



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF v1.24.0.1 – Brexit related changes

Changes introduced in v1.24.01 of all 4 electronic Application forms
Guidance for users

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Go-live of the new version 15th December 2020

Mandatory use from 1st January 2021 for procedures requiring use of terms United Kingdom
or United Kingdom (Northern Ireland)

Mandatory use for all procedures from 16th January 2021



The v1.24.0.1 provides Brexit related changes in the values available in the Member State, OMS search and country dropdown menus in all **4 application forms** (H&V)

New value United Kingdom (Northern Ireland) has been added in to the EU and EEA country groupings

United Kingdom will be removed from the EU and EEA country groupings in RMS on 31.12.2020

3 new country groupings have been created in RMS to either remove or add United Kingdom or United Kingdom (Northern Ireland) to allow removal of value United Kingdom (Northern Ireland from the EU/EEA/EFTA list) or an addition of United Kingdom in the list where EEA countries are displayed

This transitional period will coincide with the transitional period with the previous version of the eAFs (v1.23.1.3 variation, renewal, MAA Vet)/1.23.1.4 MAA Human) which was initially planned to end on 15th of December 2020.

The users will now be allowed to submit applications using version 1.23.1.3/1.23.1.4 until the end of 2020. The form has been removed from the eAF website at the time of the go-live of the Brexit related version but it will remain acceptable for submissions until the end of 2020.

The new Brexit related version can be used for submissions for procedures starting after 1.1.2021.

There will be a short transitional period for the use of previous version 1.24.0.0 until the 15th of January for those applications that do not use terms United Kingdom or United Kingdom (Northern Ireland).

From **1st of January 2021** the UK will no longer be selectable in the fields displaying EU/EEA countries and the term will no longer be available for selection in any version of the forms (in the fields where only EU/EEA/EFTA countries are listed).

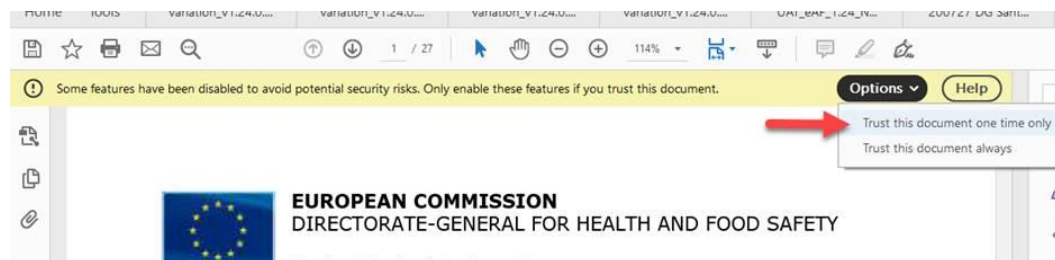
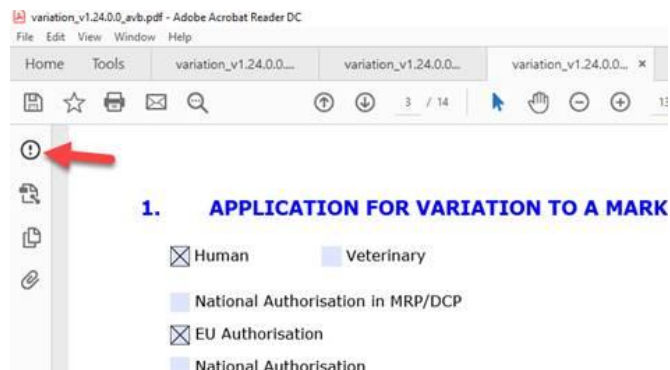
- The eAFs should be edited using **Adobe Reader DC**
- Please note that the conditions and documentation provided as a part of the scope, unfortunately do not contain the numbering from the classification guideline and the ordering of the conditions/documentation may be different from the classification guideline. We are currently looking at options in relation to this issue, however, regardless there is no need to provide separate annex as this could lead into discrepancies and additional work.
- 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 when there are significant changes to the form from the previous version. For example, it is not possible to import data from variation form v1.23.x.x due to very extensive DES changes
- If you experience any issues with the forms – please report these to the [EMA Service Desk](#) portal immediately
- If you notice that there is an error in the newly introduced RMS variations list, for example a typo, a **missing scope**, error in the Conditions or Documentation etc, please report these to the [EMA Service Desk](#) portal immediately. In most cases the missing scopes are not intentional!

Accessing control terminology lists – very important



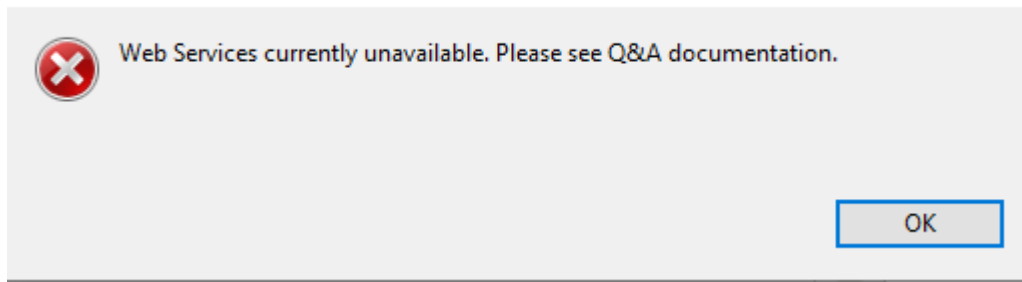
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- In order to access the control terminology lists, the forms **must be trusted** first
- Please save the form on your local drive – potentially with another name – and open the saved form using **adobe reader DC**. It is **important to use adobe reader DC to edit the forms** instead of adobe acrobat or 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



- 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.

If a National Authorisation and grouping of variations with only 1 procedure type (for example Type IB) has been selected in section 1, a form validation error will not be raised if only single scope is selected.

☒ Human ☐ Veterinary


Type of Authorisation
**Note: Please select authorisation first, before proceeding with filling the next fields of the form.*



☐ National Authorisation in MRP/DCP
☐ EU Authorisation
☒ National Authorisation

Variation procedure number(s)¹  [Click here to populate variation number in section 2](#)

Type of Application (tick all applicable options)
**Note: Any change in Type of Application, will delete any selected variation in Section 3!*

☐ Single variation
☒ Grouping of variations

☐ Including a line extension³ 
☐ Worksharing

☐ Type IA_{TM}
☐ Type IA
☐ Type IB unforeseen² 
☐ Type IB
☒ Type II
☐ Type II Art. 29⁴ 

- The availability of terms United Kingdom (Northern Ireland) and United Kingdom are linked to the application type (MRP/DCP, National, Centralised Procedure)
 - For example, in the Variation form if National authorisation in MRP/DCP has been selected, United Kingdom (Northern Ireland) will not be available in the 'Reference Member State' dropdown menu. United Kingdom (Northern Ireland) will be available in the 'Concerned Member State dropdown list'
 - For example in the MAA form, when Centralised Procedure is selected in section 2.4.4 the QPPV must be from EU/EEA and in this field United Kingdom (Northern Ireland has been removed), however, if MRP/DCP/NP has been selected, United Kingdom (Northern Ireland) will be a selectable value in the field.
- Due to a very large number of fields where these terms are available it is not possible to describe all scenarios in this document.
- If you notice or suspect that there is incorrect implementation in any field, please contact the [EMA service desk](#).



Any questions?

Further information

[EMA Service Desk](#)

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