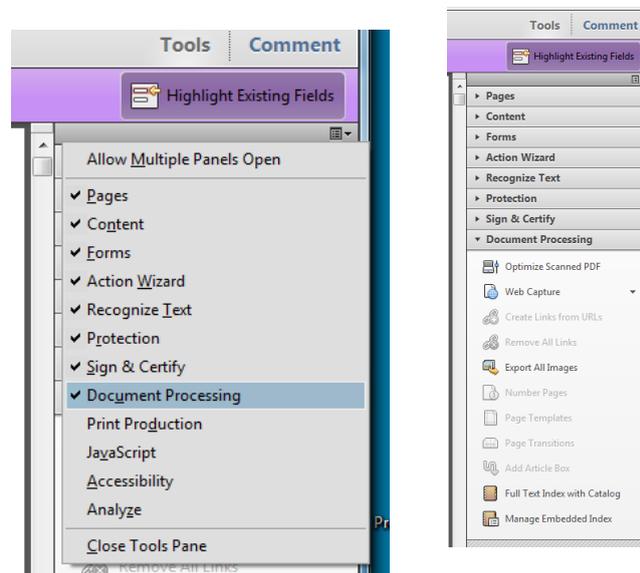
For human medicinal products the file name will be **common-form-var**.pdf. The variable part should be used as outlined in the file & folder naming convention of the updated eCTD validation criteria version 6.1. NeeS validation criteria version 4.1. In case you have to annex parts from the Classification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



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 **click** the **Validate Form** button on the last page of each of the eAFs as soon as you open the document, however it should be noted that this will make filling in the form slower as the validation is performed continuously. Once the forms are validated all mandatory fields are highlighted (in yellow or

red). Validation can be performed 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 displayed in the validation screen of the locked form.

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

Note: Validation rules are imposed to ensure that a good quality submission is enabled 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 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 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. Consult their respective websites. Additional information will be provided by CMDh and CMDv.

Up to now the effect of inserting an image which normally is an image of a relevant signature or an image of a text snippet stating that the form was signed by the person authorised by the applying company can be used as well, (e.g. stating "This form was approved/authorised following company policies by [Mr. Nick Name; Head of Reg. Affairs] with authorisation to sign. The signature is in file.") The 'signature' image is used 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, follow the recommendations below:

Unit of Measurement	Width	Height
centimetres	12.70	2.54

Inches	5	1
pixels	1500	300

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 prevent further data entry. Therefore, the insertion of that image should be the very last step completing the form. It is **strongly recommended** to always **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.

Important note: Adobe Sign or other digital signature tools **must not be used** to sign the eAF. This will impact the functioning of the form and may lead to rejection of your submission.

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, **click Save Form** at the end of the form or press Ctrl + S . Note that if you have not saved it to a specific location, the **Save As** option is displayed prompting you to save in a particular folder other than the default 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 with regard to the human marketing authorisation 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:

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Product (Invented) name

The form allows one product name to be provided. In the text field 250 characters can 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).

Pharmaceutical Form:	Powder and solvent for oral solution
Strength:	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

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>)

Keying in the first character the term begins with and it will display the list in alphabetical order. Use the mouse or the down arrow button to navigate to the correct term. Press enter or **click** the left mouse button to select the term.

If the correct term is not available use an appropriate alternative instead. Usually, new pharmaceutical form terms can be required in advance by the agency responsible to run the procedure of the new marketing authorisation application.

Strength(s)

The strength(s) will be entered in a structured way. Consider regulatory requirements relating to the rules on naming of combination products. The units of measurement are 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)

Use the drop-down menu to select the active substance. The dropdown menu also 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. Enter more characters to receive more accurate results. Scroll through the list or use the arrow-down-button of the keyboard and select the correct name. Confirm the selection by **clicking OK**.

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. **Click the OK** button to close the section. For corrections "Add Active Substances" needs to be activated and opens the dialogue again.

To select another active substance, click in the add new substance section and open the dialogue by **clicking Add Active Substances**. Do this for each additional active substance.

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)

The example above displays the case of two active substances.

Once the list is complete **click Populate data** to copy to all similar sections.

Note: 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.

Select the **Populate data in sections 2.1.2, 2.2.1 and 2.6.1** button and the form will copy data into each respective section with the exception of the Active Substance field in section 2.2.1 only. Users 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:

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

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	▼

Applicant

The applicant address details should be selected from SPOR OMS organisation dictionary as outlined in the Providing OMS details 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

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 **clicking Select** or **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/#/>

Find Organisation

Clear Address

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	

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

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

The following fields must be completed in accordance to the letter of authorisation as detailed in the user guidance 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 by clicking the Copy contact details button from previous section button.

