



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Harmonised Technical Guidance for Using of Electronic Application Forms (eAF) for human and veterinary medicinal products in the EU

Version 1.1

September 2015

Remark to the reader

This document reflects the current state of knowledge and will be subject to future updates to take new information on-board. Therefore, it is important that comments are feed back to the eAF User Group by e-mail (eaf@ema.europa.eu).

Screenshots in this document have been taken in most cases from the eAF versions 1.17. In some cases the guidance takes already advantage of the upcoming version 1.18, which will replace version 1.17 early in August 2015. It would not be possible to match this guidance document with exactly one version of the eAF. However, very recent information about new functionalities or changes can be retrieved from the release notes at <http://esubmission.ema.europa.eu/eaf/index.html>.

Document History

Change Record

Version	Author(s)	Comments
1.0	eAF User Group	This document has been prepared by the sub-group on guidance and information of the eAF User Group in collaboration with CMDh and CMDv
	eAF User Group	First draft for revision, made the document in line with reported corrections, improved consistency with the Q&A on eAF and aligned with changes of the eAFs version 1.18
1.1	eAF User Group	Indicating acceptance of an image of a text snippet for EMA, additional advice for optimising the PDF file for eCTD purpose, minor editorial changes after review

Reviewers

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

Distribution

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

Coming into Operation

Version	Date in operation	Comment
1.0	July 2015	This is a technical guidance document and 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 a interim update. A next update will follow ince the eAF version 1.19 is published.

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

PURPOSE AND GENERAL TECHNICAL RULES

Purpose of the document

It will be mandatory to use the electronic application form as a part of your submission package from 1 July 2015 for all Centralised Procedure submissions (Human and Vet) (see <http://esubmission.ema.europa.eu/esubmission.html>).

In case of a MRP/DCP or National application all Member States accept the eAF. It will be mandatory to use eAFs for all European procedures from 1 January 2016. After this date the paper MS Word application forms should no longer be used.

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

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

In addition, a Question & Answer document has been published intended to cover anticipated questions relating specifically to the electronic forms. In addition, field level help is also available in the eAF by moving the mouse pointer over each field of the electronic forms. These are called 'tooltips'.

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

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

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

- If you encounter an issue with a specific field, please refer to the 'Known Issues' in the Release Notes for the specific form. These may be found on the [eAF pages](#) of the EMA's eSubmission website. New issues may be raised via eAF service desk (eaf@ema.europa.eu).

- If the information cannot be included in the form, please review any workaround solutions provided in the release notes or use an annex. If still not all information can be included, please contact us at eaf@ema.europa.eu.
- In case of any further technical queries, please contact us at: eaf@ema.europa.eu


Access to the forms and news on updates

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

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

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

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

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

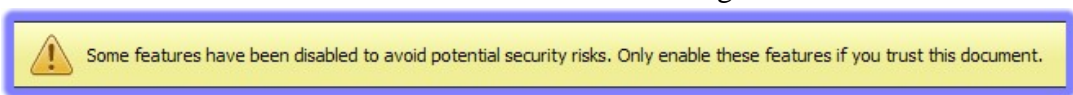
Requirements on Adobe Reader and IT security settings

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

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

In principle, it should not be a matter of Linux or Mac OS environment but rather whether the Adobe reader and internet connection are accessible.

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



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

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

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

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

Opening the form

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

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

The average response times for how long it takes to open an 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.

The average response times for the forms can be retrieved from [here](#). The EMA is constantly working to improve the performance of the forms. If you have any suggestions how to do this, please send your proposals to eAF@ema.europa.eu.

Navigation in the forms

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

TABLE OF CONTENTS	
DECLARATION AND SIGNATURE	
1. TYPE OF APPLICATION	
1.1	This application concerns
1.2	Orphan medicinal product information
1.3	Application for a change to existing marketing authorisation 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 following 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 PARTICULARS	
2.1	Name(s) and ATC code
2.2	Strength, pharmaceutical form, route of administration, container

2. MARKETING AUTHORISATION APPLICATION PARTICULARS	
2.1 NAME(S) AND ATC CODE	
2.1.1	Proposed <small>Click to return to Table of Contents.</small> inventive name of the medicinal product in the European Union Norway:


Integration of the forms into dossier

Only the final signed PDF created using the electronic forms should be submitted in the relevant part of the dossier. Indeed, the XML data can be extracted from the pdf file. This action will be performed by agencies when receiving the pdf form. Therefore, it is not necessary neither required to provide 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.

Technically we can add bookmarks and hyperlinks in pdf. However in eAF we are not allowed to add any attachments/hyperlinks to the document. But user can do bookmarks in eAF if they wanted to use that way to fill the application form easier once data entry has been locked. Otherwise, validation errors will be stated.

If the eAF.xml is stored in the CTD (eCTD or NeeS) 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. To avoid confusion, this functionality maybe removed as a future enhancement to the electronic forms.




Export of the XML data

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

1. The XML output can be used in other IT systems (for example receiving regulators can use this data to populate their systems).

2. Previously exported XML outputs may be imported into a new version of the form, as long as the underlying .xsd (XML Schema Definition) has not changed in the interim.
3. The XML file is much smaller than the PDF file so may be considered more suitable for archiving.

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

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


Note:

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

Import of the XML data

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

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

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

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

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

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

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

Update of the XML data

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

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

When any of the eAFs are opened via a computer that is connected to the internet, an automated version check is performed to inform the user if a more recent version of the eAF is available for download. Drop down terms are always updated when opening the form, but in case the user did not close and open the form for longer time in the meantime there might be updated list available. So user can click on "Update lists" button update the list. You will find the button at the far end

of the form: 

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

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

Note: The revision number of the form reflects the paper form on which the particular form is based. Please see the first page of each form for the precise revision number of the form.

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. We are currently working on finding best solution to implement structured data fields throughout the form wherever appropriate.

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



The screenshot shows a form interface. At the top right, there is a small grey box containing a '+' and a '-' button, both highlighted with red rectangles. Below this, the text "For each type of pack give:" is displayed. Underneath, there is a light blue horizontal bar representing a data field. To the left of this bar is the text "Package Size 1". To the right of the bar is another grey box containing a '+' and a '-' button, also highlighted with red rectangles.

The eAFs are intelligent forms where a lot of business rules have been built in and some sections

are only displayed depending on previous selections. It is not necessary or even possible to delete not required sections.

Once entered in the form, information in fields will remain visible when the corresponding fields are un-ticked. To reduce the risk of accidental data loss it was decided to ensure sections completed then hidden would persist. Data may only be deleted on a field by field basis by users.

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

In the forms some 'copy from xx' buttons are introduced to allow copying information from previous sections to reduce the need to re-enter data multiple times. We are also working very hard to further improve the usability of the forms as much as possible, in order for these changes to meet your needs, please provide us your proposals for implementation of certain sections/fields via eAF@ema.europa.eu.

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.

Please inform eaf@ema.europa.eu if there are certain character sets that you would hope to be supported in any future implementation.

Providing address details

Address details should be provided in the eAF in a harmonised way – the same address should be similarly filled when it is required in different sections of the forms. The version 1.18 of the forms will allow some auto-population of the address details from previous sections to improve usability.

