EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13th July 2018

Information Technology
EMA/298723/2018

eAF Release Notes – Summary

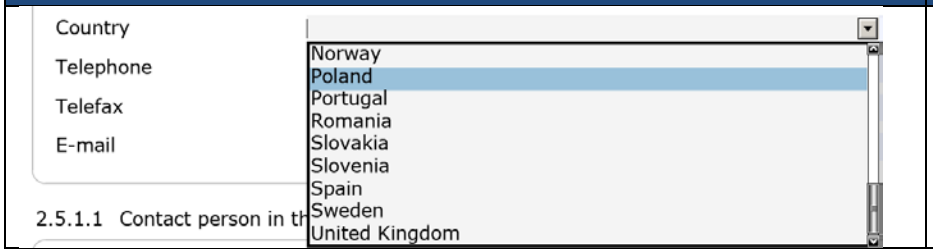
This document illustrates the differences between eAF **v1.22.0.1** and **v1.23.0.0** by using before and after screenshots of the forms.

The scope of release v1.23.0.0 contains the following change requests:

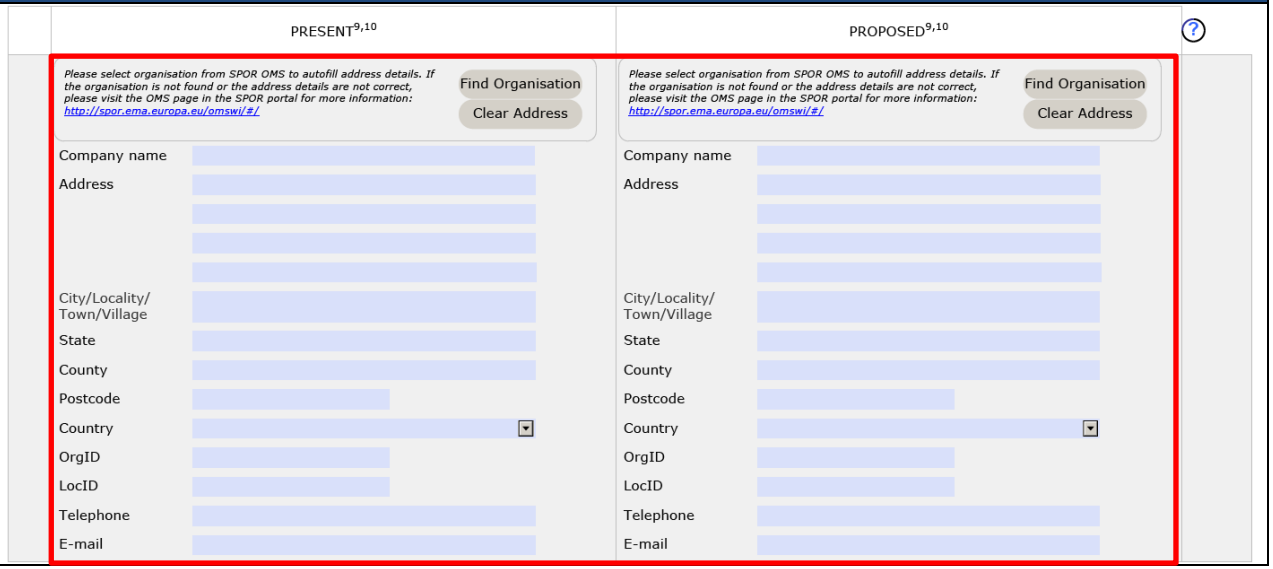
1. SD-159756 - Add Switzerland (CH) to drop-down list under 2.5.1 b
2. SD-140624 - OMS-integration in the variation form - present and proposed
3. SD-170597 - eAF OMS Integration for org last mod and addresses
4. SD-145156 - NTA changes for All 4 eAF forms
5. SD-186883 - Remove\Hide OMS entry related fields from eAFs where no OMS data exists

The release also contains a number of bug fixes reported through internal and external testing. These details can be found in the accompanying release notes accessed via the eAF esubmission website.

