



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic Application Forms

eAF Pilot Phase Training

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Business Analyst, eSubmissions Programme

An agency of the European Union





Overview

1. Introduction
2. Scope of pilot phase
3. Navigation & data entry
4. Known issues/operational constraints



Introduction

- eAF project background
- Notice to Applicants Group
- Project milestones
- Pre-requisites
- Additional sources of information



Scope of Pilot Phase

Included in pilot phase 1:

- Human Product Authorisations: Renewals & Variations
- Human Product Initial Authorisation Applications [*2008 rev. 9*]

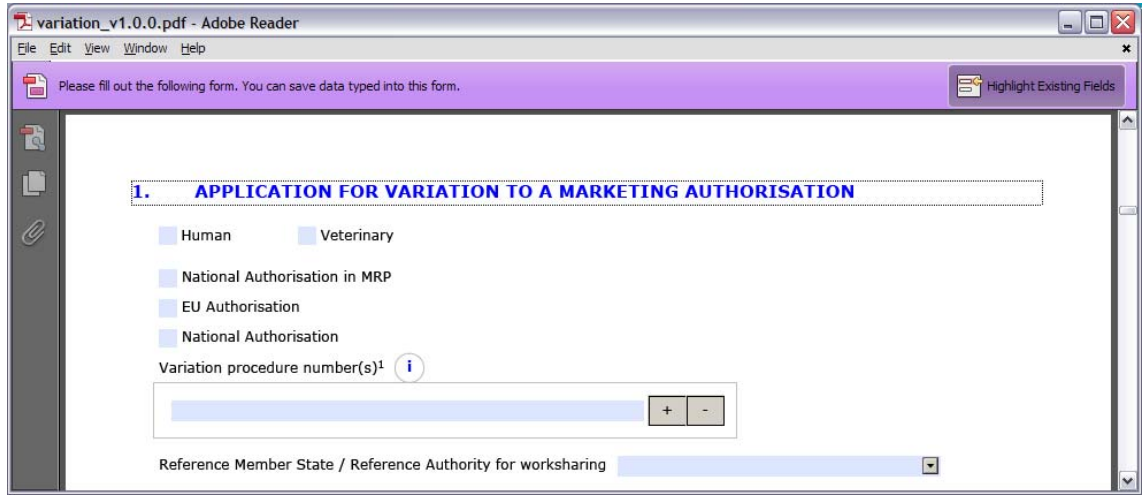
To follow in pilot phase 2:

- Veterinary product-related applications



Navigation

- Table of contents
- Hyperlinks
- Tooltips & footnotes
- Dynamic business rules





variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

Name and address of the Applicant/MA Holder⁵

Company Name
Address
City
Postcode
Country

Name and address of contact person⁶

Title
First name
Surname
Address
City
Postcode
Country
Telephone
Telefax
E-mail

Click to enter company name of the applicant/Marketing Authorisation holder (Max. 100 chars.).

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

Name and address of the Applicant/MA Holder⁵

Company Name
Address
City
Postcode
Country

Name and address of contact person⁶

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Telephone
Telefax
E-mail

Click to go to corresponding footnote.

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

when known to the Marketing Authorisation Holder. For worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.

² A variation is considered 'unforeseen' when the proposed variation is not considered a minor variation of Type IB following the Commission classification Guideline, or has not been classified as a Type IB variation in an Article 5 recommendation. When one or more of the conditions established in the guideline for a Type IA variation are not met, the concerned change may be submitted as a Type IB variation unless the change is specifically classified as a major variation of Type II.

³ Type II variation submitted under Article 29 of Regulation (EC) No 1901/2006.

⁴ If the variations are part of a grouped submission including a line-extension, this application form should be considered an annex to the application form for the extension application.

⁵ For worksharing or grouped type IA variations affecting more than one MA, indicate the MA holder to be used as reference MA holder for the handling of the procedure.

⁶ As specified in section 2.4.3 in Part IA/Module 1 Application Form. If different, attach letter of authorisation. For worksharing or grouped type variations affecting more than one MA, a single contact should be designated for the application (see also Signatory box below).

⁷ 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).

⁸ Indicate the MA numbers affected. For the MRP variation number, which is a product specific number, see the Best Practice Guide on Variations, Chapter 1 section 2, example: NL/H/0123/001-004/IB/033/G.