"Address 1" field is to enter building name/number or street

"Address 2" field is to enter city/town.

It is very important to fill in both, Address 1 and Address 2 fields. The Address 2 field was previously called 'city'. Following a large number of queries, saying that the address was not in a city but in a town, borough, area etc. it was decided to replace City by Address 2. Address 2 field should be used to provide the 'postal location i.e. the city element of the address. This can be for example; village/town/city, etc. Street and number should always enter in Address1 and city/town/village should be entered in Address 2 field.

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

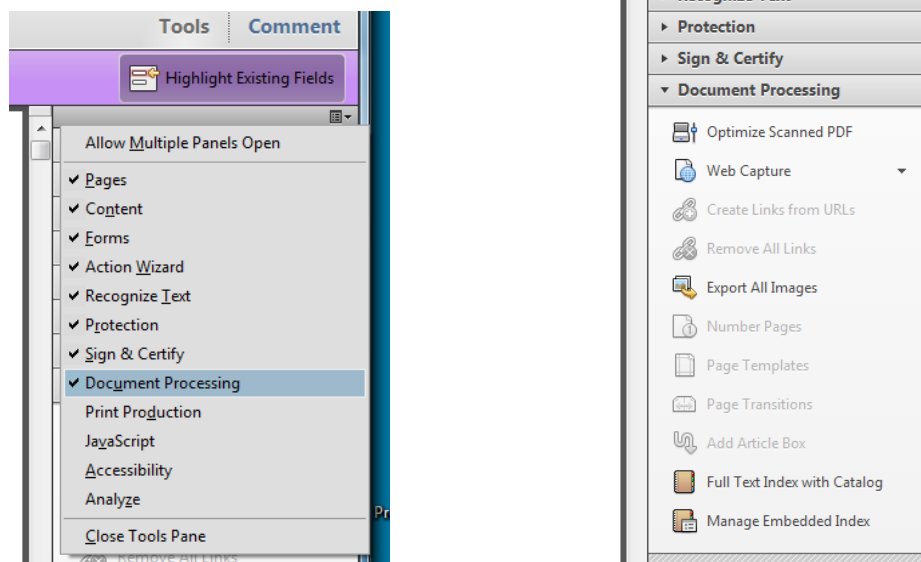
File Naming Convention

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](#) (Appendix 2: Directory / File Structure for Module 1 (Sequential Number 8)).

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 catalogs and managing embedded indexes.



Validating the form

You can choose to click the **Validate Form** button, which is on the last page of each of the eAFs as soon as you open the document. Once the forms are validated all mandatory fields are highlighted (in yellow or red). Validation can be executed as often as needed. The resulting list will provide links to the respective section where corrections or additional entries are needed.

If you are providing a separate annex to the application form instead of entering the information directly in a particular mandatory field, enter a space, N/A (not applicable) or a full stop to bypass the current minimum validation requirements. If the field does not allow text/full stop ignore the validation error and note this in the application cover letter.

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

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

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

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

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

Applicants are encouraged to contact EMA technical help (eaf@ema.europa.eu) 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 eaf@ema.europa.eu for consideration.

Signature

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

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

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

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

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

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

Important note: The inclusion of the signature (image) will lock the form and will prevent further data entry. Therefore, the inclusion of that image should be the very last step completing

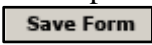
the form. It is strongly recommended to save an un-locked version of the form and to execute the validation of the form prior to including the signature image. However, export of the xml file and re-import into a new eAF pdf file will work as well (see also [section below](#)).

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](#) (Appendix 2: Directory / File Structure for Module 1 (Sequential Number 8)). 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.

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

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

MAA FORM (human)

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

ADMINISTRATIVE DATA

DECLARATION and SIGNATURE

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

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for veterinary 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 required (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name Wonderpil Extractum

Pharmaceutical Form: Powder and solvent for oral solution

Strength: 200 mg

Active Substance(s): CAPSICUM ANNUUM

Add Active Substance(s)

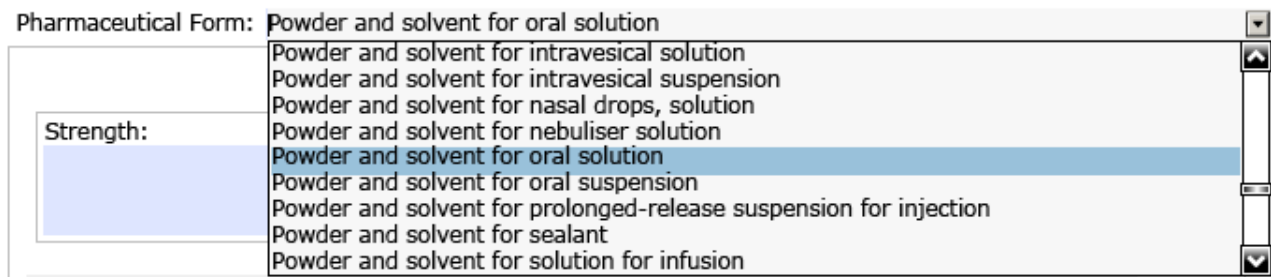
Populate data in section 2.2.1 and 2.6.1

Product (Invented) name

The form allows providing just one product name. In the text field 250 characters are possible to be used. In case of different names and marketing authorisation holders in the concerned member states a separate list needs to be appended to the application form in Annex 5.19.

Pharmaceutical form

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



The screenshot shows a dropdown menu for 'Pharmaceutical Form'. The selected option is 'Powder and solvent for oral solution'. The menu lists several other options, including '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 suspension', 'Powder and solvent for prolonged-release suspension for injection', 'Powder and solvent for sealant', and 'Powder and solvent for solution for infusion'. A 'Strength:' label is visible to the left of the dropdown.

Dropdown field to select, (“Click arrow button”)

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

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

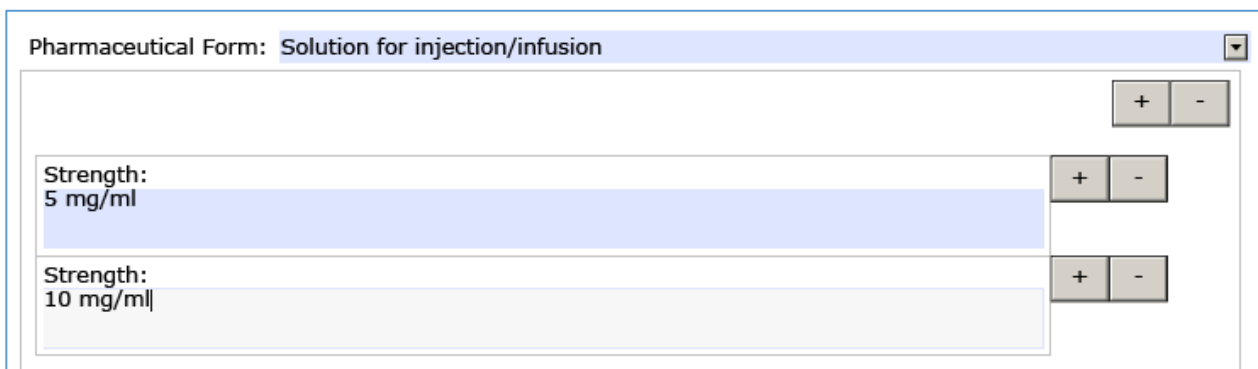
In case the correct term is not available a most appropriate alternative should be selected. Usually, new pharmaceutical form terms can be required in advance by the agency responsible to run the procedure of the new marketing authorization application.

