The European Association Medical devices - Notified Bodies

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MINUTES
47TH MEETING OF NB-MED, OCTOBER 9 AND 10, 2012

Notified Bodies Meeting 9 October 10.00- 18.00

1. WELCOME

Chris Jepson welcomes the participants and chairs the meeting.

Gero Viola send apologises because for health reasons he was not able to chair NBRG meeting and will not attend this meeting.

John Andrews informed he will not attend this meeting. He is thanks for his many attendances.

2. GENERAL AND ORGANISATIONAL MATTERS

2.1. Roll call of the participants Chair

At the beginning of the meeting 42 participants representing 38 NBs are present.

2.2. Draft agenda for Closed session Chair

Chris Jepson informed that the minutes of this first session will be sent only to the attendees.

3. NOTIFIED BODY DISCUSSION TOPICS

3.1. Code of Conduct Vice Chair

Gert Bos presented to the audience the history of the CoC and the importance to sign it. Today 18 NBs signed the version 2.7 of the CoC. They are all Team-NB members.

Commissioner Dalli was pleased with the efforts made by NBs in order to help him to keep the system in the actual line. The version 3.0. has implemented items to include IVD, unannounced audit and comments of CAs have been taken on board.

UL informs they intend to sign the CoC.

The Netherlands CA asked to be informed about the CoC.

The Hungary CA has requested the NBs to follow the CoC.

The Turkish CA asked for more information on the supervision structure. Gert Bos replies that the CA supervision, in an harmonised way, is something waited since years and probably will not happen in the best way before the application of the new regulation which mean probably 3 or 5 years. The supervision included in the CoC is a political tool because it is an awaited signal. It is a temporary tool to achieve a better harmonization and to response the thread of European Parliament.

The CoC will remain a voluntary tool until new legislation will apply.

It is fair to say that if CAs want to audit NBs against CoC requirements, we are more that happy.

On another hand, knowing that approximately 40 NBs attend NB-Med meeting, we may say that they are 50% active NBs out of the 80 NBs. Today 18 out of these 40 have signed and 4 more indicated they intended to sign. This figures show already a good representativeness.

3.2. How and whether to Audit Authorised Representatives Chair

Following a discussion, we intend to agree to establish a list of the minimum to assess in auditing a Manufacturer outside Europe regarding his Authorised Representative agreement.
The items to check are:

- Manufacturer must have identify an AR;
- there must be a single AR for each product;
- a final agreement must exist;
- the agreement must follow the MEDDEV;
- there must be a signed agreement before the EC declaration of conformity is signed;
- if the Manufacturer outsourced vigilance or other processes to the AR, there must need a PG and possibly an audit;
- NB must be notified in case of change of AR.

There will be an interest to discuss whether an AR could be considered as a crucial supplier.

3.3. Andersen Sterilisation process Chair + MP

The EtO standard ISO 11135-1:2007 Sterilization of health care products -- Ethylene oxide Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
The today objective is to reach a consensus.
Experts of some NBs consider that some details of the standards are not applicable.
Nevertheless this standard is very helpful. Seven areas of discrepancies have been identified.
This is not a standard where you can pick and choose.
There seems to be a reasonable unanimity to say that either you use this standard in totality or chose another one. And in case you follow it in totality you may claim conformity against this standard.
Following our meeting, Intertek need to go back to Andersen company with information. For information, FDA microbiologists raised a concern regarding this method.
To support Intertek, NBs who reviewed the standard internally will send a NB-Med working group represented by Mats Premford their technical concerns.
There is a request to point out in which ways the Andersen process does not meet the ISO 11135 requirements.

3.4. ISO/IEC DIS 17021-3 on Competence Vice Chair

Gert Bos presents the draft content.
It addresses competence requirements for QMS auditing and also other staff involved in the certification process. These competences are addressed in a table.
Some NBs consider there is no real added value to this document.