1. Type of application

The following examples describe the options to complete the form according to the planned procedure. Selecting one of the round boxes will add further lines while changing the selection will hide the lines as appropriate for the respective procedure.

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 product is also a

Combined Advanced Therapy Medicinal 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.

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

<input checked="" type="checkbox"/> CAT Rapporteur	Title	<input type="text"/>
	First name	<input type="text"/>
	Surname	<input type="text"/>
<input checked="" type="checkbox"/> CAT Co-rapporteur	Title	<input type="text"/>
	First name	<input type="text"/>
	Surname	<input type="text"/>
<input checked="" type="checkbox"/> CHMP Co-ordinator	Title	<input type="text"/>
	First name	<input type="text"/>
	Surname	<input type="text"/>
<input checked="" type="checkbox"/> CHMP Co-coordinator	Title	<input type="text"/>
	First name	<input type="text"/>
	Surname	<input type="text"/>
<input checked="" type="checkbox"/> PRAC Rapporteur	Title	<input type="text"/>
	First name	<input type="text"/>
	Surname	<input type="text"/>

This example is for 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	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>

CVMP Co-rapporteur

Title	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>

1.1.1. A Centralised Procedure

For extension applications as indicated in section 1.3, if the corresponding original eligibility basis no longer exists. Only a Centralised Procedure should be indicated, leaving the eligibility basis tick boxes blank. The eAF does not support this very rare case of difference 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. Type in the first character of the Member States' name. Or use the down the drop-down menu. Click the "+" button for a next line or hit return to confirm the selection.

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

Reference Member State:

Date of authorisation:

Marketing authorisation number:

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

Procedure number:

First use Repeat use (Please also complete section 4.2)

Concerned Member State (specify)	<input type="text" value="Croatia"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Concerned Member State (specify)	<input type="text" value="Finland"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Concerned Member State (specify)	<input type="text" value="Greece"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Concerned Member State (specify)	<input type="text" value="United Kingdom"/>	<input type="button" value="+"/>	<input type="button" value="-"/>

Proposed/Agreed common renewal date:

In case of Repeat -use Procedure the wave information is no longer required.

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)

Concerned Member State (specify)	Croatia	+	-
Concerned Member State (specify)	Finland	+	-
Concerned Member State (specify)	Greece	+	-
Proposed/Agreed common renewal date	2020-08-14		

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. Tick **Yes** to display the data fields:

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
<input style="width: 50px;" type="text"/>	<input style="width: 30px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>

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

2.1. Names(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 is populated automatically if the button in section 1 has been **clicked**.

Any changes you want to apply must to be executed in section 1 first and this in turn correctly populates this section.

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:	Units:	+	-
200	mg	+	-
<small>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</small>			
Full name of the active substance(s) (including salt or hydrate, if applicable):			
IBUPROFEN (LYSINE)			
<small>Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety</small>			
Add Active Substance(s)			

Strength:	Units:	+	-
20	mg	+	-
<small>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</small>			
Full name of the active substance(s) (including salt or hydrate, if applicable):			
CAFFEINE			
<small>Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety</small>			
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 fields: "ATC code" and "Group". The "ATC code" field is a dropdown menu with a list of options: "N05", "N05 (PSYCHOLEPTICS)", "N05A (ANTIPSYCHOTICS)", "N05AA (Phenothiazines with aliphatic side-chain)", "N05AA01 (chlorpromazine)", "N05AA02 (levomepromazine)", "N05AA03 (promazine)", and "N05AA04 (acepromazine)". 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 visible next to the dropdown menu. At the bottom of the form, 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 reduce the text appropriately.

It is advisable to know the ATC code in advance as the search tool may not display the entire 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 the Declaration section" it is not possible to edit the following data fields. If you need to correct an error, go back to Declaration section.

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

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:	Units
200	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:	Units
20	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.

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

Use the dropdown field to open the search menu. 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](#).

Repeat the routes field using the "+" and/or "-" buttons.

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

The screenshot shows a user interface for selecting a route of administration. At the top, there is a label 'Route of Administration' followed by a search input field containing the text 'ora'. To the right of the search field are two circular buttons: a plus sign (+) and a minus sign (-). Below the search field is a list of standard terms from the European Pharmacopoeia. The terms are: 'Intravesical use', 'Intravitreal use', 'Laryngopharyngeal use', 'Nasal use', 'Ocular use', 'Oral use', and 'Oromucosal use'. The 'Ocular use' option is currently selected and highlighted in blue. To the right of the list is a 'Select' button. The list is enclosed in a dotted border, and there are small up and down arrow icons on the right side of the list area.