Navigation

renewal_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION

HUMAN VETERINARY

National authorisation in MRP
 Community authorisation
 National authorisation only

Is the product currently marketed? Yes No

Invented Name



Navigation

renewal_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION

HUMAN VETERINARY

National authorisation in MRP MRP Procedure Number¹

Community authorisation

National authorisation only

Reference member state

Concerned member state



Navigation

renewal_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION

HUMAN VETERINARY

National authorisation in MRP
 Community authorisation
 National authorisation only

Is the product currently marketed? Yes No

Invented Name

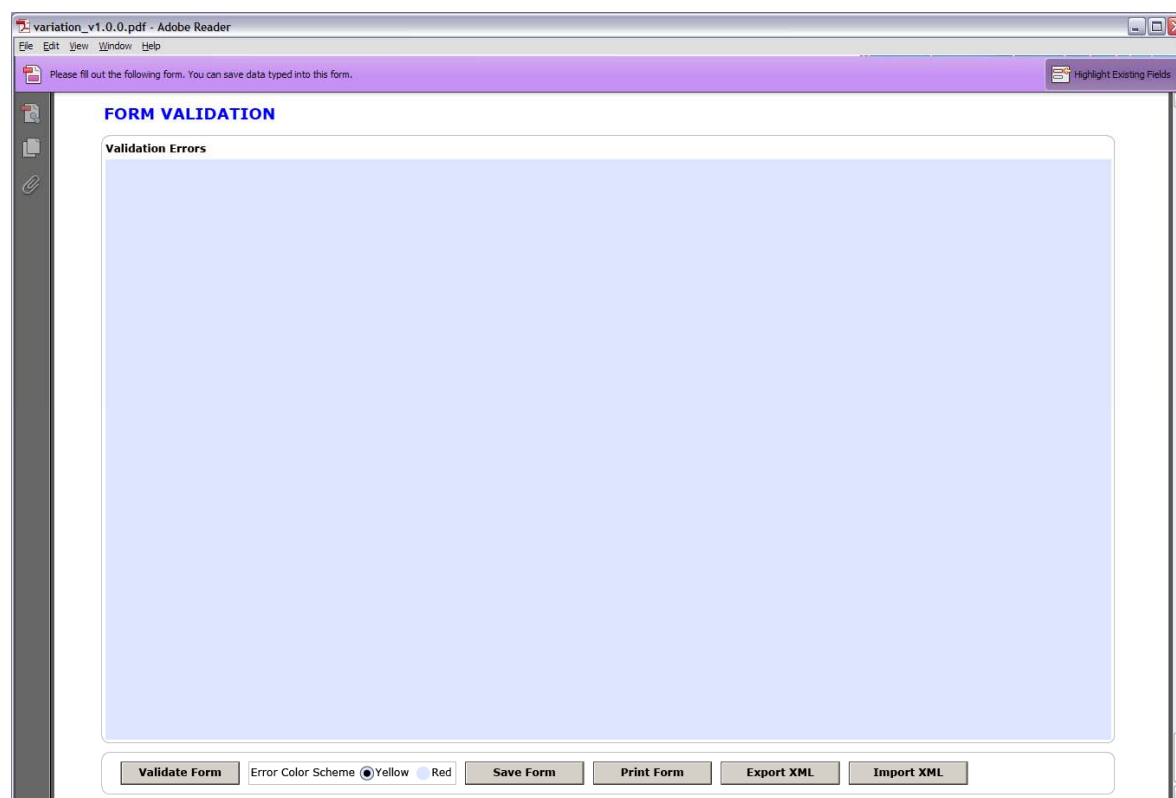


Data Entry

- Mandatory fields & validation
- Radio buttons & check boxes
- Additional groups
- Controlled terminology lists
- Dates
- Email addresses
- Signatures
- Currency amounts



Mandatory Fields & Validation





Mandatory Fields & Validation

The screenshot shows a PDF document titled 'variation_v1.0.0.pdf' in Adobe Reader. The document contains a 'FORM VALIDATION' section with a list of 36 errors. The errors are as follows:

- 'Human' Select Human or Veterinary.
- 'Veterinary' Select Human or Veterinary.
- 'National Authorisation in MRP' Select Authorisation Type.
- 'EU Authorisation' Select Authorisation Type.
- 'National Authorisation' Select Authorisation Type.
- 'Type IAIN' Select an application type.
- 'Type IA' Select an application type.
- 'Type IB unforeseen' Select an application type.
- 'Type IB foreseen' Select an application type.
- 'Type II' Select an application type.
- 'Type II Art.' Select an application type.
- 'Variation Grouping' The field must be filled in.
- 'Company Name' The field must be filled in.
- 'Address' The field must be filled in.
- 'City' The field must be filled in.
- 'Country' The field must be filled in.
- 'Title' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Address' The field must be filled in.
- 'City' The field must be filled in.
- 'Country' The field must be filled in.
- 'Telephone' The field must be filled in.
- 'E-mail' The field must be filled in.
- '(Invented) Name' The field must be filled in.
- 'Pharmaceutical form(s)' The field must be filled in.
- 'Strength(s)' The field must be filled in.
- 'Active Substance(s)' The field must be filled in.
- 'MA Holder Name' The field must be filled in.
- 'MA Number' The field must be filled in.
- 'Click to insert details regarding the precise scope and background for change, and justification for grouping, worksharing and classification of unforeseen changes (if applicable) in the free'
- 'Title' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Status (Job title)' The field must be filled in.
- 'Date' The field must be filled in.

