EUROPEAN CO-ORDINATION NB-MED NOTIFIED BODIES	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Recommendation** **NB-MED/2.12/Rec1**

Title:	**Post-Marketing Surveillance (PMS) post market/production**
Chapter:	**2.12 Market surveillance; vigilance**

Text:	**"MDD" undertaking by the manufacturer to keep up to date a systematic procedure to review "Experience gained from devices in the Post - Production phase".** **"AIMD" undertaking by the manufacturer to institute and keep updated a Post-Marketing Surveillance (PMS) system.** **"IVD" The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase**
Key words:	**surveillance, registration card, vigilance**

Post-Marketing Surveillance

Manufacturers must have an appropriate system for gaining and reviewing experience in the post production phase from the range of devices he manufactures. Notified Bodies have to audit/verify that there is an effective system in place.

Such systems are an integrated part of a manufacturer's quality assurance system. In most cases, PMS systems already exist to meet internal company needs, as an integrated part of a manufacturers quality system, and/or to meet the requirements of third parties. In the absence of an approved quality system (see MDD annex IV/3 - VII/4 and IVDD annex III-5) the manufacturer is still required to have an effective PMS system in place.

In order to audit/verify the existence and effectiveness of the PMS system, the Notified Body should apply a graduated approach based upon the intended use and the risk of the use of the device. The result of the device risk analysis should also be

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD	Annex: 2-3.1v, 4-3, 5-3vi	EN 46001/2, EN 50103
MDD	Annex: II-3.1vii, IV-3.1viii, V-3.1, VI-3.1viii, VII-4	EN 724, EN 46001/2, EN 50103
IVDD	Annex: III-5, IV-3.1, VI-3.1, VII-3.1	EN 928, EN 46001/2

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taken into account. The requirements of the PMS should be in direct proportion to the risk associated with the device based on its intended use. When establishing and operating the PMS system, the manufacturer should consider, for example

- whether or not the product or technology is new to the manufacturer,
- the extent of available scientific knowledge (e.g. on long term effects),
- the state of the art and market experience with similar products and technology.

PMS systems are based on information received from the field (e.g. complaint monitoring, feed back from sales representatives, reports from regulatory authorities, literature reviews, service/repair information) and its analysis as described and referred to in EN 46001/2 clause 4.14.

Note: Attached to this recommendation there is an annex given more information.

An example of a feedback system, in this case for AIMD:

The IAPM/EWGCP registration card project for the registration of pacemakers and pacemakers patients (which exists and has been actively in use since 1980) is a satisfactory information medium.

This registration system, together with a return goods/failure analysis and corrective action loop, is considered to be an adequate basis for a PMS system as required in the AIMD annexes.

An example to fulfil the minimum requirements from the MDD area:

The requirement for labelling the device with the manufacturers name and address, gives the user the ability to report back any experience gained in using the device.

An Example of application of PMS for the MDD:

A manufacturer of intraocular lenses received a number of complaints from the field concerning broken optics. It is identified that the number of these complaints demonstrate a statistically significant increase above that which should be expected for transport and storage of the product. On investigation, it is identified that the cases obtained from a third party are on the high end of the manufacturer's specification which has lead to excess pressure on optics, creating increased breakage. As a result, the manufacturer, through feedback to his design control, was able to adjust his specification and correct the situation, thereby reducing breakage, increasing user satisfaction and reducing costs.

Reporting of adverse incidents to the Competent Authorities is covered in MedDev vigilance paper (MedDev 2.12/1 (old number: 3/93) - latest revision).

Annex

Possible achievements of a manufacturer PMS system

These are some of the types of knowledge and feedback which can be achieved from a PMS system. Not every system will provide all of the following, the manufacturer should decide which are the priorities.

- detection of manufacturing problems
- product quality improvement
- confirmation (or otherwise) of risk analysis
- knowledge of long-term performance/reliability and/or chronic complications
- knowledge of changing performance trends
- knowledge of performance in different user populations
- feedback on indications of use
- feedback on instructions for use
- feedback on training needed for users
- feedback on use with other devices
- feedback on customer satisfaction
- identification of vigilance reports
- knowledge of ways in which the device is misused
- feedback on continuing market viability

Sources of PMS information

The following may be considered as sources of information, dependent on what endpoints are sought and in the light of the variables listed above. Some sources are proactive, some are reactive.

- expert users groups („focus groups“)
- customer surveys
- customer complaints and warranty claims
- post CE-market clinical trials
- literature reviews
- user feed-back other than complaints, either direct to manufacturer or via sales force
- device tracking/implant registries
- user reactions during training programmes
- other bodies (e.g. the CA)
- the media

- experience with similar devices made by the same or different manufacturer
- maintenance/service reports and
- retrieval studies on explants or trade-ins
- in-house testing
- failure analysis

Variables affecting choice of achievements and information sources

Each case is different and the following factors should be taken into account when setting up a PMS system:

- device type and risk classification
- manufacturer experience and history
- customer expectation and political climate
- degree of control of distributors
- different priorities/agendas of sales force

Rev. 6: Meeting of NBR Group, Brussels, June 21, 1996:
Changes agreed:
2nd last sentence: Notified Bodies have to check that there is an effective system.
Last sentence: give full reference to MEDDEV 3/93, Vigilance final draft May 1993.
1st sentence: "Post Marketing Surveillance PMS are integrated"
1st sentence 5/6th line: "See MDD annex IV.3"
New Revision no: 6

Rev. 7: Meeting of NBR Group, Brussels, Sept. 4. 1996:
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, Sept. 24 & 25. 1996:
It was decided **to give back this document to the task force** in order to rework the document on the following issues:
to add: "manufacturers must have an ... experience from all devices in the post-marketing phase." and to take into account of graduated approach based on the risk and characteristics of the device. This sentence will be put at the beginning of the document.
to add an example of another area medical devices.
to give more value to the distributor, or the manufacturer interface in this context.

