



January 2010

## European Union Medical Device Vigilance – electronic incident report exchange

Medical device vigilance information needs to be communicated by the fastest, most efficient means. The Medical Devices Experts Group on Vigilance of the European Union agreed that a standardized electronic format for the transfer of adverse event data between manufacturers and National Competent Authorities (NCA) can offer significant efficiency gains and help improve response times for all concerned parties. Electronic incident report exchange is expected to become the method of choice in the near future, not only between manufacturers and Competent Authorities, but also between NCAs and Eudamed.

We believe the following two mechanisms will allow any manufacturer and NCA working with the EU, to participate in electronic vigilance exchange, no matter what systems they operate.

1) Manufacturers who wish to develop facilities to **export data directly from their systems into an XML** file in compliance with one of the four XSD schemata, may send the file to an NCA using XML file import facilities and the NCA will import the data directly into their systems.

We have developed XSD schemata for initial, follow-up, combined initial and final reports and final incident reports for direct XML file exchange. The field structure of each of these XSDs is identical but what is mandatory varies logically from form to form.

The schemata are attached.

NOTE 1:

**NCAs without XML import facilities can nevertheless participate in electronic exchange since the XML file can be imported into a blank PDF form. This can be done either by the manufacturer before sending the file to an NCA or by the NCA after receiving the XML file. Acrobat Professional is the required tool for the import back into the PDF form; Acrobat Reader will not do in this case.**

NOTE 2:

**With respect to the XSDs**

- **Be aware that British English is used (e. g. "Authorised") in var names**
- **The adverse event type codes are not used yet**
- **UTF-8 is used (and UTF-16 planned for the future)**
- **In the field "countriesWithSimEvents" it is suggested to use 2-letter the country codes, e. g. like "AT; DE; CH; NL"**
- **Dates must follow the ISO 8601 standard (e. g. "2009-11-23")**



2) All other manufacturers may use the intelligent PDF form, which allows incident data to be added manually. Once the form has been completed the information may be sent to any Competent Authority either by clicking the button “send xml-data per e-mail” or by sending the complete form as a PDF file. In the first case, an XML file identical in structure with the above mentioned XSDs is created and attached to an e-mail. The form, including notes on how to fill in, has been published on BfArM’s web site (see [www.bfarm.de](http://www.bfarm.de); change to the English version and go to Medical Devices => Forms)

In order to encourage investment into the EU electronic vigilance exchange, competent authorities have committed themselves, supported by the EU Commission, not to change the agreed PDF form and XSD files for at least two years. The only exception would be an unlikely change in EU law that would mandate modifications then.

In case of questions, please do not hesitate to contact the undersigned via e-mail to [medizinprodukte@bfarm.de](mailto:medizinprodukte@bfarm.de).

Ekkehard Stösslein  
On behalf of the Federal Institute for Drugs and Medical Devices