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Role of Notified Bodies in the Medical Device Vigilance System

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2009-2

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1 Introduction

The medical devices Directives require manufacturers to report incidents involving their products that result in the death or serious harm of a patient or user or which have the potential to cause death or a serious deterioration in his state of health. This "Vigilance Reporting System", which is operated by all Member States, aims to improve the health and safety of patients, users and others by reducing the likelihood of the same type of incident being repeated in different places and at different times.

The Vigilance system requires active participation by manufacturers or their Authorised Representative, Competent Authorities, the European Commission and users or practitioners. The involvement of Notified Bodies in such cases however is not well defined.

The "Guide to the Implementation of Directives Based on the New Approach and the Global Approach" (Blue Guide) [1] underlines that Notified Bodies should, basically, be excluded from the responsibilities of market surveillance activities.

However, the Notified Body Operations Group (NBOG) believes that, as per MEDDEV 2.12-1 rev 5, that manufacturers should always inform their Notified Bodies of issues occurring in the post-production phase affecting certification so that the information can be used by the Notified Bodies to help them assess the continued conformity of devices to the provisions of the relevant medical devices Directive. Even though the Notified Bodies do not play a key operational role in the vigilances system, they provide a very important supporting role, as outlined in MEDDEV 2.12-1 rev 5 [2].

This guidance paper has been produced by NBOG in consultation with the Vigilance Working Group and NB-MED. It is aimed at both Notified Bodies, manufacturers or their Authorised Representative, Designating Authorities and Competent Authorities and is the guidance referenced in MEDDEV 2.12-1 rev 5 section 7.

2 Manufacturers and Notified Bodies

According to MEDDEV 2.12-1 rev 5 [2], section 3.1.1 manufacturers must keep the Notified Body advised of issues occurring in the post-production phase affecting the certification with recommendations to inform them about Field Safety Corrective Actions[1] as well as to copy Field Safety Notices[2] to the Notified Body involved in the conformity assessment procedure of the respective devices.

1 See MEDDEV 2.12-1 rev 5 section 5.4.4 and Annex 4

2 See MEDDEV 2.12-1 rev 5 section 5.4.4.1

No particular role in the investigation or the evaluation of the incident is assigned to the Notified Body but it is clearly sensible that the Notified Body should know about such events and any corrective or preventive action taken by the manufacturer to prevent a recurrence of the incident and to assess the impact of vigilance issues on the certifications granted. The Notified Body shall not interfere with the CA, when the CA is monitoring, commenting or challenging the manufacturer's incident investigation and conclusions.

Accordingly, NBOG recommends that manufacturers send their Notified Bodies copies of the incident reports at the same time as they are sent to the Competent Authority. This is essential in circumstances when the manufacturer considers that there is a severe risk to public health or where the issue may have an impact on the device certification as per MEDDEV 2.12-1 rev 5. The information should be supplemented as appropriate during the course of any investigation into the incident and always concluded with a copy of the final report. This should contain a full analysis of the incident and a description of any corrective action being taken by the manufacturer. Manufacturers should also send any trend reports or summary reports to the Notified Body that they are communicating to the Competent Authority. Such reports may relate to issues affecting device certification.

The Notified Body should consider the information contained in these reports when planning its future audit activities of the manufacturer and when approving or renewing certificates. In extreme cases, the Notified Body may need to consider withdrawing or suspending the Certificate of Conformity in respect to particular devices. This information shall be provided to the Notified Body by the manufacturer.

According to MEDDEV 2.12-1 rev 5 [2], section 6, CAs should inform Notified Bodies of relevant cases (e. g. by copying them with relevant Competent Authority reports), which should be taken into consideration by the Notified Body.

NBOG suggests that Notified Bodies require manufacturers to provide it with vigilance information at the same time as it is provided to the National Competent Authority. To avoid doubt or ambiguity, such an obligation should ideally be included within the contractual arrangements held between the manufacturer and Notified Body.

2.1 Notified Bodies regular auditing activities

In case of conformity assessment procedures, which contain an audit of the quality system, the Notified Body shall verify that:

- the vigilance procedures established by the manufacturer are in line with the applicable regulatory requirements (national requirements based on the transposition of the relevant Directive and additional regulatory requirements)
- the procedures cover initiating corrective and preventive actions (CAPA) including undertaking Field Safety Corrective Actions (FSCA) and issuing Field Safety Notices (FSN),
- the procedures are fully implemented by the manufacturer and, if applicable, – via contractual arrangements – also known and implemented by the manufacturer's Authorized Representative and national distributors,
- the manufacturer has adequate resources to handle vigilance issues.

During each of its audits the Notified Body shall verify the implementation of these procedures.