Meeting of NBR Group, Brussels, Nov. 7.1996:
Proposal by M. Binard at the NBM Plenary (Sept. 24 & 25, 1996) to extend PMS to all devices was challenged by industry members of the Group. The Group reached consensus: ... from the range of devices he manufactures in the post marketing phase. This sentence and the next one are to be moved to the beginning of the document.
Additional examples of MDs will be provided by VD based on manufacturers PMS procedures.
Interface discussion for PMS between manufacturer and distributor: inconclusive, written proposals are invited to the chair.

Meeting of NBR Group, Cologne Jan. 20 & 21. 1997:
No additional examples have been provided, and no written proposals have been received.
The comment on this document from the German Notified Bodies Group EK-Med (see NBM-document NBM/027/95) was disregarded as being not relevant as PMS is more than only vigilance, and that MEDDEV 3/93 does not cover all aspects about vigilance in this context.

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New revision no: 7

Rev. 8: Meeting of NBR Group, Essen, April 03. & 04. 1997:
A proposal from EUCOMED with regard to an "Example of application of PMS for the MDD" was tabled.

A manufacturer of IOLs received a number of complaints from the field concerning broken optics. It is identified that the number of these complaints demonstrate a statistic increase above what should be expected for transport and storage of the product. On investigation, it is identified that the cases obtained from third party are on the high end of the manufacturer's specification which has lead to excess pressure on optics, creating increased breakage. As a result, the manufacturer, through feedback to his design control, was able to adjust his specification and correct the situation, thereby reducing breakage, increasing user satisfaction and reducing costs.

It was decided to include this example. It was decided to do some minor additions. NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in June 1997.
New revision no: 8
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, June. 24 & 25. 1997:
Confirmed to be at Stage: 3

Meeting of NBR Group, Essen, September 29 & 30 1997:
It was decided to fit the document in the new *recommendations nomenclature system* (chapter 2.12 *Market surveillance; vigilance*). Therefore the recommendation gets the new number **NB-MED/2.12/R1**. The old number will be retained for a transitional period.

Medical Devices Expert Group Meeting, Brussels, February 9/10, 1998:
The stage 3 document was presented to the Medical Devices Experts Group but was not fully accepted; also the document should be reworked in the context of the current discussion on breast implants. Further the document should give an answer to the question „How long should PMS be in place?" (medium/long term tests).

Rev. 9: Meeting of NBR Group, Brussels, April 20 & 21, 1998:
In the light of the discussion in the Medical Devices Expert Group NBRG reworked the document and made the following clarifications under the 3rd and 4th paragraph:

„*In order to audit/verify the existence and effectiveness of the PMS system, the Notified Body should apply a graduated approach based upon the intended use and the risk of the use of the device. The result of the device risk analysis should also be taken into account. The requirements of the PMS should be in direct proportion to the risk associated with the device based on its intended use. When establishing and operating the PMS system, the manufacturer should consider*

- *whether or not the product or technology is new to the manufacturer,*
- *the extend of available scientific knowledge (e.g. on long term effects),*
- *the state of the art and market experience with similar products and technology.*

PMS systems are based on information received from the field (e.g. complaint monitoring feed back from sales representatives, reports from regulatory authorities, literature reviews, service/repair information) and its analysis as described and referred to in EN 46001/2 clause 4.14."

On occasion of the next NB-MED meeting on June NB-MED will be informed about this changes; further consideration will be done by the Medical Devices Experts Group.
Confirmed at stage 3
New revision no: 9

Notified Body Meeting, Brussels, June 9 & 10, 1998:
The NB-MED agreed the proposed clarification - made by NBRG - concerning „How long should PMS be in place?" and „Where the feedback is coming from in the PMS?"; this document will remain a stage 3 document. Further consideration will be done by the Medical Devices Experts Group.
Confirmed at stage 3

Notified Body Meeting, Brussels, November 3 & 4, 1998:
Since last NB-MED meeting the MDA/UK made some correspondence to the NBRG (see NBM/134/98). The NB-MED asked the NBRG to made further progress concerning the PMS-document also in light of the MDA comments and the discussion concerning tracebility. The results should presented to the next NB-MED meeting and in parallel directly to the MDA.
Confirmed at stage 3

Rev. 10: Meeting of NBR Group, Brussels, November 5 & 6, 1998:
NBRG agreed to add some parts of the MDA comments (with regard to *Possible achievements of a manufacturer PMS system*, *Sources of PMS information* and *Variables affecting choice of achievements and information sources*; see NBM/134/98) to the current issue of the NB-MED Recommendation as an informative annex. The revised Recommendation will be distributed to the NB-MED and in parallel to the MDA. Further consideration should be made within the Medical Devices Experts Group.
Confirmed at stage 3
New revision no: 10

Rev. 11: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

Meeting of NBR Group, Cologne, February 3, 2000:
The work results of a small task force (task: reworking the Recommendations) were presented to that NBRG-meeting.

The tabled revised Recommendation was discussed and NBRG agreed that the document, as discussed and revised, should be presented for adoption at the February/March NB-MED Plenary meeting. Only some editorial changes were made.
Revision no: 11
stage 2

Notified Body Meeting, Brussels, February 29 & March 1, 2000:
The document (NBM/39/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 11