In case of a missing term – as a general rule – in order to complete an eAF, please use the [eAF Term Request Form](#). Once completed, you will need to submit your form via email to mdms@ema.europa.eu

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 and ultimately added to the list for future use. For further guidance please refer to http://esubmission.ema.europa.eu/eaf/5_eAF%20Term%20Request%20Process.ppt

Strength(s)

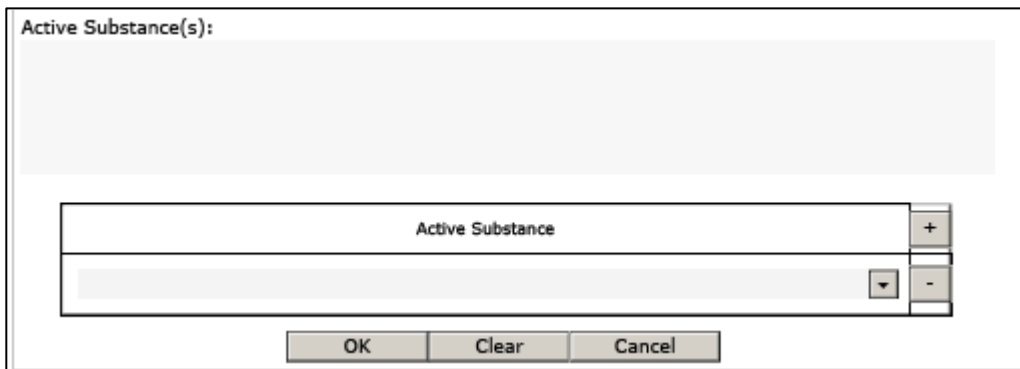
The strength(s) will be entered as text only in a free text field. The units of measurement cannot be selected from a controlled list but should follow usual standard terms as provided by EDQM. In case different strengths are related to different compositions the pharmaceutical product needs to be duplicated. If the composition does not differ duplication of just the datafield for strength needs to be multiplied.



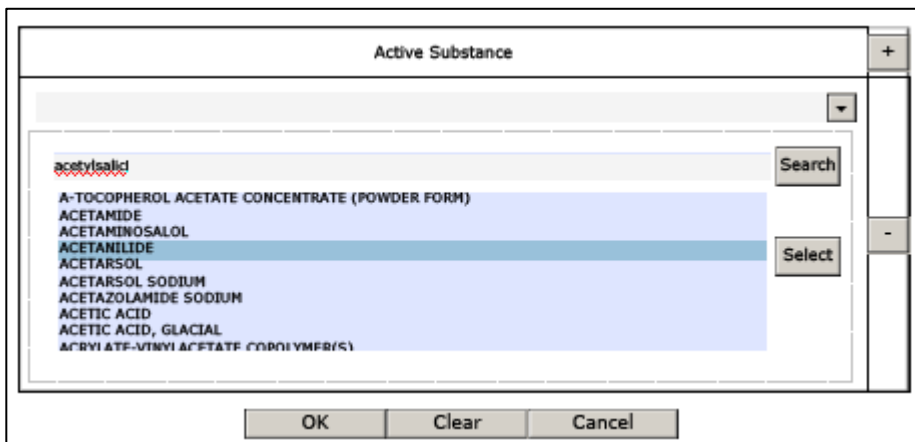
The screenshot shows a form with a 'Pharmaceutical Form' dropdown set to 'Solution for injection/infusion'. Below it, there are two 'Strength' text input fields. The first field contains '5 mg/ml' and the second contains '10 mg/ml'. Each strength field has a '+' and '-' button to its right for adjusting the value.

Active Substance(s)

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

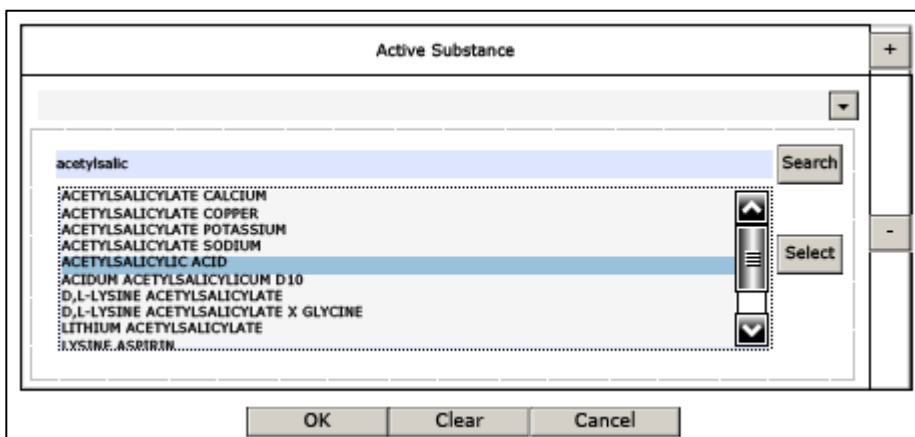


Type in minimum of three characters from the name of the active substance name and click search. If you enter more characters you will receive more accurate results. Scroll through the list and select



Select

Select the correct name and confirm selection by pressing the button



OK

Confirm the result by pressing the button

Add Active Substance(s)

To select another active substance you have to press the button
This procedure needs to be repeated for every additional active substance.

The screenshot below displays the case of two active substances.

The screenshot shows a software interface with two entries for active substances. Each entry consists of a strength field, an active substance name field, and an 'Add Active Substance(s)' button. The first entry has a strength of 200 mg and the active substance is ACETYLSALICYLIC ACID. The second entry has a strength of 10 mg and the active substance is ASCORBIC ACID. There are also '+' and '-' buttons next to the strength fields and a '+' and '-' button at the top right of the interface.

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

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

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

Applicant

Applicant	<input type="text"/>
Title	<input type="text"/>
First Name	<input type="text"/>
Surname	<input type="text"/>
Address 1	<input type="text" value="street name, building number"/>
Address 2	<input type="text" value="city / town"/>
Postcode	<input type="text"/>
Country	<input type="text"/>
Telephone	<input type="text"/>
Telefax	<input type="text"/>
E-mail	<input type="text"/>

Note:

Title field is limited to 10 characters, it corresponds to a title or diploma (e.g. Doctor, DVM...), not the job description.

Address details should be provided in the eAF in a harmonised way – the same address should be similarly filled when it is required in different sections of the forms. The version 1.18 of the forms will allow some auto-population of the address details from previous sections to improve usability.

"Address 1" field is to enter building name/number or street

"Address 2" field is to enter city/town.

It is very important to fill in both, Address 1 and Address 2 fields. The Address 2 field was previously called 'city'. Following a large number of queries, saying that the address was not in a city but in a town, borough, area etc. it was decided to replace City by Address 2. Address 2 field should be used to provide the 'postal location i.e. the city element of the address. This can be for example; village/town/city, etc. Street and number should always enter in Address1 and city/town/village should be entered in Address 2 field.

