



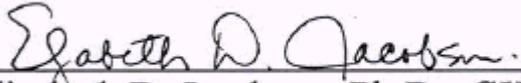
FINAL DOCUMENT

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Vigilance Reporting Related to Medical Devices

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GLOBAL HARMONIZATION TASK FORCE**GHTF SG 2 N8 R4 FINAL**

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GUIDANCE ON HOW TO HANDLE INFORMATION CONCERNING VIGILANCE REPORTING RELATED TO MEDICAL DEVICESCommunication between National Competent Authorities on Events related to Medical Devices

See attached Form for Global Medical Devices Vigilance Report. *Note: That format should be used for reporting between National Competent Authorities only (NCA).* Reference document for the procedures to follow when reporting between NCAs is Guidelines on a Medical Devices Vigilance System, MEDDEV 3/93 - latest revision.

Only information concerning actions taken, or to be taken, will be distributed unless there otherwise is an immediate danger. Reports in an earlier stage could be exchanged if a recall or a corrective action is initiated in more than one country in order to prevent occurrence or recurrence of a serious nature. Single event reports should only be exchanged if they relate to events whose cause is unknown and which may occur elsewhere with serious consequences.

Questions on confidentiality must be resolved through agreements between the countries involved, on a permanent basis. In distributing information between NCAs, it is acknowledged that the recipients will publish the information within their own countries. However, in sensitive cases, NCAs receiving information may wish to contact the authority sending the report prior to releasing information to the public.

When and how to inform nationally about adverse events - Communication within National Territory

Principle: Information should be brought to the attention of those who specifically needs it, and preferably nobody else. In fact; do not make more noise than what is strictly necessary.

Reporting of adverse events involving medical devices to NCAs is an important element in a post marketing surveillance system. The information resulting from such reports must be handled in a manner assuring that those concerned will not oppose to reporting. This can only be achieved if the resulting information is of some benefit, *and* does not harm unnecessary.

The obligation to report differs between countries. Reporting systems may either be voluntary or compulsory, and the scope of the national or regional system will also vary. The common factor seems to be an obligation for the manufacturer to report incidents he is aware of, and which involves his devices. A global reporting system can hence be based on how to handle information provided by the manufacturer to the authorities. *How the manufacturer shall obtain his information for triggering his reporting obligations is a national matter, and must be dealt with at national level.* As medical devices is a truly international affair, what can be achieved nationally, is however crucial to the quality of the overall system.

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A good reporting culture, nationally as well as world wide, can only be achieved through *confidence between all parties concerned*. The question will always remain; what happens to data handed into the system? Can everybody along the line be trusted? Will the information be properly treated? As important as confidential and discrete handling and treatment of data, will be the way conclusions are drawn. What information is to be released and used, and how will this be done. *Note: patient identification should not be disclosed in this reporting system.*

The following concerns should hence be considered before releasing information nationally:

- is the information collected, or received, of *relevance nationally*?
- if yes, *for whom?* - other authorities/ manufacturer/ distributor/ user/ hospitals/ patients/ academics/ the public?
- can the persons, natural or legal, who shall have the information be *traced and located* and given information specifically?
- will information have to be *released to the public* in order to reach persons who needs it, but which can not be reached individually?
- do the public, as such, *need* this information?
- is the information of *use, or of benefit*, to the public at large?

If the decision is to disseminate the information to the public the authority has an obligation to reach all concerned. The release can either be handled in a generic manner or type specific (make & model). Generic information should be preferred if this is adequate. Type specific information should only be given *to the public* if strictly necessary as this can do harm to companies, as well as others involved, far beyond the case in question. Dissemination of information must be handled professionally and be dealt with on a case by case approach.

Information to the public about adverse events will easily lower the health care profession's and the health care system's reputation. It will easily cause anxiety and could thus do more harm than good. On the other hand, for the public it is also assuring to see that such matters are dealt with properly.