At the bottom of the form, there are several buttons: 'Validate Form', 'Jump to selected', 'Error Color Scheme' (with radio buttons for Yellow and Red, where Yellow is selected), 'Save Form', 'Print Form', 'Export XML', and 'Import XML'.



Mandatory Fields & Validation

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

FORM VALIDATION

Validation Errors: 36

- 'Human' Select Human or Veterinary.
- 'Veterinary' Select Human or Veterinary.
- 'National Authorisation in MRP' Select Authorisation Type.
- 'EU Authorisation' Select Authorisation Type.
- 'National Authorisation' Select Authorisation Type.
- 'Type IAIN' Select an application type.
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- 'Country' The field must be filled in.
- 'Title' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Address' The field must be filled in.
- 'City' The field must be filled in.
- 'Country' The field must be filled in.
- 'Telephone' The field must be filled in.
- 'E-mail' The field must be filled in.
- '(Invented) Name' The field must be filled in.
- 'Pharmaceutical form(s)' The field must be filled in.
- 'Strength(s)' The field must be filled in.
- 'Active Substance(s)' The field must be filled in.
- 'MA Holder Name' The field must be filled in.
- 'MA Number' The field must be filled in.
- 'Click to insert details regarding the precise scope and background for change, and justification for grouping, worksharing and classification of unforeseen changes (if applicable) in the free text area' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Status (Job title)' The field must be filled in.
- 'Date' The field must be filled in.

Validate Form Jump to selected Error Color Scheme Yellow Red Save Form Print Form Export XML Import XML



Mandatory Fields & Validation

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- 'City' The field must be filled in.
- 'Country' The field must be filled in.
- 'Title' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Address' The field must be filled in.
- 'City' The field must be filled in.
- 'Country' The field must be filled in.
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- 'E-mail' The field must be filled in.
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- 'Strength(s)' The field must be filled in.
- 'Active Substance(s)' The field must be filled in.
- 'MA Holder Name' The field must be filled in.
- 'MA Number' The field must be filled in.
- 'Click to insert details regarding the precise scope and background for change, and justification for grouping, worksharing and classification of unforeseen changes (if applicable) in the free title' The field must be filled in.
- 'First name' The field must be filled in.
- 'Surname' The field must be filled in.
- 'Status (Job title)' The field must be filled in.
- 'Date' The field must be filled in.

At the bottom of the form, there are several buttons: 'Validate Form', 'Jump to selected', 'Error Color Scheme' (with radio buttons for Yellow and Red), 'Save Form', 'Print Form', 'Export XML', and 'Import XML'. A small tooltip below the buttons says 'Click to jump to the field of the selected validation error.'

Mandatory Fields & Validation

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

Human Veterinary

National Authorisation in MRP
 EU Authorisation
 National Authorisation

Variation procedure number(s)¹ i

Reference Member State / Reference Authority for worksharing

Concerned Member State(s)

Type of Application (tick all applicable options)

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

Name and address of the Applicant/MA Holder⁵ i

Company Name

Address

City

Postcode

Country

8.27 x 11.69 in



Radio Buttons & Check Boxes

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

3. SCIENTIFIC ADVICE

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

Yes No

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

Yes No

Attach copy of scientific advice(s) (Annex 5.14)



Radio Buttons & Check Boxes

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

3. SCIENTIFIC ADVICE

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

Yes No

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

Yes No

Member State + -

Date

Reference(s) of the scientific advice(s)

Attach copy of scientific advice(s) (Annex 5.14)

Click check box to confirm a copy of scientific advice(s) has been attached (Annex 5.14).



Additional Groups

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

3. SCIENTIFIC ADVICE

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

Yes No

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

Yes No

Member State	<input type="text"/>	+ -
Date	<input type="text"/>	
Reference(s) of the scientific advice(s)	<input type="text"/>	

Member State	<input type="text"/>	+ -
Date	<input type="text"/>	
Reference(s) of the scientific advice(s)	<input type="text"/>	

Attach copy of scientific advice(s) (Annex 5.14)



Additional Groups

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

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

(Value populated from the "Declaration" section.)