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

Person authorised for communication, on behalf of the Applicant

The following fields need to be completed in accordance to the letter of authorization as detailed in the USER GUIDANCE.

Person authorised for communication*, on behalf of the Applicant:	
Title	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate.
It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**.

On behalf of the applicant

Title	<input type="text"/>
First name*	<input type="text"/>
Surname	<input type="text"/>
Function	<input type="text"/>
Address 1	<input type="text"/>
Address 2	<input type="text"/>
Postcode	<input type="text"/>
Country	<input type="text"/>
Telephone	<input type="text"/>
Telefax	<input type="text"/>
E-mail	<input type="text"/>
Date	<input type="text"/>
Signatory	<input type="text"/>

* Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4

** Note: if fees have been paid, attach proof of payment in Annex5.1 - see information on fee payments on EMA/CMDh website.

1. TYPE OF APPLICATION

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

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

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

1.1. This application concerns

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

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

1.1.1.1 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

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:

In case of Advanced Therapy Medicinal Products

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

The CAT Rapporteur and Co-Rapporteur are required only in case of a advanced therapy medicinal product

The second example is on veterinary products only:

<input checked="" type="radio"/>	1.1.1 A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)		
<input type="radio"/>	"Mandatory scope" (Article 3(1))		
<input type="radio"/>	"Optional scope" (Article 3(2))		
<input type="radio"/>	"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

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

1.1.2. A Mutual Recognition Procedure

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. Orphan Medicinal Product Information (human only)

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. NAME(S) AND ATC CODE

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

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

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

2.1 NAME(S) AND ATC CODE
2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway: Wonderpil Extractum (Value populated from the "Declaration" section.)
<input checked="" type="checkbox"/> 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.

Note: Annex A and Annex B buttons in the form are not links. Clicking either of the buttons will simply add text ‘See Annex A/B’ in the relevant fields to indicate for the receiving authority that a separate Annex has been added to the application form and is available in the same folder (1.2) where the application form can be found.

2.1.2. Name of the active substance(s)

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

2.1.3. Pharmacotherapeutic group (Please use current ATC code)

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

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

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Select for ATC Code field from the lowest level.

N05
 N05 (PSYCHOLEPTICS)
 N05A (ANTIPSYCHOTICS)
 N05AA (Phenothiazines with aliphatic side-chain)
 N05AA01 (chlorpromazine)
 N05AA02 (levomepromazine)
 N05AA03 (promazine)
 N05AA04 (acenpromazine)

Group

Select for Group field from the third or fourth level description.

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

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

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

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

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

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


DECLARATION AND SIGNATURE



Active Substance(s):
 AMLODIPINE
 VALSARTAN

The chosen active substance(s) is automatically displayed in section 2.6.1 on the ‘Name of active substance field(s)’.

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION	
Name of active substance	
AMLODIPINE	▼
VALSARTAN	▼

If a salt/ester/maleate/monohydrate etc. form is required either in 2.1.2 section or in 2.6.1 section, this can be added via the following workaround solution:


Go to section 2.6.1 and add a row in the ‘Name of Excipient’ section (in 2.6.1) by clicking  ‘plus’ button

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	
▼	▼	▼	

at the end of the field.

Search for the salt/ester/maleate/monohydrate relevant to this application and select it from the list to display it in the ‘Name of Excipient’ section.


Name of Excipient
AMLODIPINE MALEATE ▼

Return to section 2.1.2 and select the relevant terms from the list. Select it and if you need to add another active substance add an additional row by pressing .




2.1.2 Name of the active substance(s)


Note: Only one name should be given in the following order of priority: INN, Ph.Eur., National Pharmacopeia, common name, scientific name;*

** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

Active Substance	
▼	
AMLODIPINE AMLODIPINE MALEATE VALSARTAN	
	

Select the active substance from the list to display them in the form.

Active Substance	
AMLODIPINE MALEATE ▼	
VALSARTAN ▼	

Return to section 2.6.1 and go to ‘Name of active substance’ section and add the relevant active substances by clicking the arrow and by adding extra row(s) if needed. Select the relevant salt/ester/maleate/monohydrate from the list and fill in the relevant information in the other columns. Delete any unnecessary fields displaying incorrect terms if relevant using  button.

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

Name of active substance


AMLODIPINE MALEATE

AMLODIPINE
AMLODIPINE MALEATE
VALSARTAN

Select

VALSARTAN

Name of active substance	Quantity / Unit	Reference / Monograph Standard	
AMLODIPINE MALEATE			+
AMLODIPINE MALEATE			-
VALSARTAN			-

Return to the 'Name of excipient' section and remove the row with the selected salt/ester/maleate/monohydrate form by clicking the  ('minus') button at the end of the row.

Name of Excipient

Quantity / Unit

Reference / Monograph Standard

LACTOSE MONOHYDRATE

Remove excipient field, if req

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

Note: Do not press 'populate in section 2.2.1 and 2.6.1' button while and after doing this step as it could add incorrect active substance in the form.

In case you want to continue with the MAA veterinary form you should follow the link.

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

Route of Administration

+

-

Route of Administration

Search

Select

Dropdown field to select ("Click arrow button")

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

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



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


For each type of pack give:

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



2.2.4. 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

There is no specific technical information to be considered.

2.4. MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

There are two options you have to select from: Centralised Procedure and National Procedures:

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

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Contact person at this address

Title

First name

Surname

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

Has SME status been assigned by the EMA?

Yes No

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

For Member State(s)

Billing address (when relevant)

Company name

VAT number

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Purchase order(PO) number

In the second case the address details will be assigned to the respective Member State:

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

Member State(s) [dropdown] [+] [-]

Company name [text box]

Address 1 [text box]

Address 2 [text box]

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

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

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

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

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

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

Has SME status been assigned by the EMA?

Yes No

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

For Member State(s)

Billing address (when relevant)

Company name

VAT number

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Purchase order(PO) number

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

Finally the address details can be copied to section 2.4.2 by pressing the button

2.5. MANUFACTURERS

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

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

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

Subsections are defined to describe different roles:

- Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision)
- Official batch release for Blood products and Vaccines
- Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated

for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)

- Contact person in the EEA for product defects and recalls
- Batch control Testing arrangements

The screenshots below illustrate the principle of the two options which are offered for all address fields in section 2.5:

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

The screenshot shows a form with the following fields and options:

- Company name
- Do you have admin address and manufacturer address? Yes No
- Address 1
- Address 2
- Postcode
- Country (dropdown menu)
- Telephone
- Telefax
- E-mail
- Manufacturing Authorisation number
- Attach copy of manufacturing authorisation(s) (Annex 5.6)
- Or
- Enter EudraGMP manufacturing authorisation reference
- If available
- Attach latest GMP certificate (Annex 5.9)
- Or
- Enter EudraGMP certificate reference number

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

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

The form contains the following fields and options:

- Company name
- Do you have admin address and manufacturer address? Yes No
- Admin Office Address 1
- Admin Office Address 2
- Postcode
- Admin Office Country (dropdown menu)
- Admin Office Telephone
- Admin Office Telefax
- Admin Office E-mail
- Manufacturing Facility Address 1
- Manufacturing Facility Address 2
- Postcode
- Manufacturing Facility Country (dropdown menu)
- Manufacturing Facility Telephone
- Manufacturing Facility Telefax
- Manufacturing Facility E-mail
- Manufacturing Authorisation number
- Attach copy of manufacturing authorisation(s) (Annex 5.6)
- Or
- Enter EudraGMP manufacturing authorisation reference
- If available
- Attach latest GMP certificate (Annex 5.9)
- Or

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



So, fields should be duplicated for each manufacturer.