1. **SD-159756 - Add Switzerland (CH) to drop-down list under 2.5.1 b – This change is applicable for Human & Vet MAA forms only.**

eAF 1.22.0.1	eAF 1.23.0.0
	

2. **SD-140624 - OMS-integration in the variation form - present and proposed sections**

eAF 1.22.0.1	eAF 1.23.0.0
	

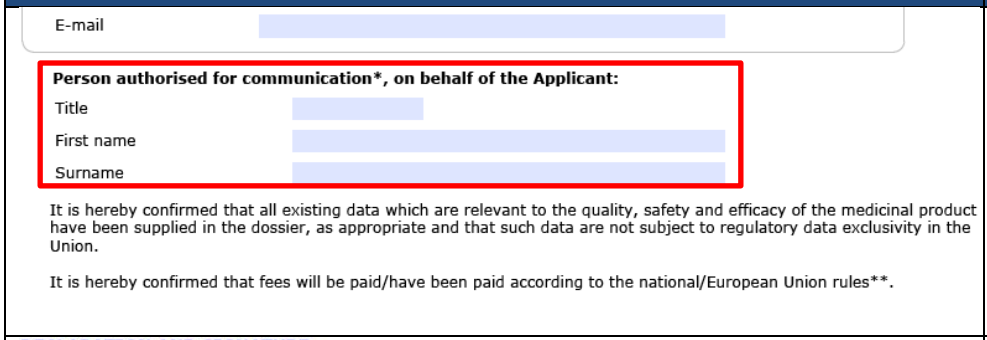
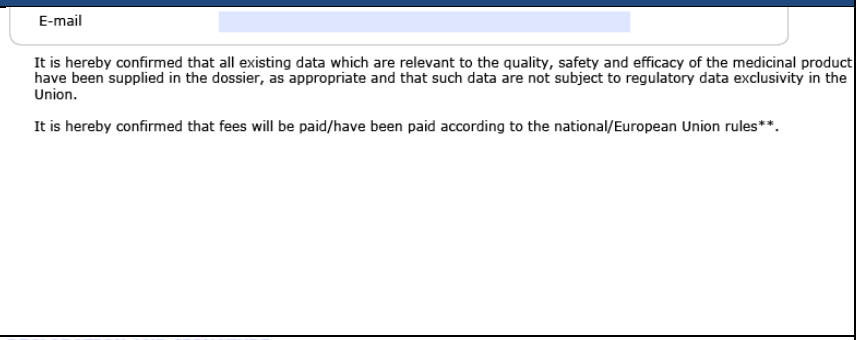
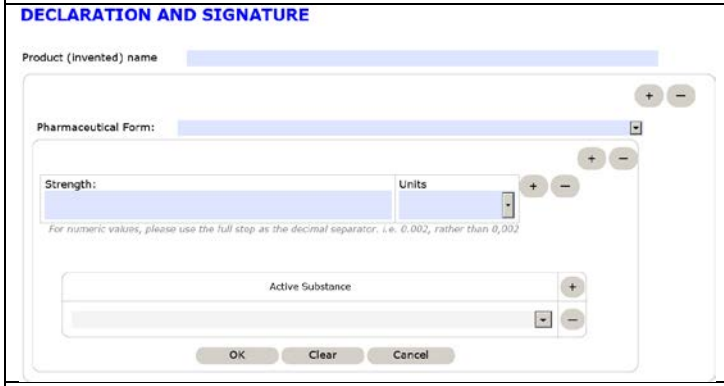
3. SD-170597 - eAF OMS Integration for org last mod and addresses