2.2.3. Container, closure and administration device(s)

Include a description of material from which it is constructed. Use the current list of standard terms - European Pharmacopoeia.

Provide details for each of the pack sizes that are planned for marketing. The package sizes fields are can be repeated using the "+" / "-" button.

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

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

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	<input type="text" value="Blister"/> <input type="button" value="+"/> <input type="button" value="-"/>
Material	<input type="text" value="HDPE"/>
Closure	<input type="text" value="Child-resistant closure"/> <input type="button" value="+"/> <input type="button" value="-"/>
Administration Device	<input type="text"/>

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

2.2.3.5 Proposed storage conditions

2.2.3.6 Proposed storage conditions after first opening

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

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

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 applies 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 **clicking** the **Add Selected** or **Remove All** buttons.

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 right, there are '+' and '-' buttons. Below them is a yellow tooltip that says "Click to create selected member states." In the center, there are three buttons: "Add All", "Add Selected", and "Remove All". The "Add Selected" button is highlighted with a red box. To the left of these buttons is a white tooltip that reads: "The button 'Add All' should not be used as in that case the RMS will not be added." Below the buttons is a list of five member states, each with a dropdown menu and '+' and '-' buttons:

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

The adjustment of the list can easily be achieved by deleting single Member States **clicking** the - button.

2.4. Marketing authorisation holder / contact persons / company

Select from 2 options: Centralised Procedure and National Procedures in section 1.1. It is not possible to change the selection in this section. Copy address details from the Declaration section by **clicking** on one of the following buttons.

Copy contact details from Declaration Section

Copy address from above address details

Copy contact details from 2.4.1 Section

2.4.1. Proposed responsible marketing authorisation holder/person

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 simplify data entry a button to insert contact details from Declaration section is available. To add the Member States selected in that section **click 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 [dropdown] + -

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 [input]

For MRP/DCP/National procedure; The Member State field allows 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 and it will be expected that all relevant member states have the same marketing authorisation holder contact person.

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 Germany [dropdown] + -

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 [dropdown]

Telephone 0049 228 99 307 9999

E-mail Bill.miller@bfarm.de

Purchase order(PO) number

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

If the fees have not been paid in advance and an invoice is going to be sent 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 a 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

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 Qualified Person in EEA for Pharmacovigilance can be increased 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 needs 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 entire dossier must be consistent regarding 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 available so applicants who have multiple manufacturers doing batch releases can include details of, for example, which packaging the manufacturer is responsible for. This is an optional field that can be left blank if it is not required.

The following screens illustrate the principle of the two options 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:- Administrative and manufacture address(es) are the same

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:

+
-

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/omswil/#/>

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) [\(Annex 5.6\)](#)

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

For additional authorised manufacturer’s data fields can be repeated, where required, using the “+” / “-” buttons:

Any manufacturer responsible for batch release in the EEA should be listed under section 2.5.1 of the application form. This is the only section where this information should be provided. 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/omswi#!/>

Find Organisation
Clear Address

Company name	<input style="width: 95%;" type="text"/>
Admin Office Address	<input style="width: 95%;" type="text"/>
	<input style="width: 95%;" type="text"/>
	<input style="width: 95%;" type="text"/>
City/Locality/Town/Village	<input style="width: 95%;" type="text"/>
Admin Office State	<input style="width: 95%;" type="text"/>
Admin Office County	<input style="width: 95%;" type="text"/>
Postcode	<input style="width: 95%;" type="text"/>
Admin Office Country	<input style="width: 95%;" type="text"/>
Admin Office Telephone	<input style="width: 95%;" type="text"/>
Admin Office E-mail	<input style="width: 95%;" type="text"/>

+
-

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	<input style="width: 95%;" type="text"/>
Manufacturing Facility Address	<input style="width: 95%;" type="text"/>
	<input style="width: 95%;" type="text"/>
	<input style="width: 95%;" type="text"/>
City/Locality/Town/Village	<input style="width: 95%;" type="text"/>
Manufacturing Facility State	<input style="width: 95%;" type="text"/>
Manufacturing Facility County	<input style="width: 95%;" type="text"/>
Postcode	<input style="width: 95%;" type="text"/>
Manufacturing Facility Country	<input style="width: 95%;" type="text"/>
Manufacturing Facility Telephone	<input style="width: 95%;" type="text"/>
E-mail	<input style="width: 95%;" type="text"/>

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)

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

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

A free text field is included to add a description of the partial product (e.g. vial with solvent, vial with powder, solvent etc. can be included to indicate which part of the product a specific manufacturer produces. This field is optional.

