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New electronic report form

EU medical device vigilance information needs to be communicated by the fastest, most efficient means. The EU Vigilance MDEG agreed that a standardized electronic format for the transfer of adverse event data between manufacturer's and National Competent Authorities can offer significant efficiency gains and help improve response times for all concerned parties. It is expected that electronic incident report exchange will become the method of choice in the near future, not only between manufacturers and Competent Authorities, but also between Competent Authorities and Eudamed.

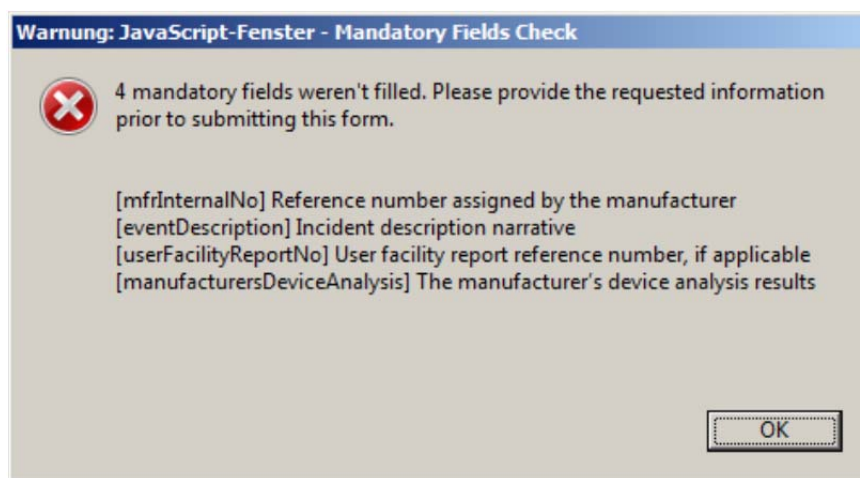
For over a year a small group of EU Competent Authorities led by BfArM, and including MHRA, AfSSAPS and IMB, have worked with manufacturers and/or their representatives to develop and trial mechanisms for electronic vigilance exchange. The electronic report form developed is based on the incident form for manufacturers to the national competent authority contained in MEDDEV 2.12-1 rev 6 at Annex 3.

The form is qualified to fulfill the legal requirements on electronic reporting according to § 7(2) of the German Medical Devices Safety Plan Ordinance.

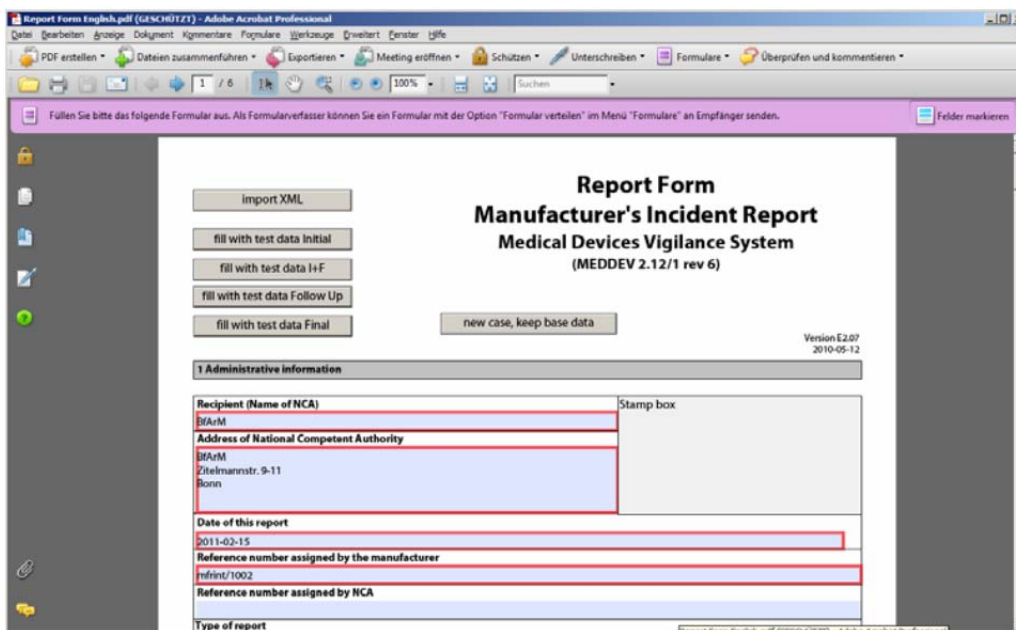


Notes on the use

- 1) Use the Acrobat Reader or Acrobat Professional version 9.1 or higher.
- 2) There is a built-in logic identifying the mandatory field depending on the type of report (Initial, Follow-up or Final Report). They can be identified by hitting the button “Highlight Fields” in the right upper corner of the Reader. If one misses to fill all mandatory fields before hitting the button “send xml by Email” at the end of the form a message box comes up informing what fields are not filled.



- 3) In case the submitter of the report is the manufacturer or the authorised representative (to be identified via the radio buttons in section 2), the information from section 3 or 4 will be copied line by line into section 6.
- 4) The form can be used to make templates. Fill all areas of interest (usually administrative data) and store the template under an individual name.
- 5) The button “new” next to the headline in sections 2-6 and 9 deletes all data of that specific section.
- 6) Date format is YYYY-MM-DD
- 7) If you open the form with Acrobat Professional, xml files can be imported or test files created. To use this option one must save a copy (!) of the file to withdraw the extended Readers functions (save the form with content) as Acrobat only allows either the extended Readers functions (save form and content) or the import options in one form.



7) Hitting the button “send xml-data per Email” checks whether all mandatory data are filled, produces the xml file with the data entered and opens the local (!) E-mail client. The xml file is attached and the recipient of the mail is set to pharmakovigilanz2@pei.de. You can change the body of the email and add / delete recipients in usual manner. PLEASE DO NOT CHANGE THE ATTACHED XML FILE.

For your internal documentation purpose, the form is write protected after submission (!). For follow- up or final reports safe the document before submitting or use Acrobat Pro for an import into a blank form.

The form is ready for electronic signature which is not mandatory but recommended to use. You may create and use the internal Adobe signature. It is easy to use AND you must safe a copy within the signature procedure.

8) It is sufficient to send the xml file only as we will load the information back into the form. You may, if you wish, send an electronic copy in addition. Do not send print outs per regular mail to PEI.

In case you have question please do not hesitate to contact

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