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

2.1.2 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

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Group

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



Additional Groups

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

2.1.2 Name of the active substance(s)

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Active substance	<input type="text"/>	Find	+ -
Active substance	<input type="text"/>	Find	+ -
Active substance	<input type="text"/>	Find	+ -
Active substance	<input type="text"/>	Find	+ -
Active substance	<input type="text"/>	Find	+ -

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

<input type="text"/>



Additional Groups

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File Edit View Window Help

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* 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

Active substance

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Group

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

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

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)
(The values of the following fields have been populated from "Declaration". Any changes here will be reflected into the respective fields of that section.)



Controlled Terminology Lists

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Tools Sign Comment Extended

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

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** 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

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Group

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

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)
(The values of the following fields have been populated from "Declaration". Any changes here will be reflected into the respective fields of that section.)

Pharmaceutical form(s)



Controlled Terminology Lists

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Tools Sign Comment Extended

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

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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 cef

Find

- ACEFLURANOL
- ACEFURTIAMINE
- ACEFYLLINE
- ACEFYLLINE CLOFIBROL
- ACEFYLLINE PIPERAZINE
- AMBROXOL ACEFYLLINATE
- CEFACTOLE

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Group

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

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



Controlled Terminology Lists

ma_a_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

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Active substance

- CEFALEXIN
- CEFALEXIN HYDROCHLORIDE
- CEFALEXIN MONOHYDRATE
- CEFALEXIN SODIUM
- CEFALOGLYCIN
- CEFALONIUM
- CEFEPIM

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code

Group

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

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

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)
(The values of the following fields have been populated from "Declaration". Any changes here will be reflected into the respective fields of that section.)



Controlled Terminology Lists

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Note: Only one name should be given in the following order of priority: INN, Ph.Eur., National Pharmacopoeia, 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 + - Find

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code + -

Group

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

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

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)
(The values of the following fields have been populated from "Declaration". Any changes here will be reflected into the respective fields of that section.)

Pharmaceutical form(s) + -

Controlled Terminology Lists

maa_human_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

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 + - Find

Active substance + - Find

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code + -

Group

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

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

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)
(The values of the following fields have been populated from "Declaration". Any changes here will be reflected into the respective fields of that section.)

Pharmaceutical form(s) + -



Dates

maa_human_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Function
Place Date

* 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 in the Notice to Applicants, Volume2A, chapter 7.

maa_human_v1.0.0.pdf - Adobe Reader

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Function
Place

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February 2012						
Mon	Tue	Wed	Thu	Fri	Sat	Sun
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	1	2	3	4
5	6	7	8	9	10	11
Today: 29/02/2012						

maa_human_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Function
Place Date
2012-02-29

* 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 in the Notice to Applicants, Volume2A, chapter 7.



Email Addresses

renewal_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Name and address of MA holder

Company Name

Address

City

Postcode

Country

Telephone

Telefax

E-mail

renewal_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Name and address of MA holder

Company Name

Address

City

Postcode

Country

Telephone

Telefax

E-mail gabriel.boronat@

Warning: JavaScript Window - Email format

The format of email is not valid.

OK

renewal_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Name and address of MA holder

