



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF v1.25.0.0 – ‘Medical Devices’ release

Changes introduced in v1.25.0.0 of all 4 electronic Application forms
Guidance for users

Kristiina Puusaari
Go-live of the new version 1st October 2021
Mandatory use from 1st November 2021





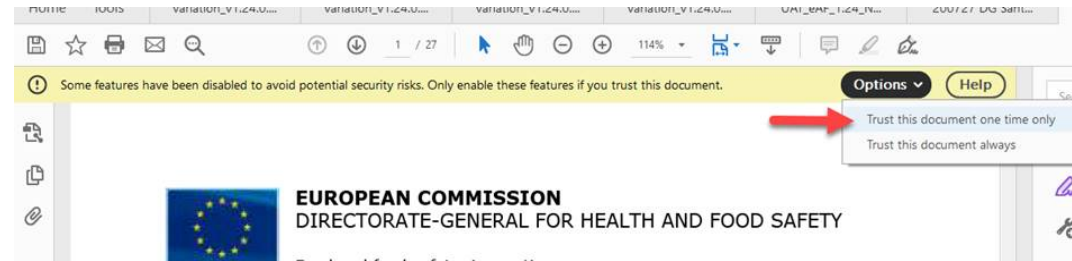
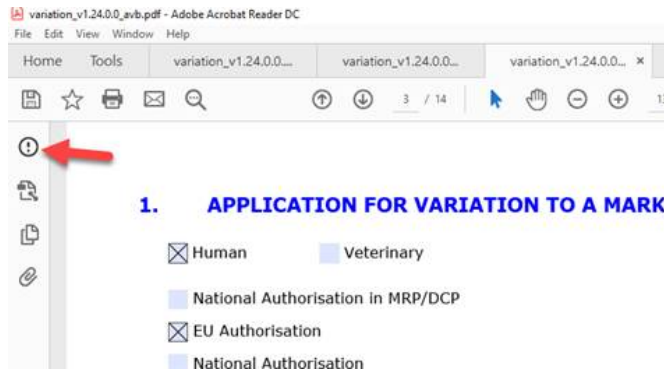
The v1.25.0.0 is called 'Medical Devices' release as the main trigger for this new version was the introduction of the Medical Device regulation Art 2(1) of Regulation (EU) 2017/745 which triggered a Notice to Applicant review of the Human application forms. Number of improvements/changes agreed previously were also included in this particular release.

This release contains a new version of all **4 application forms** (H&V).

The detailed changes are listed in the release notes and in the following slides.

The forms become available for use on 1st of October 2021 and the mandatory use of this version starts on 1st of November 2021.

- In order to access the control terminology lists, the forms **must be trusted** first
- Please save the form on your local drive – potentially with another name – and open the saved form using **adobe reader DC**. It is **important to use adobe (acrobat) reader DC to edit the forms** instead of adobe acrobat or adobe acrobat pro **as using these will result in issues with locking the forms and may lead to rejection**
- Once you open the form, there should be an **exclamation mark** on the top of the left hand pane. If the pane is closed, click the small sideways arrow to open the pane
- When you click exclamation mark, a yellow banner will open across the top, please select trust this document one time only

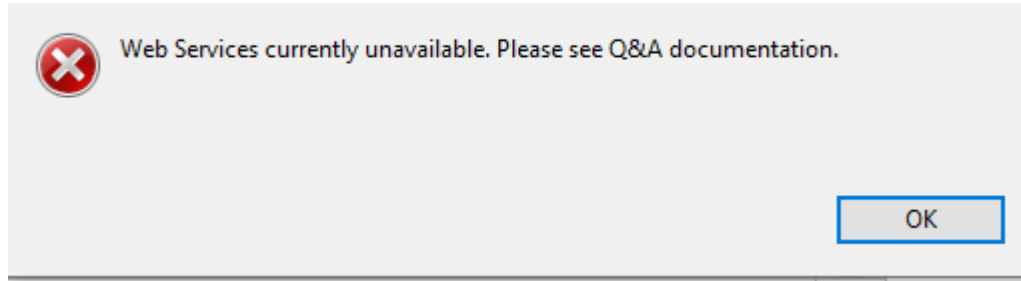




- The eAFs should be edited using **Adobe (Acrobat) Reader DC**
- Please note that the forms must be signed using an image of a signature or a signature snippet. **Adobe sign** or **other digital signature** tools **must not** be used
- Please note that imports of data from an older version do not work so well when there are significant changes to the form from the previous version. For example, it is not recommended to import data from previous versions of the forms due to very extensive DES changes. If you however, decide to use the importing feature, please note that you may need to repeat the export-import action, meaning you first import from an older version to the version 1.25.0.0. Then again export from the v1.25.0.0 to a newly opened v1.25.0.0 – this should in most cases solve the issue. Please check all the fields carefully and use 'update lists' feature if needed.
- If you experience any issues with the forms – please report these to the [EMA Service Desk](#) portal immediately
- If you notice that there scopes missing from the variations form, please report these to the [EMA Service Desk](#) portal immediately. In most cases the missing scopes are not intentional!

- If you repeatedly get this error message;

Warning: JavaScript Window - Web Service Issue



- It most likely indicates that you have **an issue with trusting the document** or that you will need to add the following url:
<http://eaf.ema.europa.eu/eaf/services/EutctService?wsdl> on your trusted list.
- If your local IT policy 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>
- Depending on your IT infrastructure you may need to take some additional steps to allow access to the lists.