In verifying the system, the Notified Body should sample a number of examples of any incidents registered by the manufacturer, check that the procedures have been complied with, confirm that all relevant serious incidents have been identified and reported to Competent Authorities

and the Notified Body in an appropriate timeframe, and confirm that any necessary corrective and preventive actions have been implemented. Notified Bodies should pay particular attention to any adverse events or incidents not reported by the manufacturer under the vigilance system where it believes such events or incidents should, in fact, have been reported as an incident. The Notified Body should examine the justification provided by the manufacturer when an issue is not reported.

In case the NB's audit team observes that incidents or FSCAs have not been handled in compliance with the legal requirements it should note an audit deviation and should ask the manufacturer for corrective actions. If the manufacturer, on reflection, agrees with the Notified Body assessment, the manufacturer should report the incident to the Competent Authority, investigate the matter as usual and take any necessary corrective action. In this case, no particular action is needed by the Notified Body other than to verify the implementation of any corrective action plan.

If, however the manufacturer disagrees, the Notified Body should report such an event to its Designating Authority and the Competent Authority of the manufacturer. The impact upon the continued validity of any certificate issued should be considered.

Within the audits, determinations made by manufacturers about which incidents and complaint may affect device certification, and should therefore be reported to the Notified Body, should also be reviewed. Deviations and inappropriate determinations should be viewed as a serious matter.

2.2 Assessment of the impact of vigilance issue on the certification granted

It follows from the above that – in addition to procedures covering the regular audit activities – the Notified Body should have a documented procedure to review the vigilance information in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation of the information by the Notified Body and any decisions taken as a result should be thoroughly documented. Where the Notified Body decides to suspend or withdraw a certificate it should inform its Designating Authority without delay.

Upon receipt of information about vigilance cases from the manufacturer or the Competent Authorities the Notified Body should decide about the following options:

- no action required as the vigilance case is obviously not related to the certification granted,
- observation of the manufacturer's and Competent Authority's activities and the results of the manufacturer's investigation to allow a conclusion that the certification granted is not endangered or adequate corrective action has been performed,
- performance of extraordinary surveillance measures (document review, audit, product testing, etc.) if there is a high likelihood that certification granted is endangered.

The manufacturer should communicate adequate measures initiated or taken to the Competent Authority and the Notified Body. Decisions need to be documented.

If the manufacturer does not follow the appropriate measures, the Notified Body should apply provisions of Article 11 of directive 90/385/EEC, Article 16 of directive 93/42/EC or Article 15 of 98/79/EC regarding its responsibility for the issued EC certificates.

NBOG recommends that Notified Bodies take into account notifications sent by the manufacturer or Competent Authorities to evaluate the need for:

- performing extraordinary surveillance activities (document review, audit or product testing, reassessment of design examination),

- increasing the frequency of surveillance inspections of manufacturer's quality systems,
- reviewing specific products during the next or following audit,
- reviewing specific processes during the next or following audit,
- reviewing specific elements of the quality systems during the next or following audit, or
- any other relevant measure.

All information concerning incidents should be taken into account by the Notified Body in any initial, surveillance, renewal or other audit activity.

3 Designating Authorities and Notified Bodies

During the monitoring activities of the Notified Body by the Designating Authority (DA), the DA shall verify that the NB has documented procedures covering the activities described in section 2.

The application of these procedures should be checked during on site assessment of the NB as well as during observed audits [3]. For preparation, the DA should check the information within the European vigilance system and compare with that known by the NB. The reasons for any discrepancies should be investigated and their impact upon the continued validity of any certificates issued considered.

4 Liaison between National Competent Authorities and Notified Bodies

Under the vigilance system the manufacturers are required to inform the Competent Authorities on reportable incidents (for details see [2]). During the subsequent investigation process, the CA can also consult the NB on matters related to the conformity assessment.

The subsequent investigation into the incident may call into question the medical device's concept/design or manufacture without necessarily finding any fault with the quality of the Notified Bodies conformity assessment activity in respect of that particular manufacturer or device. In such cases the CA should consider:

- Requesting the NB to review their records relating to the certification in question in the light of the incident and information gleaned during the investigation of that incident.
- Informing the DA to request that the NB review the certificate, especially in case of public health and safety measures planned or taken by the CA.

  If, following the transmission of information by a CA, the NB requests the manufacturer to implement some actions, the NB should inform the CA of this request.

If the CA's evaluation finds fault with the NB's conformity assessment work in respect of that particular manufacturer or device, the CA should consider – using the NBOG communication protocol [5] – requesting the NBs Designating Authority to conduct a special assessment.

References Directive 93/42/EEC, Directive 90/385/EEC, Directive 98/79/EC

Sources [1] NANDO (New Approach Notified and Designated Organisations) Information System

[2] CEN/TR 15133 : 2005 "Nomenclature – Collective terms and codes for groups of medical devices"

[3] NBOG Designating Authorities Handbook

[4] NANDO Guide to Using Vers.1.0, 31 January 2008

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