3.5. Notified Body Feedback on reviews of designation Chair

Following Dalli commissioner request to members States to review the designation of their NBs, what is the status in different Members states?

It seems that UK CA focus on class III with the clinical competences within NBs.
Irish CA seems to be on the same wavelength than UK CA.
In Denmark, the CA insists on NBs to perform unannounced audit.
In the Netherlands, there were no additional requirements but they check competences.
In France, the CA looks at the class III certification process.
In Germany, the CA focused on competences and clinical evaluation.

It looks that generally CAs have acted following commissioner Dalli request letter.

3.6. Recommendation on Auditing and anticipated changes to be introduced in 2013 Chair
Unannounced audits and sampling/testing

An unannounced visit has been performed by Denmark NB pushed by their CA following a problem detected by CA.
An audit was performed in Ireland.
A 1h notice announced visit took place in Germany following the concern of a NB concerning a product. The audit took place in Asia. There were 2 auditors.
A Belgium NB performed an audit in a company where they had suspicions of problems and the company went bankrupt.
A Turkish NB made an audit following a complaint.

For information, in those audits, the environments were quite hostile and it is better bringing drinks and lunch. There are also questions whether the invoices will be paid.

It is fair to say that as far as it will become something that all NBs have to do, probably Manufacturers will become used to it and it will become easier.

As far as sampling and testing is concerned, it is still more difficult. There will be some practical limitations such as:

- price / value of devices;
- cost testing;
- lead time;
- what needs to be tested?
- what in case there are no products on site during visit?
- non continuous production;
- can sampling be done under all conformity assessment routes?
- what are critical test?
- statistic valid sampling.

Moreover some aspects are probably beyond the legal possibilities within the today legal framework.

What about only witness testing made on site by the Manufacturer?

3.7. Implementation of IAF MD 9 Feedback from Notified Bodies Chair

MD9 have been put as a requirement for NB in some countries although it is usually asked by accreditation bodies.

MD9 requirement on NBs	**MD9 requirement on ISO certificate only**
• Turkey • Belgium • Hungary	• Germany (for ISO only) • Netherlands (for ISO only) • UK (for ISO only) • Norway (for ISO only) • Ireland (for ISO only)

3.8. Proposals for Regulations on medical devices and IVD Devices Vice Chair

EC COMMISSION JOINS MEETING

4. NOTIFIED BODY + COMMISSION TOPICS

4.1. Harmonisation and the Role of Harmonised Standards MK

The European Commission noticed deviation of use of harmonized standards as mandatory documents and wants to point out that it is not along the rules.

No doubt that harmonized standards are not mandatory with the exception of labelling. Some NBs consider them as mandatory and some Manufacturers do not want to follow some standards.

As far as state of the art is concerned, it is the role of CAs and NBs to define what can be use to show compliance.

Manfred Kohler shares our fears of risks of deviation.

The aim in the future is to have CTS on MDs.

In summary, for a Manufacturer using harmonized standards is a kind of legal protection, it a presumption of conformity but it is not a proof of conformity to state of the art and neither a mandatory route.

It is to be mentioned that state of the art was discussed and defined in a document S/03/07 in 2007. That definition takes into consideration 2 dimensions (technological and medical practice).

The Commission informs that objections are now withdrawn. Last amendment regarding ISO 13485 and ISO 14971 are not yet published.

Points 4.2. to 4.5. will be discussed in the plenary session.

4.2. Implementing Regulation on Designation of Notified Bodies
4.3. Recommendation on Audits
4.4. Actions to explain Conformity Assessment systems HHJ
4.5. Proposals for Regulations on medical devices and IVD Devices

4.6. AOB

4.6.1. IMDRF presented by L. seilles from the Commission;

It addresses the submission in an electronic way of electronic product information from Manufacturers to regulatory agencies.
The Commission calls for volunteers.