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

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

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

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

Manufacturing authorisation number

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

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person

(if not mentioned in manufacturing authorisation)

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

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

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

if available,

D-U-N-S number⁷

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

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

Yes No

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

Yes No

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

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

Do you have admin address and manufacturer address? <input checked="" type="radio"/> Yes <input type="radio"/> No	
Company name	<input type="text"/>
Admin Office Address 1	<input type="text"/>
Admin Office Address 2	<input type="text"/>
Postcode	<input type="text"/>
Admin Office Country	<input type="text" value="▼"/>
Admin Office Telephone	<input type="text"/>
Admin Office Telefax	<input type="text"/>
Admin Office E-mail	<input type="text"/>
<input type="button" value="+"/> <input type="button" value="-"/>	
Company name	<input type="text"/>
Manufacturing Facility Address 1	<input type="text"/>
Manufacturing Facility Address 2	<input type="text"/>
Postcode	<input type="text"/>
Manufacturing Facility Country	<input type="text" value="▼"/>
Manufacturing Facility Telephone	<input type="text"/>
Manufacturing Facility Telefax	<input type="text"/>
Manufacturing Facility E-mail	<input type="text"/>
<input type="button" value="+"/> <input type="button" value="-"/>	
Company name	<input type="text"/>
Manufacturing Facility Address 1	<input type="text"/>
Manufacturing Facility Address 2	<input type="text"/>
Postcode	<input type="text"/>
Manufacturing Facility Country	<input type="text" value="▼"/>
Manufacturing Facility Telephone	<input type="text"/>
Manufacturing Facility Telefax	<input type="text"/>
Manufacturing Facility E-mail	<input type="text"/>

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

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

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: For all manufacturing sites a brief description of their duties need to be included.

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

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

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

¹

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

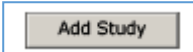
finished product’ or “Manufacturing of the VMP” are covered by the term ‘Processing of medicinal product”

The contents of the controlled vocabulary is coming directly from EUTCT and the terms have been decided by the European inspectors from documents issued from Inspection


Note: When Centralised procedure selected in Section 1 – Only drop down field will be visible & mandatory, free text field will not be visible.

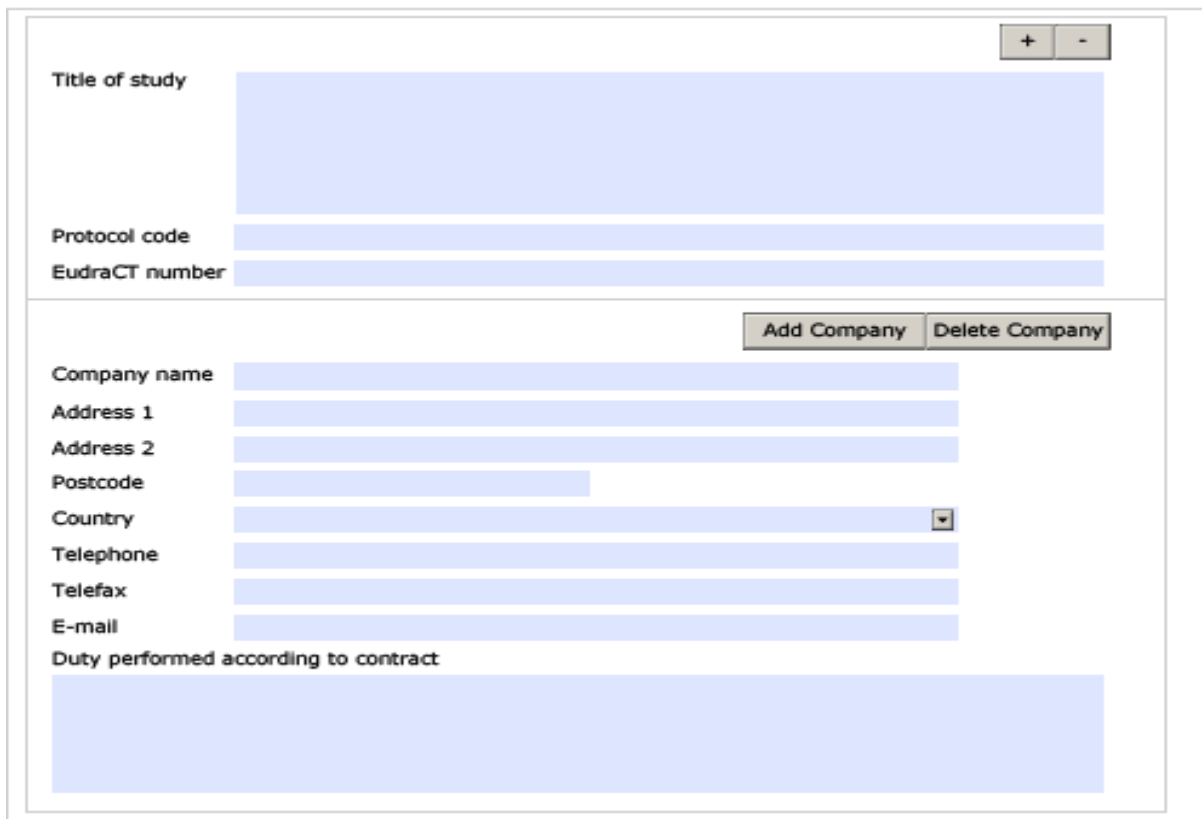
When other procedures selected in Section 1– both free text field and drop down field will be visible and either one is mandatory.

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

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

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

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



The screenshot shows a web form interface. At the top right, there are two small buttons: a plus sign (+) and a minus sign (-). Below these are three text input fields: "Title of study", "Protocol code", and "EudraCT number". Below these fields is a section for company details. At the top right of this section are two buttons: "Add Company" and "Delete Company". Below these are several text input fields: "Company name", "Address 1", "Address 2", "Postcode", "Country" (with a dropdown arrow), "Telephone", "Telefax", and "E-mail". At the bottom of this section is a large text area labeled "Duty performed according to contract".

For the name and country of origin of the original/reference product, please state the same information already given in section 1.4.2. Article 10.1. (a) (iii).

2.6. QUANTITATIVE AND QUALITATIVE COMPOSITION

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

Under “reference/monograph standard” should be indicated the current Ph. Eur. reference or the reference to an in-house monograph when no Ph. Eur. monograph exists.

In the case of radiopharmaceutical products or vaccine titers, interval of concentration should be indicated or for some excipients used “q.s.p.” for a pH, an interval of values will have to be indicated.

For instance, for interval of data, select range in the first field of quantity unit. Further fields are then open and can be filled from (minimum of the range) to (maximum of the range):

Name of active substance	Quantity / Unit		
	range	From: 10	%
		To: 100	

How to express ‘quantum satis’ (quantity sufficient) amount

“quantum satis” means adding enough of an ingredient to achieve a specific final volume or total weight. This term is not a unit/measure as it does not describe a precise measurement nor a quantity operator as it expresses the concept of “up to”. It exists in the unit and measurements list only as a legacy term.