Company Name

Address

City

Postcode

Country

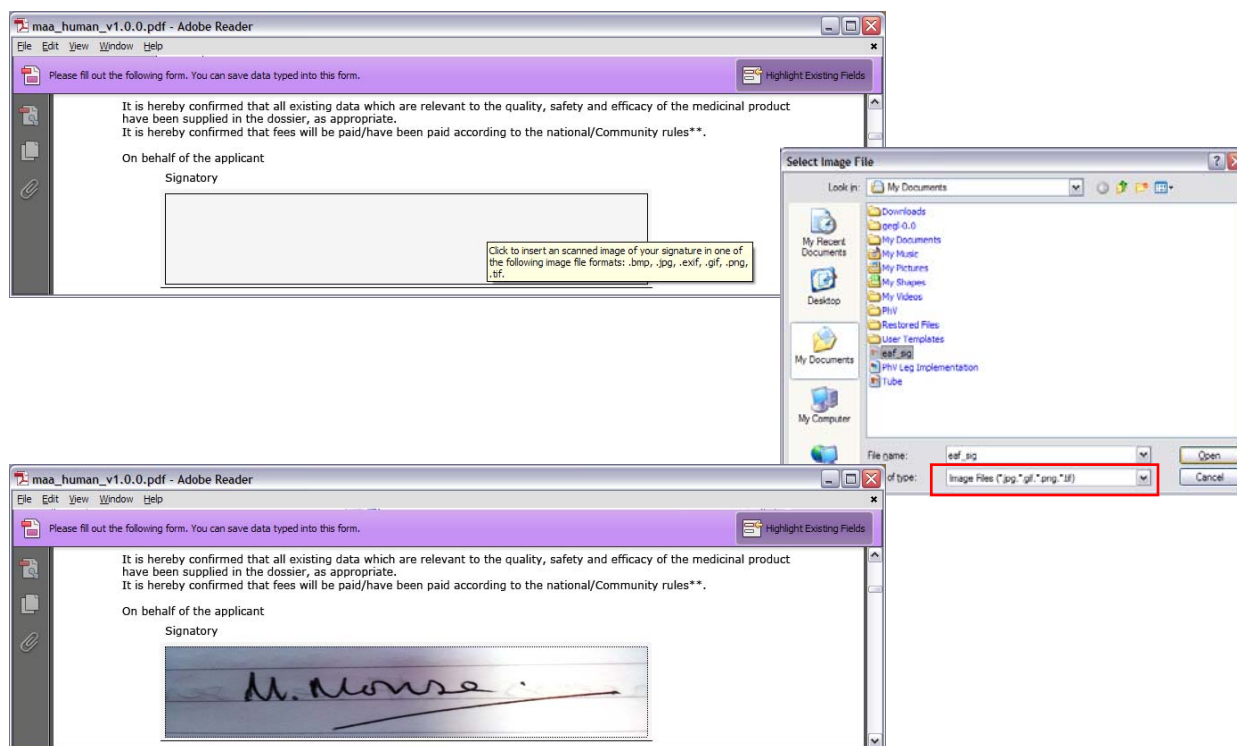
Telephone

Telefax

E-mail gabriel.boronat@ema.europa.eu



Signatures





Currency Amounts

variation_v1.0.0.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Fees paid or will be paid, if applicable¹⁸ ⓘ

Amount/Currency:

Payment status	<input type="text"/>	+ -
Amount	12345	
Currency	<input type="text"/>	

Please specify fee category under National rules¹⁸ ⓘ



Variation Scopes

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

3. TYPES OF CHANGE(S)

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.

Variation included in this application: Please follow instructions below to add variation
To add a variation Item, Click Show All Types and select check boxes for the required variation items. When all items have been selected click Show only Selected.

Show All Types

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable)
(include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification).

variation_v1.0.0.pdf - Adobe Reader

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3. TYPES OF CHANGE(S)

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Variation included in this application: Please follow instructions below to add variation
To add a variation Item, Click Show All Types and select check boxes for the required variation items. When all items have been selected click Show only Selected.

Show Only Selected / Collapse All

A. Administrative change		Procedure type	
<input type="checkbox"/> z)	Other variation	<input type="checkbox"/> IA <input type="checkbox"/> IB <input type="checkbox"/> II	<input type="checkbox"/> Art. 5 Implement. Date: <input type="text"/>

A.1 **Change in the name and/or address of the marketing authorisation holder**

		Procedure type	
<input type="checkbox"/>		<input type="checkbox"/> IA _N <input type="checkbox"/> IB ³	Implement. Date: <input type="text"/>

³ If one of the conditions is not met and the change is not specifically listed as Type II.

A.2 **Change in the (invented) name of the medicinal product**

		Procedure type	
<input type="checkbox"/> a)	for Centrally Authorised Products	<input type="checkbox"/> IA _N <input type="checkbox"/> IB ³	Implement. Date: <input type="text"/>
<input type="checkbox"/> b)	for Nationality Authorised Products	<input type="checkbox"/> IB	

³ If one of the conditions is not met and the change is not specifically listed as Type II.

variation_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form.

3. TYPES OF CHANGE(S)

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.

Variation included in this application: Please follow instructions below to add variation
To add a variation Item, Click Show All Types and select check boxes for the required variation items. When all items have been selected click Show only Selected.

Show All Types Refresh Selected

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable)
(include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification).



Substances, Forms & Strengths

renewal_v1.0.0.pdf - Adobe Reader

Please fill out the following form. You can save data typed into this form. Highlight Existing Fields

Invented Name

Pharmaceutical form(s)³ + -

Strength(s)³ + -

Active Substance(s)

Pharmacotherapeutic classification (Group + ATC code)

Route of Administration³ Find + -

MA Number³ + -

8.27 x 11.69 in



Operational Constraints

Attachments – do not use.

Import/export XML – final step in processing only.