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 it is 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 is 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.

If the site is outside the EEA provide the following information:

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 in 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 in the application 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 in 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/oms/wi/#/>

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 in the 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

Use the drop-down menu to select between the manufacturing steps performed.

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_004706.pdf

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	+
<input type="text"/>	-

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) (including bioavailability and bioequivalence studies) included in the application or used for the validation of blood product manufacturing processes.

For each contract company, state where analytical tests are performed and where clinical data is collected and open data fields by clicking the **Add Study** button.

In cases where multiple studies have been performed by only 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 can be repeated using the "+" / "-" buttons.

The screenshot shows a web form interface. At the top right, there are two buttons: "Add Study" and "Delete Study". Below these, there is a section for adding or deleting a study. It contains a "Title of study" label followed by a large text input field. To the right of this field are two small buttons: "+" and "-". Below the title field are two smaller text input fields labeled "Protocol code" and "EudraCT number".

Below the study section, there is a section for adding or deleting a company. It contains two buttons: "Add Company" and "Delete Company". Below these buttons are several text input fields: "Company name", "Address 1", "Address 2", "Postcode", "Country" (with a dropdown arrow), "Telephone", "Telefax", and "E-mail". Below the "Address 2" field, there is a note: "(name of: city, town, village, etc)". At the bottom of this section is a large text area labeled "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)'. Additional information on the active substance including all excipients in a separate list can be added.

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

In centralised procedures multiple strengths can be included on one application form. For this purpose the following frame of strength needs to be duplicated. In case of national procedures only 1 strength per pharmaceutical form can be mentioned in 1 MAA form.

In the free text field, 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)	equal to 200 mg	Ph.Eur.
calculated as		
Name of active substance	Quantity / Unit	Reference / Monograph Standard

Operator dropdown menu options: approximately equal to, equal to, equivalent to, less than, less than or equal to, more than, more than or equal to, quantity sufficient, range.

The quantity is built with an operator, a value and the unit of measure: equal to 20 mg. A reference can also be added, e.g. Pharm.Eur. If you select range as the quantity operator, the value field will be split into a lower and upper value.

Quantity / Unit
range From: [] To: []

The quantity operator 'quantity sufficient' is defined as 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 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
<input type="text"/>	<input type="text"/>
	<div style="border: 1px solid black; padding: 2px;"> <p>approximately equal to</p> <p>equal to</p> <p>equivalent to</p> <p>less than</p> <p>less than or equal to</p> <p>more than</p> <p>more than or equal to</p> <p>quantity sufficient</p> <p>range</p> </div>

If multiple active substances have been selected in the 'Declaration' section, these are automatically displayed.

Delete any unnecessary fields displaying incorrect terms using  button.

Process steps in case of a missing substance name/term

If you need to request a missing substance to complete an eAF, submit a request for substance insertion with the corresponding SmPC using the [EMA Service Desk portal](#).

To request a new term (e.g. pharmaceutical form or unit of measurement) or a request for an update of an existing term in order to complete the eAF, please submit a request through the [SPOR Portal](#) and provide 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: 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 available [here](#).

In case of declaration of overages it is mandatory to complete this section:

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

Active Substance	Overage	+
<input type="text"/>	<input type="text"/>	-
<p><i>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</i></p>		
Excipient	Overage	+
<input type="text"/>	<input type="text"/>	-
<p><i>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</i></p>		

Press the “+” button and select from the drop-down menu the substance as included in the composition then add the overage value. Use a full stop to indicate decimal numeric values.

2.6.2. List of materials of animal and/or human origin contained/ 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 with regards to the veterinary marketing authorisation 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.

Declaration and signature

The following example is provided to illustrate some principles in this section which are entirely the same human medicinal products.