List of criteria for deciding on how to disseminate information on adverse events nationally:

1. How to determine if the information collected, or received, is or could be, of *relevance nationally*?
 - contact manufacturer or authorized representative in the region (EEA, USA &c)
 - find out where the device is marketed
 - find out in what countries the device is, has been, or may have been sold
2. What is, or could be, the *purpose or benefit* of handing on the information?
 - any further use of the device could be dangerous
 - possible substantial risk connected to further use of the device
 - the device should be recalled from the market
 - there is an existing risk, guidance on use should be given while awaiting further investigation

- the patient should consult a medical doctor for follow up or investigation
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- the device should be checked/ adjusted/ altered/ modified in order to avoid risk
- customers should register to receive further information

3. To *whom* could the information be of relevance nationally? -

- other authorities
- manufacturers
- distributors
- the health care system
- hospitals
- users
- end users/ patients
- professionals/ academics
- the public

3. Can the persons, natural or legal, who shall have the information be *traced and located*, and be given the information? To facilitate this the health authorities should have *access to registers* for:

- manufacturers of medical devices, or their authorized representatives
- distributors of medical devices
- health care providers
- hospitals and other health care facilities
- owners or administrators of hospitals

Dissemination of information, *as a first choice*, should be taken care of by *the manufacturer*, or his representative. This should be supervised by the national authority, who also should assist in this mission if necessary. Alternatively the authority may carry out this dissemination.

4. From here further steps will then be:

- is the distribution chain possible to trace?
- is it possible to identify the customers?
- is the customer the end user? and if not
- can the user trace the patient?

If the result of the above checking is that the persons concerned can be reached directly, this is the preferred approach. If the answers are negative, the next questions will be:

5. Will information have to be released via media in order to reach persons who specifically needs it? Will newspapers or television have to be used, or are there more targeted, focused or discrete ways? In any case the following should be taken into consideration:

- is the device for professional use?
- is it handed on to, or carried by the patient?
- is it an implant?
- is the device in extensive use?

- is it extensively used by patients as end users?
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- is the device for unprofessional/ patient use?
- is it a single use, disposable device?

6. Before deciding on releasing the information to the public the following questions should also be considered:

- do the public, as such, *need* this information?
- do the public have «*a right*» to know?
- will releasing the information benefit *public health*?
- will the information be of *benefit* to anybody?
- is the information of *use, or of general interest*, to the public at large?
- will the information *enlighten* the public in any way?
- will it be sufficient with *generic* information?

- could releasing the information *scare*, or harm, the public?
- will it be necessary to set up some kind of *follow-up means*?

When an authority decides to disseminate information to the public the following procedure is recommended:

A. Make sure the manufacturer or his authorized representative is *informed in advance* about the case(s), the conclusions and the intended actions. Agreement on what information to disseminate should preferably be obtained.

B. Whenever possible, *the manufacturer or his representative should do the information work*, in accordance with the instructions given by, as well as *supervised by, the authorities*.

C. When choosing ways of informing, the following *steps of priority* should be preferred:

1 - by giving specific information to the customers, when this assuredly can be conveyed to the users, professionals or non-professionals, and to the end users concerned.

2 - by contacting or writing directly to all *possible* customers if this is deemed satisfactorily. *Example: all hospitals for a device which could not be used elsewhere.*

3 - by sending out hazard notes to relevant health care providers.

4 - by announcing the information in media directed specifically towards professionals, where there is a great possibility of reaching all concerned.

5 - by announcing in national papers, radio or television, taking note of the following:

a - making sure of describing the case in a precise and understandable way so that those concerned can identify themselves, and all others will know they are not to worry.

b - give adequate information about the problems and possible risks involved.

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c - include proper follow-up means for those concerned. Inform about whom to contact with what information at hand, as well as about legal and economic matters. Make sure the capacity will be adequate - personnel and telephone lines - to handle the contacting public.

d - consider possible support or further follow-up, including general or specific information to the public.

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