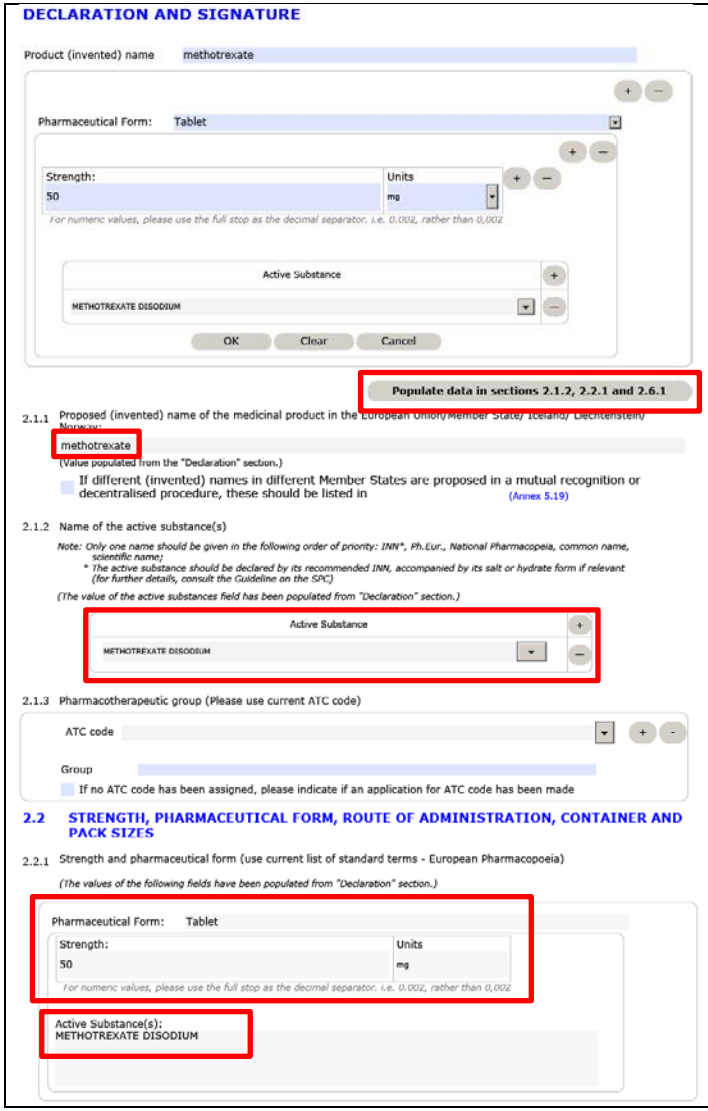
This change is in the XML schema file – there is no visible change in the form, therefore no screenshot.

4. SD-145156 - NTA changes for All 4 eAF forms

a. Common changes across more than one form

i. Changes applicable to Human & Vet MAA forms only

<table>
<tr><th>eAF 1.22.0.1</th><th>eAF 1.23.0.0</th></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>In v1.22.0.1 when selecting the "Populate data in sections 2.1.2, 2.2.1 and 2.6.1" button from the Declaration & Signature section - the form would copy data to each respective section including the Proposed (invented) name, Active Substance, Pharmaceutical Form, Strength & Unit.</td><td>However in v1.23.0.0 - when selecting the "Populate data in sections 2.1.2, 2.2.1 and 2.6.1" button - the form will copy data into each respective section with the exception of the Active substance field in section 2.2.1 only. Users will need to manually enter and select an</td></tr>
</table>



active substance for this field.

Users also now have the ability to provide the base\active moitey details of the Active substance.

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

Date of acceptance/confirmation by CHMP:

CHMP Rapporteur

▪Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA:

Strength(s)	Units	Marketing authorisation holder	Marketing authorisation number	Date of authorisation

Enter EudraGMP manufacturing authorisation reference

If available

Attach latest GMP certificate (Annex 5.9)

Or

Enter EudraGMP certificate reference number

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

Yes No

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

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

Applicant part version number

Date of submission

Date of last update

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

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

Date of acceptance/confirmation by CHMP:

EMA Product number:

CHMP Rapporteur

▪Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:

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

Enter EudraGDMP document reference number

If available

Attach latest GMP certificate (Annex 5.9)