4.6.2. Unannounced visit

Some unannounced visits took place for causes, sometimes asked by CAs.
Gert Bos presented a summary of the experiences.
It is fair to say that it looks possible although there are some logistical and practical problems.
We also want to indicate that we will need time to implement these audits because we will need to solve some problems regarding contracts and to train auditors.
For information, the Recommendation could be circulated on November and adopted by the end of this year. A meeting is planned on October 30th with Members States. The Recommendation could expect a gradual implementation in 2013. Commission is aware of capacity problems but would like NBs to start increasing their staff.

4.6.3. Sampling/Testing

The concerns addressed in the beginning of the meeting are presented to the Commission.
The Commission asks for a writing summary on the problems identified in the existing legal framework.

PLENARY MEETING 10 October 9.00 -16.00

1. WELCOME

Chris Jepson welcomes the participants and chairs the meeting. Gert Bos is vice-chair and Steve Mcroberts will take notes to propose a summary minutes of the meeting

2. GENERAL AND ORGANISATIONAL MATTERS

2.1. Roll call of the participants Chair

Each participant presents himself.

2.2. Adoption of the draft agenda, Chair

The agenda is approved.
2 topics are added.

2.3. Approval of the minutes of the 46th NB-MED meeting (see NBM-xxx-11) Chair

The minutes are quite extensive. The minutes are approved unless participant sent request of changes to Chris Jepson.

2.4. Date and place of the next meetings of NB-MED, Chair

- 16/17 April 2013 Metropole Hotel
- 15/16 October 2013 Metropole Hotel

2.5. Changes to CIRCA Chair

It looks that the new CIRCA will not be in place before months and we stay as we are.

3. FEEDBACK FROM NOTIFIED BODY SESSION

See Notified Body agenda for topics. Where the topic has a specific agenda item the feedback will be incorporated into that debate.
There will be 2 sets of minutes. The minutes of the NB only meeting will be circulated to the participants only. The plenary meeting minutes will be available on CIRCA.

The CoC was discussed twice, one in the NB Med meeting and once in the Team-NB meeting. The CoC new version 3.0. has additional items such IVD included in the scope, a scrutiny mechanism, design and file dossier review and unannounced visit information.
The CoC version 3.0. has adopted it as a mandatory requirement to become a member.

The AR minimum auditing item to assess was agreed. Clearly, no CE certificate must be issued if those proof are not in the Manufacturer system (see list above)

The unannounced visit experience and the sampling/testing difficulties were pointed. This topic will be at the plenary agenda as well. (see below)

4. INFORMATION FROM THE EU CIE AND DISCUSSION ON LEGAL ISSUES

4.1. Draft Implementing Regulation on Designation of Notified Bodies Commission

The Regulation following PIP scandal will probably not be published before April 2013. A meeting will take place with Members States on October 30th. The Commission does not yet know whether the draft document will be available before formal adoption.

4.2. Draft Recommendation on Audits Commission

This recommendation include a part for unannounced audits
A Recommendation may be adopted independently from Members States by Commission and could be adopted before the end of the year. This recommendation has a special status. It is not a binding measure but it may be use in court as mean to reach objectives.

4.3. Joint Audits Commission

4.4. Other measures of the PIP Action Plan Commission

4.5. Eudamed Commission

4.6. Animal Tissue Regulations Vice Chair

Regulation 722/2012 has been adopted in August 9th 2012 to include AIMDD.
It will be effective within 12 months and in 24 months as far as AIMDD are concerned.
It includes a summary evaluation report sent to CAs. CAs have 4 to 12 weeks to review the summary.
The animal tissue directive will be withdrawn and the MEDDEV guidance will be revised.

4.7. Harmonised Standards

State of play formal objections/harmonisation Commission

The standardization machinery is not back to an adequate functioning. Only some standards are available.

Harmonisation of EN ISO 13485:2012 Chair

There is an agreement to suspend the formal objection. The Annex Z will be modified.
For information, it is proposed that there will be no invalidation of certificate thanks to deharmonization.