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/oms/wj/#/>

Applicant

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

E-mail

1. Type of application

The following examples describe the options to complete the form according to the planned procedure. Ticking 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))

<input checked="" type="checkbox"/>	CVMP Rapporteur	Title	<input type="text"/>
		First name	<input type="text"/>
		Surname	<input type="text"/>
<input checked="" type="checkbox"/>	CVMP Co-rapporteur	Title	<input type="text"/>
		First name	<input type="text"/>
		Surname	<input type="text"/>

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 I of Regulation (EC) NO 1234/2008, 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	<input type="text"/> <div style="border: 1px solid black; padding: 2px;"> 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 </div>	<input type="button" value="+"/> <input type="button" value="-"/>
Application for	<input type="text"/>	<input type="button" value="+"/>

MRL	Target Tissues	<input type="button" value="+"/>
2 microgram/litre	Milk	<input type="button" value="-"/>

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

substance(s)

BENZYPENICILLIN SODIUM

Marker residue

Other Provisions For bovine milk only

Therapeutic classification

Animal species Bovine

MRL	Target Tissues	<input type="button" value="+"/>
2 microgram/litre	Milk	<input type="button" value="-"/>

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

- Yes
- Not applicable

substance(s)

Species

Remarks

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.

The form requires excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given. If this is the case, tick "not applicable" and provide justification in the "remarks" field.

In case an MRL application has been submitted to the EMA and the procedure is still pending, tick **Yes** and provide details on the application including submission date in this 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 Declaration and signature and is populated automatically.

If the box is ticked provide Annex 5.18.

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

2.1.2. Active substance(s)

The declaration of the active substance is populated automatically if the button in section 1 is clicked.

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 ATC Code (select vet specific terms) and Group fields are linked and both should be completed. It is recommended to key in the third or fourth level description. However, the description of the third or fourth level of the ATC vet code may be too long to include completely.

The screenshot shows a form titled "2.1.3 Pharmacotherapeutic group (Please use current ATC vet code) & 2.1.4 Target Species". It features two "Target species" dropdown menus, one currently set to "Bovine, including buffalo" and another to "Beef cattle". Below these is an "ATC code" dropdown menu. A list of ATC codes is displayed, with "QJ01C" selected. The list includes: "QJ01C (BETA-LACTAM ANTIBACTERIALS, PENICILLIN)", "QJ01CA (Penicillins with extended spectrum)", "QJ01CA01 (ampicillin)", "QJ01CA02 (pivampicillin)", "QJ01CA03 (carbenicillin)", "QJ01CA04 (amoxicillin)", and "QJ01CA05 (carindacillin)". A "Select" button is next to the list. The "Group" field is set to "Penicillins with extended spec". A note at the bottom states: "If no ATC vet code has been assigned, please indicate if an application for the ATC vet Code has been made".

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.

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

The screenshot shows a form titled "2.2.2 Route(s) of administration (click 'find' to use the current list of standard terms - European Pharmacopoeia)". It features a "Route of Administration" dropdown menu set to "Intradermal use" and a "Target species" dropdown menu set to "Bovine, including buffalo". A red box highlights the dropdown arrow for the "Route of Administration" field.

The drop-down menu 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](#). Repeat the routes if required using the "+" / "-" 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)

Provide details for each of the pack sizes planned for marketing. Repeat the package sizes fields if required using the "+" / "-" buttons as displayed in the example above.

In this example highlighted fields indicate the mandatory section to be input as a minimum. The highlight appears after **clicking** 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, request the term as soon as possible 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 as 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.

2.5. Manufacturers

For details refer to the human products application form.

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.

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 if 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 on 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

Type IA_{TM}

Grouping of variations

Type IA

Including a line extension³ [?](#)

Type IB unforeseen² [?](#)

Worksharing

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 click Add all to add all member states at once. To remove them all in one go by click Remove all. It is also possible to remove single member states line by line.

Select the type of variation next. In case of variations other than IA/IAIN additional information about the scope of the variation should be indicated.

Please note that the selection in this section will directly impact the scopes available in section 3 and any changes in section 1 will delete the selected scopes in section 3.

If grouping is selected in section 1, multiple scopes can be selected in section 3. It is possible to add more scopes by using the dropdown menu, by +/- buttons or using a clone button.

If single is selected in section 1, only one scope can be selected in section 3.

For example, if procedure type Type IA has been selected in section 1, only scopes applicable type Type IA will be available for selection in section 3.

Type of Application (tick all applicable options)

Single variation

Grouping of variations

Including a line extension³ ⓘ

Worksharing

Type IA_{TN}

Type IA

Type IB unforeseen² ⓘ

Type IB

Type II

Type II Art. 29⁴ ⓘ

Type of Application (tick all applicable options)

Single variation

Grouping of variations

Worksharing

Type IA_{TN}

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

Following Urgent Safety Restriction

Quality

Annual variation for human influenza vaccines

Non-food producing target species

Other

Additional information on the scope is requested.