To express for example: “to five grams of NaCl add enough (quantum satis [qs]) water to make 100 ml”

Ingredient = water

Quantity operator = “less than” (in this case understood as “up to”);

Value =100

Unit = “mL”

Name of Excipient	Quantity / Unit	Reference / Monograph Standard
WATER FOR INJECTION	less than 100 ml	

This logic should apply to any ingredient but in the case of excipients it hasn’t yet been fully addressed in eAF. This will be done in the next version of eAF and in the meantime, as a workaround solution the eAF

team kindly asks the applicants to provide a separate Annex called 2.6.1. excipients in the same folder as the application form inside the eCTD / VNeS package.

Process steps in case of a missing substance name

If you need to request a missing substance or other term in order to complete an eAF, please use the [eAF Term Request Form](#). Once completed, you will need to submit your form via email to mdms@ema.europa.eu

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 how to request additional terms in eAF can be found [here](#).

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

3. SCIENTIFIC ADVICE

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

There is no specific technical information to be considered.

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

These sections may be replicated where needed.

4. OTHER MARKETING AUTHORISATION APPLICATIONS

There is no specific technical information to be considered.

5. ANNEXED DOCUMENTS (where appropriate)

There is no specific technical information to be considered.

MAA FORM (veterinary)

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

ADMINISTRATIVE DATA

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

DECLARATION and SIGNATURE

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

The screenshot displays the 'APPLICATION FORM SUMMARY OF THE DOSSIER' section, specifically the 'APPLICATION FORM : ADMINISTRATIVE DATA' part. It includes a detailed description of the form's purpose and usage, followed by a 'DECLARATION AND SIGNATURE' section. The form contains several input fields for applicant information and a section for product details.

APPLICATION FORM
SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for veterinary 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 required (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form:

Strength:

Active Substance

OK Clear Cancel

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant
Title
First Name
Surname
Address 1
Address 2
Postcode
Country
Telephone
Telefax
E-mail

1. TYPE OF APPLICATION

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

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

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

1.1. This application concerns

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

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

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

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

CVMP Rapporteur

Title	<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

There is no specific technical information to be considered.

1.1.2. A Mutual Recognition Procedure

There is no specific technical information to be considered.

1.1.3. A Decentralised Procedure

There is no specific technical information to be considered.

1.1.4. A National Procedure

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

1.3. This application is submitted in accordance with the following articles in Directive 2001/82/EC 4

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

+
-

Pharmacological active substance(s)
+

-

+
-

Marker residue

Other Provisions

Therapeutic classification

Animal species

+
-

MRL	Target Tissues
	+

Application for a Maximum Residue Limit has been made to the EMA Yes Not applicable

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

Animal species
+
-

- All food producing species except poultry
- All mammalian food producing species
- All other food producing species
- All ruminants
- Bees
- Bovine**
- Caprine
- Chicken
- Deer, including reindeer

+

MRL	Target Tissues
2 microgram/litre	+
	-

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

Pharmacological active substance(s)		+	-
BENZYL PENICILLIN POTASSIUM		-	

Marker residue		+	-
Other Provisions	For bovine milk only		
Therapeutic classification			
Animal species	Bovine	+	-

MRL	Target Tissues	+
2 microgram/litre	Milk	-

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.

The form requires that excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification is given. As a workaround the appropriate justification should currently be provided under the “remarks” section. A short justification can be added e.g. “out of scope”, “not pharmacologically active” etc.

After validation, no error is indicated, although the values are not entirely correct according to the Commission Regulation (EU) No 37/2010:

Application for a Maximum Residue Limit has been made to the EMA Yes Not applicable

Pharmacological active substance(s)		+	-
		-	

Date of Submission

Species

Remarks

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

There is no specific technical information to be considered.

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

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

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

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

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

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

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

2.1.2. Name of the active substance(s)

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

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

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

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

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

+ -

Target species Bovine, including buffalo + -

Target species Beef cattle + -

ATC code ▼

QJ01C

QJ01C (BETA-LACTAM ANTIBACTERIALS, PENICILLIN

QJ01CA (Penicillins with extended spectrum)

QJ01CA01 (ampicillin)

QJ01CA02 (pivampicillin)

QJ01CA03 (carbenicillin)

QJ01CA04 (amoxicillin)

QJ01CA05 (carindacillin)

Select

Group Penicillins with extended spec

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

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

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

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

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

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

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

+ -

Route of Administration Intradermal use ▼

Target species Bovine, including buffalo ▼

Dropdown field to select (“Click arrow button”)

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

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



Complete the section by selecting the target species again.

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

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

For each type of pack give:

Package Size 1 + -

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

Description:

For each container give:

+ -

+ -

Container

Material

Closure

Administration Device

2.2.3.2 Proposed shelf life

2.2.3.3 Proposed shelf life (after first opening container)

2.2.3.4 Proposed shelf life (after reconstitution or dilution)

2.2.3.5 Proposed storage conditions + -

2.2.3.6 Proposed storage conditions after first opening + -

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

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

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

2.3. LEGAL STATUS

There is no specific technical information to be considered.

2.4. MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

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

2.5. MANUFACTURERS

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

2.6. QUANTITATIVE AND QUALITATIVE COMPOSITION

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

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

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

There is no specific technical information to be considered.

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

There is no specific technical information to be considered.

3. SCIENTIFIC ADVICE

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

There is no specific technical information to be considered.

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

These sections may be replicated where needed.

4. OTHER MARKETING AUTHORISATION APPLICATIONS

There is no specific technical information to be considered.

5. ANNEXED DOCUMENTS (where appropriate)

There is no specific technical information to be considered.

VARIATION FORM

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

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

Human Veterinary

National Authorisation in MRP/DCP
 EU Authorisation
 National Authorisation

Variation procedure number(s)¹ i

DE/H/2020/001-002/II/098
+ -

Click here to populate data in section 2

Reference Member State / Reference Authority for worksharing Germany ▼

Concerned Member State(s)

Austria	+ -
Belgium	+ -
Bulgaria	+ -
Croatia	+ -

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.

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

Type of Application (tick all applicable options)

<input type="radio"/> Single variation	<input checked="" type="checkbox"/> Type IA _{IN}
<input checked="" type="radio"/> Grouping of variations	<input type="checkbox"/> Type IA
<input type="checkbox"/> Including a line extension ³ i	<input type="checkbox"/> Type IB unforeseen ² i
<input checked="" type="checkbox"/> Worksharing	<input type="checkbox"/> Type IB
	<input type="checkbox"/> Type II
	<input type="checkbox"/> Type II Art. 29 ⁴ i

Type of Application (tick all applicable options)

- Single variation
- Grouping of variations
- Worksharing
- Type IA_{IN}
- Type IA
- Type IB unforeseen² i
- Type IB
- Type II
- Type II Art. 29⁴ i

Additional information
on the scope is requested.