Or

Enter EudraGDMP document reference number

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

Yes No

Name of the ASMF holder

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

Find Organisation

Clear Address

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

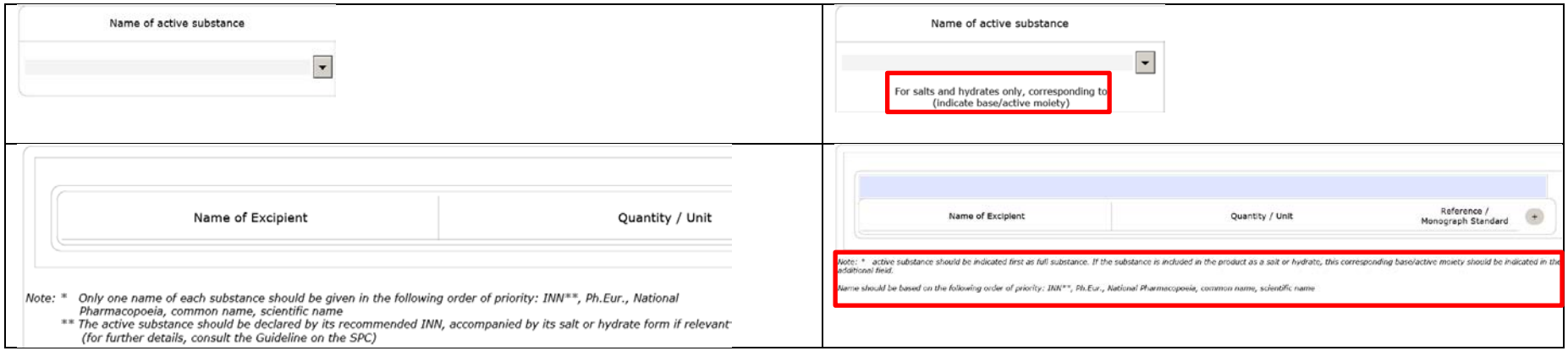
Telephone

E-mail

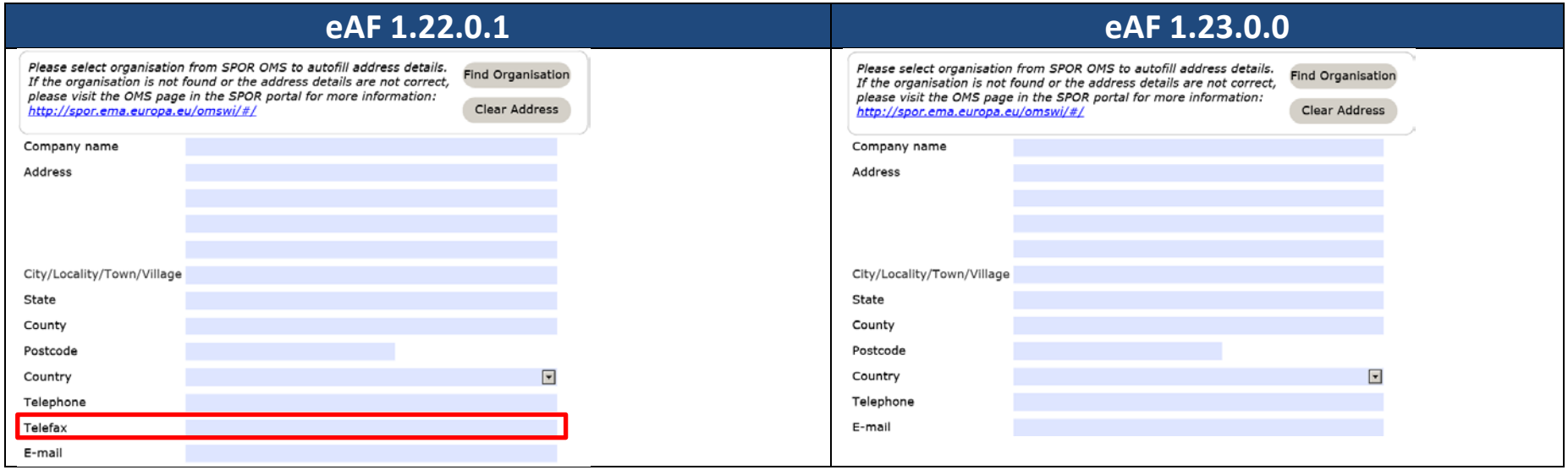
2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Dosage form unit to which quantity the composition refers (e.g. 1 capsule)



ii. Changes applicable to all 4 forms



b. Human MAA

eAF 1.22.0.1	eAF 1.23.0.0
EUROPEAN COMMISSION **HEALTH AND CONSUMERS DIRECTORATE-GENERAL** Health Systems and products eAF Version Number: 1.22.0.1 Brussels, (2015) **Revision 12**	**EUROPEAN COMMISSION** **HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL** Health systems, medical products and innovation eAF Version Number: 1.23.0.0 **Revision 13**
Medicinal Products for Human Use VOLUME 2B Module 1.2: Administrative information Application form September 2015	**Medicinal Products for Human Use** VOLUME 2B Module 1.2: Administrative information Application form February 2018
To be noted: Mandatory use of electronic Application Forms for Centralised Procedure that explains parts in light grey. As from 01/01/2016, mandatory use of electronic application forms for all procedures **Revision 12** Update from September 2015 of section 1.4.1; taking into account the review of chapter 1 of July 2015	**To be noted:** As from 01/01/2016, mandatory use of electronic application forms for all procedures. This document is for information purposes only. Not to be used for submissions. **Revision 13** Update from February 2018.
1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC² *Note: Section to be completed for any application, including applications referred to in section 1.3* *For further details, refer to Notice of Applicants, Volume 2A, Chapter 1*	**1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC²** *Note: Section to be completed for any application, including applications referred to in section 1.3* *For further details, refer to Notice of Applicants, Volume 2A, Chapter 1* *information on active substance status (new/known) should be provided in section 2.1.2*
1.4.1 ◉ Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*) ** for extensions of complete applications, cross references can only be made to pre-clinical and clinical data* ☐ Claim for new active substance* * *Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)* *** please provide evidence and justification to support the claim of new active substance status in (Annex 5.23)*	1.4.1 ◉ Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*) ** for extensions of full applications, cross references can only be made to pre-clinical and clinical data*

