



29 November 2013

eAF defects – workaround solutions

A number of defects have been identified in the electronic application forms and the EMA is committed to fix these as soon as possible, however, to enable the use of the eAFs meanwhile, the applicants should use the following workaround solutions where applicable. Only one option for each section is mentioned, however, other workaround solutions might be possible and may be accepted.

There are other known issues in the form for which we have not listed a workaround solution, in majority of cases this is by adding a separate Annex to the form, it is important to add this Annex in section 1.2 of the eCTD sequence with a clear name. It is recommended to mention that a workaround has been used in the application cover letter.

If you encounter further issues in any of the electronic application forms, please contact eAF@ema.europa.eu

MAA-Human revision 10.1

Section 1.2 Orphan Medical Product Designation (section name will be corrected to Orphan Medicinal Product Information)

Description of the error:

When 'Trust this document always' is selected to enable the use of drop-down lists and controlled data an error in section 1.2.1 is encountered. It is not possible to permanently save the orphan designation number and the number in the community register of orphan medicinal products in 1.2.1 if 'trust the document' option is selected. The numbers can be entered but once the document is closed and re-opened the information is no longer present.

Recommended workaround solution:

A recommended workaround is for the applicants to fill in this section as a separate Annex to the application form and submit that in the eCTD section 1.2 together with the application form and other annexes. It can be simply named Annex 1.2.1.

Please mention in the application cover letter that a workaround solution has been used.

Section 1.6.1 Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')

Description of the error:

If 'No' is selected in the section 1.6.1, the section 1.6.3 will open and data can be entered, it however, will not be displayed after the form is validated and signed.

Recommended workaround solution:

A recommended workaround is for the applicants to fill in this section as a separate Annex to the application form and submit that in the eCTD section 1.2 together with the application form and other annexes. It can be simply named Annex 1.6.3. Please mention in the application cover letter that a workaround solution has been used.



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

Description of the error:

If 'Yes' is selected in section 2.5.3 for 'Has the site been inspected for GMP compliance by an EEA authority..' and "Attach latest GMP certificate in Annex 5.9" box has been ticked, a form validation error is displayed. Error indicates that 'EudraGMP certificate reference number' should be entered after the form has been saved and reopened when form validation is run.

Solution:

Ignore the validation error, this is a known technical error and will not affect content validation.

Section 5. Annexed Documents

Description of the error:

When 'No' is selected in section 2.4.1 Proof of payment, the box '5.1 Proof of payment' is ticked in section 5. 'Annexed documents'. Please mention in application cover letter that the box is ticked due to a known technical error in the eAF.

Variation Revision July 2013

Description of the error:

Scope for my variation is missing, for example B.I.z

Recommended workaround solution:

Please use the free text field in section 3 of the eAF – 'Precise scope and background for change' instead of selecting 'Show All Types' and choosing the scope from the list. If the application is for more than one scope, the other scopes should be selected from the list under 'Show all Types'. Please mention in the application cover letter that workaround solution has been used for section 3. Types of Change.

All forms:

Description of the error:

The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).

Solution:

User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.