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

- Indication
- Paediatric requirements
- Safety
 - Following Urgent Safety Restriction
- Quality
- Annual variation for human influenza vaccines
- Non-food producing target species
- Other

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

The products involved in the variation need to be named. This section can be repeated as often as needed:

The screenshot shows a form titled "2. PRODUCTS CONCERNED BY THIS APPLICATION⁷". The form contains several fields and buttons:

- (Invented) Name:** Wonderpil. A callout box points to a "+" and "-" button at the top right of this field with the text: "Button to repeat the entire section for another product".
- Pharmaceutical Form:** Tablet and powder for oral solution. A callout box points to a "+" and "-" button at the top right of this field with the text: "Button to add another active substance".
- Strength:** 200 mg. A callout box points to a "+" and "-" button at the top right of this field with the text: "Button to add another strength in case of a combination".
- Active Substance(s):** TRAMADOL HYDROCHLORIDE EP. A callout box points to a "+" and "-" button at the top right of this field with the text: "Button to add another pharmaceutical product".
- Add Active Substance(s):** A button located below the active substance field.
- MA Holder Name:** Grünethal GmbH.
- MA Number^B:** 12345.00.00. A callout box points to a "+" and "-" button at the top right of this field with the text: "Button to add another pharmaceutical product".
- see Annex A** and **see Annex B**: Two buttons at the bottom right of the form, enclosed in a green box. A green arrow points from this box to the text below.

Sometimes the list of products concerned by the application is very extensive and it is easier to provide the information using an Annex. The variation eAF has 2 buttons called 'see Annex A/see Annex B' that can be used to indicate that the detailed information is provided in an annex. These buttons are not links and they don't automatically create or attach an Annex to the form. Clicking either of the buttons will simply add text 'See Annex A/B' in the relevant fields to indicate for the receiving authority that a separate Annex has been added to the application form and is available in the same folder (CTD folder 1.2 or VNeS folder 1a-admin-info) where the application form can be found and they also remove the 'validation error' (yellow highlight) from the section and from fields that use controlled terminology where it is not otherwise possible to indicate use of annex..

⁷ If this list is very extensive (more than 20 products) it may be added as annex to the application form. For products authorised via the Centralised Procedure, the Annex A of the product(s) concerned should be provided as an Annex to the application form. For worksharing procedures submitted to the EMA, which include nationally authorised products, relevant product and Member State details should be provided as an Annex B to the application form (Using the *template on the EMA website*). For MRP/DCP procedures, "list of concerned products" can be provided as Annex to the application form.

2. PRODUCTS CONCERNED BY THIS APPLICATION? ⓘ

(Invented) Name

Pharmaceutical Form:

Strength:

Active Substance(s):

Add Active Substance(s)

MA Holder Name

MA Number⁸

see Annex A see Annex B

2. PRODUCTS CONCERNED BY THIS APPLICATION? ⓘ

(Invented) Name

Pharmaceutical Form:

Strength:

Active Substance(s):

Add Active Substance(s)

MA Holder Name

MA Number⁸

Clear Annex A

Note: If your application concerns MRP/DCP products an Annex called ‘List of concerned products’ can be provided for the same purpose and either button can be used to indicate that annex is used.

MA Holder Name

MA Number⁸

MRP Variation Number⁸

Clear Annex A

3. TYPE(S) of CHANGE(S)

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

<input checked="" type="checkbox"/>	Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked.
-------------------------------------	---

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

Once you have made your selection you can close the list /collapse the list to show only the selected items by pressing at the end of the list.

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

<input type="button" value="Show All Types"/>		<input type="button" value="Refresh Selected"/>	
Variation	Selected		
B.I.a z)	1		
A.7	1		
A.4	1		

List of selected items

<input checked="" type="checkbox"/>	A.4	Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)	Procedure type		
			<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB*	Implement. Date: <input type="text"/> <input type="text"/>

*If one of the conditions is not met and the change is not specifically listed as Type II.

<input checked="" type="checkbox"/>	A.7	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	Procedure type		
			<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB*	Implement. Date: <input type="text"/> <input type="text"/>

*If one of the conditions is not met and the change is not specifically listed as Type II.
*Note: Where notice has been given by the authorities of the intention to perform an inspection, the deletion of the relevant site shall be notified immediately.

B.I.a	Change in manufacture of the active substance	Procedure type		
<input checked="" type="checkbox"/>	z) Other variation	<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB	<input type="checkbox"/> II

Art. 5
Implement. Date:

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

		Procedure type		
<input type="checkbox"/> A.4	Change in the name and/or address of a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)	<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB ^a	Implement. Date: <input type="text"/> <input type="text"/>

^aIf one of the conditions is not met and the change is not specifically listed as Type II.

Deselected items

		Procedure type		
<input type="checkbox"/> A.7	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB ^a	Implement. Date: <input type="text"/> <input type="text"/>

^aIf one of the conditions is not met and the change is not specifically listed as Type II.
*Note: Where notice has been given by the authorities of the intention to perform an inspection, the deletion of the relevant site shall be notified immediately.

B.I.a	Change in manufacture of the active substance	Procedure type			
<input checked="" type="checkbox"/> z)	Other variation	<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB	<input type="checkbox"/> II	Art. 5 Implement. Date: <input type="text"/> <input type="text"/>

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

Updated list after pressing the refresh button

B.I.a	Change in manufacture of the active substance	Procedure type			
<input checked="" type="checkbox"/> z)	Other variation	<input checked="" type="checkbox"/> IA	<input type="checkbox"/> IB	<input type="checkbox"/> II	Art. 5 Implement. Date: <input type="text"/> <input type="text"/>

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

For the absence of the possibility to add a "z" variation in some categories of variations, the following temporary workaround is provided:

Type the scope in the field called 'Precise scope and background for change'. The lack of the z-scopes is the reason why it is not currently mandatory to select a scope from the list. Once all the z-scopes have been included, it will become mandatory to select at least one scope from the list.