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)*

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

Active Substance

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

2.1.2 Active substance(s)

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

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

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

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

Active Substance

Base/active moeity of the active substance(s) (if different from above)

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

Claim for new active substance(s)

Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)

please provide evidence and justification to support the claim of new active substance status in annex 5.23

Known active substance

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

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

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

Pharmaceutical Form:

Strength: | Units

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

Active Substance

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

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

Pharmaceutical Form:

Strength: | Units

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

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

Active Substance

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

Yes

2.2.4 Medical devices

Does this application include 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 intended to administer a medical product?

No Yes

2.2.4.2 Device(s) identification

Name of the device(s)

Serial numbers or other indications necessary to delimit precisely the device(s) incorporated

If yes, does this medical device and the medicinal product form a single integral product, which is intended exclusively for use in the given combination and which is not reusable?

☒ No ☐ Yes

Note: If no, CE markng of the devic is mandatory. If yes, CE marking of the device is optional. Furhter details must be provided in sections 2.2.4.3 and 2.2.4.4

2.2.4.1 Device(s) identification

Name of the device(s)

Brief description of the device

Serial numbers or other indications necessary to delimit precisely the device(s) incorporated

Pharmacovigilance system master file

Number

Copy contact details from 2.4.2 Section

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

Find Organisation

Clear Address

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

☐ The Pharmacovigilance system master file location has been registered in Article 57 database

c. Vet MAA

eAF 1.22.0.1	eAF 1.23.0.0
EUROPEAN COMMISSION **ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL** Consumer goods **Pharmaceuticals** eAF Version Number: 1.22.0.1 Brussels, 10.08.2017 **Revision 7.5**	**EUROPEAN COMMISSION** **HEALTH AND CONSUMERS DIRECTORATE GENERAL** Health Systems and products eAF Version Number: 1.23.0.0 Brussels, 01.11.2017 **Revision 8**
Medicinal Products for Veterinary Use VOLUME 6B Presentation and content of the dossier-Part 1 Summary of the dossier Part 1A Application form August 2017	Medicinal Products for Veterinary Use VOLUME 6B Presentation and content of the dossier-Part 1 Summary of the dossier Part 1A Application form November 2017
Revision 7.5 Mandatory use of electronic Application Forms for Centralised Procedure	**Revision 8** Mandatory use of electronic Application Forms for all Procedures
1.2 **IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF COMMISSION REGULATION (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?** ○ Yes *(complete sections below and also complete 1.4)* ○ No *(complete section 1.3 and 1.4.)*	1.2 **IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF COMMISSION REGULATION (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?** ○ Yes ○ No *(complete section 1.3 and 1.4.)*
1.3.1 ◉ Article 12(3) application, (i.e. dossier with administrative, quality, safety and clinical data*) **for extensions of complete applications, cross references can only be made to safety and clinical data.* ○ New active substance ** *Note: constituent of a product not yet authorised by a competent authority or by the European Union (for centralised procedure)* ☐ ** *please provide evidence and justification to support the claim of new active substance status in* (Annex 5.22) ○ Known active substance *Note: - constituent of a product already authorised by a competent authority or the European Union* *- same or different marketing authorisation holder*	1.3.1 ◉ Article 12(3) application, (i.e. dossier with administrative, quality, safety and clinical data*) **for extensions of complete applications, cross references can only be made to safety and clinical data.*

2.1.2 Name of the active substance(s)

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

Active Substance

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)*

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

Has SME status been assigned by the EMA?