New, repeatable section **2.2.3.7** Proposed storage conditions after reconstitution or dilution

2.2.3.7 Proposed storage conditions after reconstitution or dilution

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It is now possible to repeat the section for **Ph.Eur. Certificate of suitability in section 2.5.3**
(+/- buttons has been added)

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

In both, renewal and variation forms, the **Proof of payment** section has been made more visible (the Proof of payment tick box is ticked by default and can be unticked if not relevant)

Proof of payment (when relevant)

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Have all relevant fees been prepaid to competent authorities?

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

No

In the renewal form **an incorrect business rule** in section 3. Qualitative and Quantitative composition in terms of the Active Substances and Excipients: the **excipient is always an optional field**

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
			-
			Clone

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



- Updated section **2.2.4 Medical Devices**
- New section **2.2.5 Companion Diagnostics**

2.2.4 Medical devices

Please tick the applicable statement(s) and duplicate section 2.2.4. as needed for each device component used with the medicinal product.

Does this application refer to one or more medical devices within the meaning of Article 2(1) of Regulation (EU) 2017/745 or one or more accessories to a medical device within the meaning of Article 2(2) of Regulation (EU) 2017/745 and meets any one of the following conditions:

a) medical device which incorporates, as an integral part, a medicinal product and the action of that medicinal product is principal and not ancillary to that of the device (Art 1(8), second subparagraph of Regulation (EU) 2017/745)

Yes No

b) medical device intended to administer a medicinal product where they form a single integral product which is intended exclusively for use in the given combination and which is not reusable (Art 1(9) second subparagraph of Regulation (EU) 2017/745)

Yes No

Note: in accordance with Annex I, Section 3.2, point 12 to Directive 2001/83/EC as amended by Article 117 of Regulation (EU) 2017/745, conformity of the device part with the general safety and performance requirements of Annex I to Regulation 2017/745 should be demonstrated by providing a manufacturer's EU declaration of conformity, a EU certificate issued by a Notified Body or a Notified Body opinion where applicable.

c) medical device incorporated as integral part of an ATMP (article 2 (d) of Regulation 1394/2007)

Yes No

d) medical device is co-packaged with the medicinal product.

Note: the device must comply with Regulation (EU) 2017/745 including being CE-marked.

Yes No

e) medical device which is supplied separately but referenced in the product information of the medicinal product

Note: the device must comply with Regulation (EU) 2017/745, including being CE-marked

Yes No

2.2.5 Companion diagnostic

2.2.5.1 Is the medicinal product to be used with a companion diagnostic within the meaning of Article 2(7) of Regulation 2017/746?

Yes No

New 'Changes concerns' tick box has been added to indicate 'Medical Device'. This new tick box is always visible and when selected, a new section 4.d is shown to include details on Medical Devices and Companion Diagnostics

Change(s) concern(s)

Medical Device

When Type of Application is 'Type II' a new value is available for selection in Changes concerns section: "Variation to changes related to the active substance of a human coronavirus vaccine"

Variation to changes related to the active substance of a human coronavirus vaccine

Title fields in the form are now optional

- New section **4.d Medical Devices**
- New section **4.d Companion Diagnostics**

4.d Change to the design or indented purpose of the medical device component, or introduction of a new device/ device constituent part

Does this variation application refer to:

- a change to the design or intended purpose of a device component previously listed in the marketing authorisation of the medical product. Please explain the purposed changed in present/purposed section
- a new device introduced in the marketing authorisation of the medical product

Companion diagnostic

Is the medicinal product to be used with a companion diagnostic within the meaning of Article 2(7) of Regulation 2017/746?

- Yes No



Details of the changes – Variation form human domain

If “National Authorisation” or “National Authorisation in MRP/DCP” (or both) are selected and Type of Application is ‘Type II’ a new section under proof of payment has been added to allow the applicant to declare parallel variations; “Declaration of the applicant about submission(s) of the same type II variation application for the same product in other Member States – for MRP/DCP/purely nationally authorised products”

Declaration of the applicant about submission(s) of the same type II variation application for the same product in other Member States – for MRP/DCP/purely nationally authorised products

Does the same variation application to the same product concern any other Member State(s)?

No

Yes

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Country

Invented name

Date of submission

Procedure number (if applicable)

Variation pending

Variation accepted Date of granting

Variation refused Date of refusal

Variation withdrawn Date of withdrawal



Details of the changes – Variation form human domain

If “National Authorisation” or “National Authorisation in MRP/DCP” (or both) are selected a new section “Information on harmonisation of product information for MRP/DCP/purely nationally authorised products under proof of payment has been added to allow the applicant to provide information on harmonisation of product information “Information on harmonisation of product information for MRP/DCP/purely nationally authorised products’

Information on harmonisation of product information for MRP/DCP/purely nationally authorised products:

1) Has/have the concerned MA(s) been harmonised or partially harmonised, by an Article 30 or 31(1) referral?

- No
 Yes

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Procedure(s) reference number

Specify the section(s) of SmPC/PIL/labeling

2) Has harmonisation of a section/some sections of the SmPC/PIL/labeling been achieved through a variation worksharing?

- No
 Yes

+ –

Procedure(s) reference number

Specify the section(s) of SmPC/PIL/labeling



Any questions?

Further information

[EMA Service Desk](#)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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