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

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

2. Products concerned by this application

The variation form allows you 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 within a structured manner, this section has completely been revised. The principles of that construct are explained in the following example:

The screenshot shows a variation form with several fields and controls. Callouts provide the following information:

- Variation No.:** The Variation number will be optional for NP, and will be mandatory for MRP/DCP.
- Active Substance:** 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):** Adds a blank row/removes a row.
- MA Number(s):** +/- 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:** Free Text Field. Pull down for selecting one of the previous entries. This is a mandatory Field.
- MA Holder Name(s):** Free Text field. Pull down for selecting one of the previous entries. This is a mandatory Field.
- Pharmaceutical Form:** This is a controlled list. User will be able to select from drop down list. This is a mandatory field.
- Strength:** Free text field. Pull down to select a previous entries. This is a mandatory field.
- Unit:** This is a controlled list. User to select from drop down list. This is a mandatory field.
- Clone Button:** 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					
Active Substance	IBUPROFEN (LYSINE)					
Member State	Germany					
MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
1234.00.00	Advil	Company	Tablet	200	mg	
1234.00.01	Advil forte	Company	Tablet	400	mg	
Member State	Austria					
MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
PVK 1234	Advil	Company	Tablet	200	mg	
PVK 1235	Advil forte	Company	Tablet	400	mg	
Member State	Netherlands					
MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
RVG 120034	Advil	Company	Tablet	200	mg	
RVG 120035	Advil forte	Company	Tablet	400	mg	
Footnote	This describes all employed strenghts					

3. Types(s) of changes (s)

Select the changes you want to submit: The variation items according to EU Commission Guidelines will be selectable from RMS using a dropdown menu **clicking Show Variation Lists**.

The selections in section 1 (single/grouping and the procedure type) is reflected above the dropdown menu to remind the user of their previous selections. It is very important to note that any change in Type of Application in section 1 will delete any selected variation in section 3.

3. TYPES OF CHANGE(S)

Variations included in this application: Please follow instructions below to add variation *fill Section 1 of the form first, so as for the proper variations to be loaded. Navigate through the dropdown lists, in order to show the variation.*

You can select the variation by clicking the relevant checkbox of the variation box.

Note: Any change in Type of Application in Section 1, will delete any selected variation!

Variation	Selected
-----------	----------

Show Selected Variations

Show Variation Lists

Single Variation is being selected. You may choose only type IA variation changes and only one scope.

	▼
A. ADMINISTRATIVE CHANGES	
B. QUALITY CHANGES	
C. SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES	
D. PMF / VAMF	

Grouping of variations is being selected. You may choose variation changes of types that are selected on section 1.

B. QUALITY CHANGES	▼
B.I ACTIVE SUBSTANCE	▼
B.I.b) Control of active substance	▼
B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reag	▼
	▼
B.I.b.1.a Tightening of specification limits for medicinal products subject to Official Control Authority Batch Release	
B.I.b.1.b Tightening of specification limits	
B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method	
B.I.b.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	
B.I.b.1.e Deletion of a specification parameter which may have a significant effect on the overall quality of the active sub	
B.I.b.1.f Change outside the approved specifications limits range for the active substance	
B.I.b.1.g Widening of the approved specifications limits for starting materials/intermediates, which may have a significant	
B.I.b.1.h Addition or replacement (excluding biological or immunological substance) of a specification parameter with it	
B.I.b.1.i Where there is no monograph in the European Pharmacopoeia or the national pharmacopoeia of a Member Stat	▼

Drill down the selection to select the variation scopes. If only one option is applicable/available according to previous selections, it will be automatically ticked and cannot be manually changed.

For grouped variations there are +/- buttons and clone button to copy/add multiple scopes.

Depending on the selections, implementation date/note box will be available. If Art. 5 is applicable, the box will be automatically ticked and cannot be manually changed.

The conditions and documentation have been integrated into the scope in RMS and are now part of the scope selection. Only relevant conditions and documentation for each scope will be shown. Applicable conditions and documentation can be selected using a tick box. If any of the options is not applicable/not met, a mandatory free text field must be used to provide justification or further details. The free text fields are always available and can be used to provide additional, relevant information as previously when this information was provided as a separate annex to the application form.

Example of 'single Type IA'

3. TYPES OF CHANGE(S)

Variations included in this application: Please follow instructions below to add variation *fill Section 1 of the form first, so as for the proper variations to be loaded. Navigate through the dropdown lists, in order to show the variation.*
You can select the variation by clicking the relevant checkbox of the variation box.
Note: Any change in Type of Application in Section 1, will delete any selected variation!

