Text for a Notified Bodies Recommendation
(After NB-Med April 2007)

NBM/013/ 06

Involvement of the Notified Bodies in the Vigilance System

1. Introduction:

The "Guide for Directives under the New Approach and Global Approach" (Blue Guide) underlines that Notified Bodies should, basically, be excluded from the responsibilities of market surveillance activities. According to the (draft) guidance on vigilance MEDDEV. 12/2 the Notified Bodies do not play a key role in the vigilance system but the overall functioning of the vigilance system may be influenced by Notified Bodies' activities in the following areas:

- assessment of vigilance procedures
- audit of the implementation of the vigilance procedures, e.g. CAPA, FSCA (Field Safety Corrective Action)
- assessment of the impact of vigilance issues on the certification granted
- liaise with the Competent Authorities (CAs) if required, e. g. specific investigations/audits based on a request of the NCA (National Competent Authority)

2. Purpose

This Notified Bodies Recommendation serves as guidance for Notified Bodies, manufacturers and Competent Authorities. In particular it clarifies the extend and limits of involvement of the Notified Bodies in the vigilance system.

3. Implementation

3.1 Assessment of vigilance procedures and audit of their initial implementation

In case of conformity assessment procedures, which contain an audit of the quality system, the Notified Body should verify during the initial and renewal audits that:

- the procedures of the manufacturer are in line with the relevant Directive (Guidance is given in MEDDEV 2.12.1)
- the manufacturer has resources to handle vigilance issues
- that the manufacturer has a procedure to issue Field Safety Notices (FSN) and Field Safety Corrective Actions (FSCA) in place

In case of EC-Type Examination orEC-Design-Examination the Notified Body is not involved in the evaluation of the manufacturer's vigilance procedures at all. In case of EC-Verification the Notified Body may request information about the vigilance procedures because of to the undertaking mentioned in the respective Annexes of the Directives.

3.2 Monitoring of vigilance procedures during surveillance and renewal audits:

During surveillance and renewal audits vigilance implementation of procedures should be addressed. The manufacturer should be prepared to present related documentation. The audit team of the Notified Body should on a sampling basis verify whether the procedures have been followed (particularly that data related to serious incidents). It should be presented the risk assessment documentation in order to be able to check the risks evaluation.
In case the 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, which may include training of personnel, provision of adequate resources and/or information of the relevant Competent Authority through the manufacturer. Regarding the notification of vigilance cases it should be the role of the Notified Bodies to get the assurance that the Competent Authorities have been informed **and that the follow-up and/or final reports have been provided to the CA, as well as all relevant documents.** Only in extraordinary circumstances information of the Competent Authorities by the Notified Body may be necessary.

3.3 Information of the Notified Bodies:

Irrespectively of the type of conformity assessment procedure the Notified Body should have an agreement with the manufacturer to inform him about vigilance related issues in case they could be related to the certification granted.
The extent of this information can be part of the Notified Body's contractual arrangements with the manufacturer and can be during the period of validity of the certificates individually adjusted.
The main purpose of this information is that the Notified Body gets information about the devices and quality systems covered by his certificates to improve his knowledge and to perform an efficient surveillance.

Upon receiving 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) if there is a high likelihood that certification granted is endangered. All the measures should be defined in agreement with the manufacturer, who should already have communicated adequate measures to the Competent Authority in the meantime.

According to MEDDEV. 2.12/5. it is recommended that Notified Bodies are informed of corrective actions taken by their manufacturers as a result of the vigilance system to enable them to confirm timely and appropriate action has been implemented. This information should be provided to them by the manufacturers but it is also recommended that 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. **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.**

Notified Bodies should try to avoid extensive costs for manufacturers for the routine handling of vigilance information as long no extraordinary surveillance measures by the Notified Bodies are required.

3.4. Information Requested by the Competent Authority from Notified Bodies:

In case the Competent Authority requests information from the Notified Body, the Notified Body should inform the Competent Authority accordingly and should copy this information to the manufacturer.
In case the Competent Authorities request extensive information or investigations from the Notified Body, he should clarify with manufacturer or authorities the amount of costs for his additional activities.