Yes No

Proof of payment (when relevant)

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- 5.1 Proof of payment
- 5.2 Informed consent letter of marketing authorisation holder of authorised veterinary medicinal product.
- 5.3 Proof of establishment of the applicant in the EEA.
- 5.4 Letter of authorisation for communication on behalf of the applicant/MAH.
- 5.5 (empty)
- 5.6 Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply). A reference to EudraGMP will suffice when available.
- 5.7 (empty)
- 5.8 Flow-chart indicating all sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). Note: ALL manufacturing and control sites mentioned throughout the dossier MUST be consistent regarding their names, detailed addresses and activities
- 5.9 Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s) (not older than 3 years). References to Eudra GMP will suffice when available. Where applicable a summary of the other GMP inspections performed in the last 2 years.

2.1.2 Active substance(s)

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

Active Substance

Base/active moeity of the active substance(s) (if different from above)

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

*Note: *active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field; Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.*
*** please provide evidence and justification to support the claim of new active substance status in annex 5.22*

New active substance **

Note: constituent of a product not yet authorised by a competent authority or by the European Union (for centralised procedure)

*** please provide evidence and justification to support the claim of new active substance status in* (Annex 5.22)

Known active substance

Note: - constituent of a product already authorised by a competent authority or the European Union
- same or different marketing authorisation holder

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

Has SME status been assigned by the EMA?

Yes No

Proof of payment (when relevant): not applicable for centralised procedure

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- 5.1 Proof of payment
- 5.2 Informed consent letter of marketing authorisation holder of authorised veterinary medicinal product.
- 5.3 Proof of establishment of the applicant in the EEA.
- 5.4 Letter of authorisation for communication on behalf of the applicant/MAH.
- 5.5 (empty)
- 5.6 Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply). A reference to EudraGMP will suffice when available.
- 5.7 (empty)
- 5.8 Flow-chart indicating all sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). Note: ALL manufacturing and control sites mentioned throughout the dossier MUST be consistent regarding their names, detailed addresses and activities
- 5.9 Proof of GMP compliance (or GMP certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s) (not older than 3 years). References to Eudra-GMDP will suffice when available. Where applicable a summary of the other GMP inspections performed in the last 2 years.

☐ 5.19 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of each of the manufacturing authorisation holders (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated).	☐ 5.19 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of each of the manufacturing authorisation holders (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated and all relevant sites are listed on the single declaration). The declaration should refer to an audit and the date of the audit.

d. Variation Form

eAF 1.22.0.1	eAF 1.23.0.0
EUROPEAN COMMISSION **HEALTH AND CONSUMERS DIRECTORATE-GENERAL** Health Systems and products eAF Version Number: 1.22.0.1 **June 2015**	**EUROPEAN COMMISSION** **HEALTH AND CONSUMERS DIRECTORATE-GENERAL** Health Systems and products eAF Version Number 1.23.0.0 **February 2018**
Name and address of the Applicant/MA Holder[5]	Name and address of the MA Holder[5]
[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 variations affecting more than one MA, a single contact should be designated for the application (see also Signatory box below). In case of national marketing authorisations, several contact points in different Member States can be introduced for type II variations and worksharing.	[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 variations affecting more than one MA, a single contact should be designated for the application (see also Signatory box below).
[7] If this list is very extensive 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.	[7] Veterinary products only: If this list is very extensive it may be added as annex to the application form. For medicinal products for human, the table should be completed. 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.
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.	**4.a Type IB and 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.
TABLE OF CONTENTS 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION 2. PRODUCTS CONCERNED BY THIS APPLICATION[7] 3. TYPES OF CHANGE(S) 4.a Type II variations - new indications - orphan medicinal product information 4.b Type II variations - Paediatric requirements 4.c Type II variations - Extended data/market exclusivity	**TABLE OF CONTENTS** 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION 2. PRODUCTS CONCERNED BY THIS APPLICATION[7] 3. TYPES OF CHANGE(S) 4.a Type IB and Type II variations - new indications - orphan medicinal product information 4.b Type IB and Type II variations - Paediatric requirements 4.c Type II variations - Extended data/market exclusivity