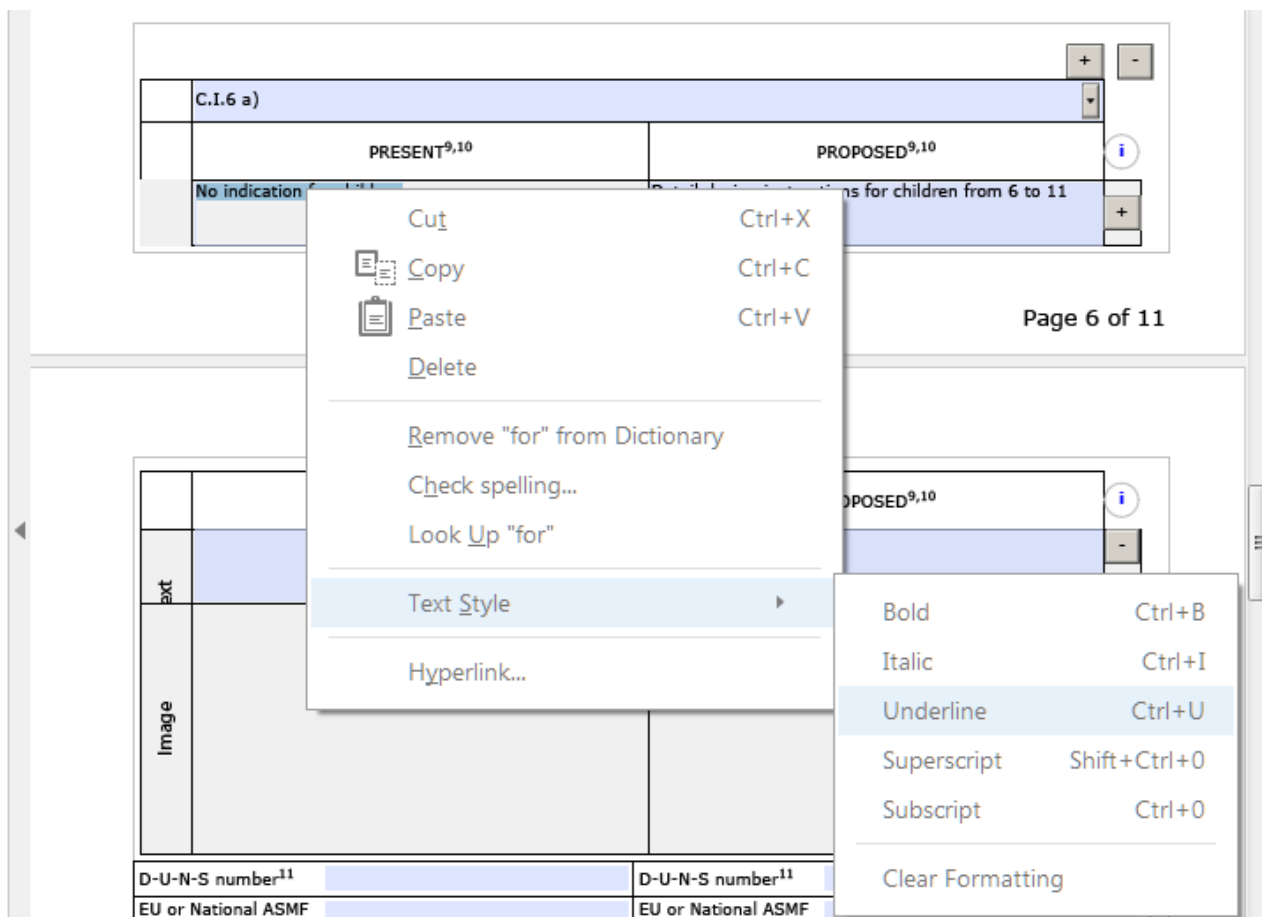
	PRESENT ^{9,10}	PROPOSED ^{9,10}	i
	C.I.6 a)		▼
	PRESENT ^{9,10}	PROPOSED ^{9,10}	i
Text	No indication for children	Detail dosing instructions for children from 6 to 11 years	+ -
			+ -
Image			+ -
			+ -
D-U-N-S number ¹¹		D-U-N-S number ¹¹	i
EU or National ASMF reference number ¹²		EU or National ASMF reference number ¹²	i

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

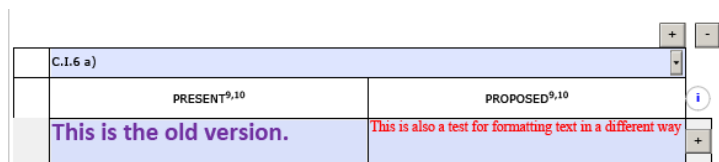
The formatting can be changed based on the following rules:

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

Using the right mouse button, you can select “Text style” providing the same options:



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



Complex table as part of the present and proposed section in the variation eAF cannot be included. Where a table is needed in the present and proposed section of the eAF you are able to include the information in separate annex included in folder 1.2 of the eCTD structure for Human applications or in the "1a-admin-info" folder of the VNeedS 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 VNeedS submissions.

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

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

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

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

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

Has orphan designation been applied for, for this new indication?

Yes No

Orphan designation procedure number:

Pending

Orphan Designation Granted

Orphan Designation Refused

Orphan Designation Withdrawn

Information relating to orphan market exclusivity

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

Yes No

Please specify the EU Orphan Designation Number(s):

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

Yes No

4b Type II variations – Paediatric Requirements

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

4.b Type II variations - Paediatric requirements 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

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

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

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

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

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

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

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

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

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

ANNEXED DOCUMENTS (WHERE APPROPRIATE)

ANNEXED DOCUMENTS (WHERE APPROPRIATE)	
The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:	
<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

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

RENEWAL FORM

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

1. APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION

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

The screenshot displays the 'APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION'. At the top, there are two radio buttons for 'HUMAN' and 'VETERINARY', with red arrows pointing to them. Below these are three radio buttons for 'National authorisation in MRP/DCP', 'EU authorisation', and 'National authorisation only'. A red box highlights the question 'Is the product currently marketed?' with 'Yes' and 'No' radio buttons. Below this is a text field for 'Invented Name'. The main part of the form is a large container with several input fields: 'Pharmaceutical form(s)³' with an information icon and expand/collapse buttons; 'Strength(s)³' with an information icon and expand/collapse buttons; and 'Active Substance' with an expand/collapse button. At the bottom of this container are 'OK', 'Clear', and 'Cancel' buttons. A button at the very bottom says 'Click here to populate data in section 3'.

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 know from the MAA form or the variation form. Again you have the option to populate the product details in section "Qualitative and quantitative composition" (section 3).

Further product characteristics have to be provided:

+ -

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 + -

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

+ -

Target Species³ ▼ + - ⓘ

ATC code ▼

Group

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

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

Name and address of MA holder

Member state

Company Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Name and address of Contact⁴



Title

First name

Surname

Company Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Applicant's reference

2. APPROVED MANUFACTURERS

2. APPROVED MANUFACTURERS

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)

		+ -
Do you have admin address and manufacturer address?		<input type="radio"/> Yes <input type="radio"/> 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		

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.

		<input type="button" value="+"/> <input type="button" value="-"/>
Laboratory Name	<input type="text"/>	
Do you have admin address and manufacturer address?	<input type="radio"/> Yes <input type="radio"/> No	
Company name	<input type="text"/>	
Admin Office Address 1	<input type="text"/>	
Admin Office Address 2	<input type="text"/>	
Postcode	<input type="text"/>	
Admin Office Country	<input type="text" value=""/>	
Admin Office Telephone	<input type="text"/>	
Admin Office Telefax	<input type="text"/>	
Admin Office E-mail	<input type="text"/>	
		<input type="button" value="+"/> <input type="button" value="-"/>
Company name	<input type="text"/>	
Manufacturing Facility Address 1	<input type="text"/>	
Manufacturing Facility Address 2	<input type="text"/>	
Postcode	<input type="text"/>	
Manufacturing Facility Country	<input type="text" value=""/>	
Manufacturing Facility Telephone	<input type="text"/>	
Manufacturing Facility Telefax	<input type="text"/>	
Manufacturing Facility E-mail	<input type="text"/>	

Copy address details from 'batch release'

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

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

Copy address details from 'batch release'

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

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

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

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

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

4. DOCUMENTS APENDED TO THIS APPLICATION

Depending from your selections you have to complete the list of documents you will attach.

DECLARATION and SIGNATURE

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

DECLARATION AND SIGNATURE

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

Proof of payment (when relevant)

Title

First name

Surname

Status (Job Title)

Date

Signatory

Additional Signatory