Variation	Selected
A.5.b	1

Show Selected Variations

Show Variation Lists

Single Variation is being selected. You may choose only type IA variation changes and only one scope.

select	A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release
<input checked="" type="checkbox"/>	
Procedure Types:	IA <input checked="" type="checkbox"/> IB <input type="checkbox"/>
Implement. Date:	<input type="text"/>
Implement. Note:	<input type="text" value="6 months after approval"/>
Conditions:	
<input checked="" type="checkbox"/>	The manufacturing site undergoing the name and/or address change and all manufacturing operations must remain the same.
Note:	<input type="text"/>
Documentations:	
<input checked="" type="checkbox"/>	Copy of the modified manufacturing authorisation, if available; or a formal document from a relevant official body (e.g. Chamber of Commerce, or if not available, from a Regulatory Agency) in which the new name and/or address is mentioned.
Note:	<input type="text"/>
<input type="checkbox"/>	If applicable, amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate), including revised product information as appropriate.
Note:	<input type="text" value="Not applicable"/>

Example of Grouping of Type IB and Type II

Variation	Selected
B.II.b.1.a	1
C.I.11.b	1

Show Selected Variations

Show Variation Lists

Grouping of variations is being selected. You may choose variation changes of types that are selected on section 1.

select <input checked="" type="checkbox"/>	B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site	+ - Clone
Procedure Types: IAIN <input type="checkbox"/> IB <input checked="" type="checkbox"/>		
Conditions:		
<input checked="" type="checkbox"/> Site appropriately authorised (to manufacture the pharmaceutical form or product concerned). Note: <input type="text"/>		
<input checked="" type="checkbox"/> Satisfactory inspection in the last three years by an inspection service of one of the Member States of the EEA or of a country where an operational Good Manufacturing Practice (GMP) mutual recognition agreement (MRA) exists between the country concerned and the EU. Note: <input type="text"/>		
Documentations:		
<input checked="" type="checkbox"/> Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 0B format for veterinary products, as appropriate). Note: <input type="text"/>		
<input checked="" type="checkbox"/> Proof that the proposed site is appropriately authorised for the pharmaceutical form or product concerned. Note: <input type="text"/>		
<input checked="" type="checkbox"/> The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form. Note: <input type="text"/>		
select <input checked="" type="checkbox"/>	C.I.11.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required*	+ - Clone
Procedure Types: II <input checked="" type="checkbox"/>		

Once you have made your selection(s) you can close the list /collapse the list to show only the selected items by **clicking Show Selected Variations**.

If you wish to change the selections, simply unselect the selected scope and if necessary to show the selection dropdown menu, click **Show Variation Lists**.

It is essential to select the scopes by ticking the **Select** tick box. If this is not done the scope is not selected and any change in the dropdown menu will delete the changes you have made. Always ensure that the selected scope is shown in the summary box before proceeding to select more scopes/moving to next sections.

Depending from the items you have to complete, the following table describes 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 work sharing or grouping procedures affecting more than one product.

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	<input type="text"/>	<input type="text"/>
EU or National ASMF reference number ¹²	<input type="text"/>	<input type="text"/>

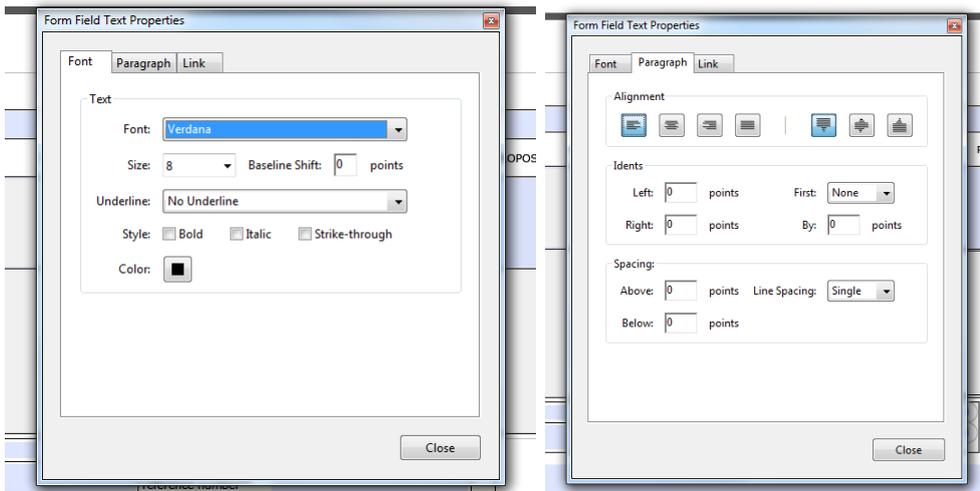
OTHER APPLICATIONS¹³

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. 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, the pop-up will provide 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 the rtf format. Copy and paste the formatted text in to the present and proposed fields.