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

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

e. Renewal Form

eAF 1.22.0.1	eAF 1.23.0.0
EUROPEAN COMMISSION **ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL** Consumer goods **Pharmaceuticals** eAF Version Number: 1.22.0.1 **June 2015**	**EUROPEAN COMMISSION** **ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL** Consumer goods **Pharmaceuticals** eAF Version Number: 1.23.0.0 **February 2018**
1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION ☒ HUMAN ☐ VETERINARY ○ National authorisation in MRP/DCP ○ EU authorisation ○ National authorisation only	**1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION** ☒ HUMAN ☐ VETERINARY ○ National authorisation in MRP/DCP ○ EU authorisation[2] ○ National authorisation only
[2] For centrally authorised products a list of EU Member States / Norway / Iceland where the product is on the market should be provided in a separate appendix	[2] The MA validity period is calculated from the date of notification of the Commission Decision to the MAH. Notification dates of the Commission Decision can be found in the EC Pharmaceuticals - Community Register

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

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

- (●) Yes
- ( ) No

Name of the CEP holder	
Name of the manufacturer if different from the above	
CEP number	
Date of last update	

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

- (●) Yes
- ( ) No

If yes, please provide the following information

Name and contact details of the ASMF holder	
Name of the manufacturer if different from above	
EU ASMF reference number if available	
National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)	
Applicant part version number	
Date of last update	

(If revised product information (SmPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form).	*(If revised product information (SmPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the sections of the EU-CTD affected and precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form).* The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable : ☐ Summary of Product Characteristics Conditions of the Marketing Authorisation[6] ⓘ ☐ Labelling ☐ Package leaflet ☐ Mock-ups[7] ⓘ ☐ Specimens[7] ⓘ
	4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY Product subject to shortened renewal ☒ Shortened Procedure Reason **Module 1** ☐ 1.0 Cover letter ☐ 1.1 Comprehensive table of content (not applicable for centrally authorised medicinal products)
	4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR VETERINARY MEDICINAL PRODUCTS ONLY Product subject to shortened renewal ☒ Shortened Procedure Reason ☐ 1 Cover Letter ☐ 1.1 Comprehensive table of content

NOTES

[1] Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential MRP/DCP Number according to Volume 2A, Chapter 2, 7. Numbering System for the Procedures for Mutual Recognition and Decentralised Procedure aspublished on the Website of the European Commission (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)
Veterinary Medicinal Products: Renewal number to be issued by the Reference Member State before submission of the application according to the corresponding CMD(v) Best Practice Guide (http://www.hma.eu)

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

[3] For centrally authorised products this information, including packaging and pack size(s), should be provided in tabular format in a separate appendix (cf. Annex A to CHMP/CVMP Opinion)

[4] As specified in section 2.4.3 in Part 1A. If different, attach letter of authorisation

[5 & 6] Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU, may be submitted provided that:
• The declaration makes it clear that it is signed on behalf of all the involved QPs.
• The arrangements are underpinned by a technical agreement as described in Chapter 7 of the GMP Guide and the QP providing the declaration is the one identified in the agreement as taking specific responsibility for the GMP compliance of the active substance manufacturer(s).

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[2] The MA validity period is calculated from the date of notification of the Commission Decision to the MAH. Notification dates of the Commission Decision can be found in the EC Pharmaceuticals - Community Register

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

[4] For centrally authorised products this information, including packaging and pack size(s), should be provided in tabular format in a separate appendix (cf. Annex A to CHMP/CVMP Opinion)

[5] As specified in section 2.4.3 in Part 1A. If different, attach letter of authorisation

[6] only for centrally auhtorised products (Annex II of the EU MA)

[7] see Chapter 7 of Volume 6A of the Notice to Applicants or Transfer of information contained in Notice to Applicants, Volume 2A, Chapter 7 (http://www.hma.eu) or Dossier requirements for Centrally Authorised Products (http://www.ema.europa.eu)

[8 & 9] Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU, may be submitted provided that:
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5. **SD-186883 - Remove\Hide OMS entry related fields from eAFs where no OMS data exists**
    a. For the following sections:
        i. MAA-Human form - Section 2.4.1 - payment section only and in section 2.5.4 for CROs
        ii. MAA-VET form - Section 2.4.1 - payment section only and in section 2.5.4 for CROs
        iii. Renewal form - payment section only
        iv. Variation form - payment section only

    The ability to use the OMS lookup entry has been removed as these types of organisations are not yet present in the OMS dictionary. Therefore for these entries, Users will be required to enter free text fields only.

eAF 1.22.0.1	eAF 1.23.0.0