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

A complex table as part of the present and proposed section in the variation eAF cannot be included. When 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) click the left mouse button into the cell. Select from your file share an image as appropriate. If the size needs to be adjusted, please provide the image as an annex as the image cannot be enlarged.

Additionally, 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.

PRESENT ^{9,10}	PROPOSED ^{9,10}
<p>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/oms/w/#/.</p> <p>Find Organisation Clear Address</p>	<p>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/oms/w/#/.</p> <p>Find Organisation Clear Address</p>
<p>Company name</p> <p>Address</p> <p>City/Locality/ Town/Village</p> <p>State</p> <p>County</p> <p>Postcode</p> <p>Country</p> <p>OrgID</p> <p>LocID</p> <p>Telephone</p> <p>E-mail</p>	<p>Company name</p> <p>Address</p> <p>City/Locality/ Town/Village</p> <p>State</p> <p>County</p> <p>Postcode</p> <p>Country</p> <p>OrgID</p> <p>LocID</p> <p>Telephone</p> <p>E-mail</p>

Depending on the role of the company of which the address needs 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.

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

This section is only displayed if variation type IB or 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

4.b Type IB and Type II variations – Paediatric Requirements

This section is only displayed if variation type IB or type II has been selected. This section can be flagged out, if not applicable

4.b Type II variations - Paediatric requirements i

(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:

<input type="checkbox"/> PIP Decision Number ¹⁵	+	-	i
<input type="checkbox"/> 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

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

This section is only displayed 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:	
<input checked="" type="checkbox"/>	Summary of product characteristics
<input type="checkbox"/>	Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation ¹⁷
<input type="checkbox"/>	Labelling
<input checked="" type="checkbox"/>	Package leaflet
<input type="checkbox"/>	Mock-ups ¹⁸
<input type="checkbox"/>	Specimens ¹⁸

Declaration of the applicant

Signature

Complete these sections in the same way as previous forms.



RENEWAL FROM

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

HUMAN VETERINARY

National authorisation in MRP/DCP
 EU authorisation
 National authorisation only

Is the product currently marketed? Yes No

Invented Name

Member state

Pharmaceutical form(s)³

Strength(s)³ Units

Active Substance

[Click here to populate data in section 3](#)

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.)

Provide further product characteristics:

ATC code

Group

If no ATC code has been assigned, please indicate if an application for ATC code has been made

Route of Administration³

Member state

MA Number³

When selecting "Veterinary" this section is adapted to add the target species and it is likely the ATC vet code and respective group are chosen (although not explicitly mentioned):

Target Species³

ATC code

Group

If no ATC code has been assigned, please indicate if an application for ATC code has been made

The name and address of the Marketing Authorisation Holder will be handled in the same way as in other forms.

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 ?

+ -

Copy contact details from previous Section

Add All Add Selected Remove All ?

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:

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/#/>

Company name	<input type="text" value="BfArM-Pharma"/>
Admin Office Address	<input type="text" value="Kurt-Georg-Kiesinger Allee 3"/>
	<input type="text"/>
	<input type="text"/>
City/Locality/Town/Village	<input type="text" value="Bonn"/>
Admin Office State	<input type="text"/>
Admin Office County	<input type="text"/>
Postcode	<input type="text" value="53121"/>
Admin Office Country	<input type="text" value="Germany"/>
Admin Office Telephone	<input type="text" value="0049 228 99 307 9999"/>
Admin Office E-mail	<input type="text" value="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/#/>

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

The free text field 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. Leave this field blank if not required.

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	BfArM-Pharma
Address 1	Kurt-Georg-Kiesinger-Allee 3
Address 2	Bonn <small>(name of: city, town, village, etc)</small>
Postcode	53175
Country	Germany <input type="text" value="▼"/>
Telephone	+492282079999
Telefax	<input type="text"/>
E-mail	bill.miller@bfarm.de

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

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

If

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

3. Quantitative and qualitative composition in terms of the active substance(s) and the excipient(s)

This section is 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	
		+ -
		+ -
		+ -

If you formatted text is to be used 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 displayed 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 on your selections, 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 EU⁵

Declaration and Signature

Complete this section in the same way as previous forms.

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 +