4.8. CMC Role and Work Items M N

- Draft Decision of EC Declaration of Conformity

CMC agreed on EC Declaration of Conformity content in an aim of harmonization.

- Decision 3 on Addresses Eucomed

Eucomed points out a lot of discrepancies among the Members states which lead to confusion.
CMC issued on July 16th a revised document including a note saying that "not all the details may be part of the registered address..."
In general, Eucomed seeks for legal clarity regarding CMC decisions.

4.9. Prohibition of PSA self test devices in France

ANSM took the decision to prohibit the PSA self test devices in France.
The French NB has not been asked to cancel the issued certificates for these products but they are thinking to suspend them. French authorities expect European decision.

4.10.

MEDEV 2-12-1 Rev 8 on Vigilance Vice Chair

4.11. Court Ruling on Phamacological Action Vice Chair

This court ruling was circulated on CIRCA as NBM-028-12 document.
The document is defining in a way the pharmacological action. It could lead that some products where there is a claim of physical interaction and which are today classified as a MD could be in the future reclassified as drugs.

5. WORKSHOP ON MEDICAL DEVICE DIRECTIVE REVISIONS

5.1. Status of the Revision Commission

Note: Proposal for a Regulation on medical devices and a Proposal for a Regulation on in vitro diagnostic medical devices published 26 September and attendees will be expected to have downloaded these documents for this meeting

5.2. A participatory session led by the Vice Chair with the objective of initiating a debate on some of the significant issues concerned with the forthcoming revision to the directives.

- Specific Topics to be decided on the day

Unannounced visits

- NBs and client agreed on period which are practicable (closed - exhibition)
- Criteria for the visit and auditor
- Mechanism for education industry to reduce hostile environment
- Principles to be set (not an UV the day after a scheduled visit)
- reporting requirements
- outsources processes sites to visit - contractual obligations
- how to deal with OBL manufacturers
- rules for NB in terms of days and auditors: 1 day & 2 auditors and 1/2 day for outsourced process

Risk for devices without medical benefit

Products in Annex XV are MD without medical purposes

- fully inclusive list
- Device is used as part of a voluntary procedure
- No assessment of "cosmetic" benefice
- Clear identification of intended purpose
- Problems in evaluation (rely on PMS of existing products and minimization of risks by Manufacturer)
- these products are regulated in other jurisdictions (eg FDA)

Product verification

2 different schemes

- product verification for all manufacturer, on all directives, on all products:
  - seems reasonable;
  - good auditing practice;
  - Concerns: what is adequate sample? what means that we have to verify all critical components? what is expected to verify compliance with legal requirements?
- product verification on DD or type tested devices:
  - this scheme is very difficult;
  - purpose is testing the conformity of the device type;
  - sampling and testing criteria shall be defined in advance;
  - sampling and testing criteria not to be defined by each NB;
  - request to define sampling and testing criteria by a Committee.

Person responsible for regulatory compliance

- Criteria well defined;
- Apply to Manufacturer and AR;

- question: within the company? on the pay roll or subcontracted?
- define equivalence course of study (Bologna / what about outside Europe);
- at least 1 qualified person; OK for several persons with defined scope;
- need back up person in case of holidays or illness or…;
- check by NB: diploma / CV/ records of skills and trainings / interview.

COEN forms requesting 'state of the art comparative analysis"

- the aim is to get comparative analysis of clinical claims and intended use in IFU between dossiers from a number of Manufacturers looking for 'state of the art"
- concern: change of "state of the art" definition;
- probably non-transparent (no NB involved);
- improvement: define more ways to define "state of art" of clinical safety;
- initial input by Manufacturers and NBs.

6. REPORT OF NBRG

In the absence of Gero Viola, Michel Binard chaired the meeting.

6.1. Relationship to NBOG

Report on NBOG meetings Hans-Heiner Junker

Report from NBOG: Rainer Edelhauser

CIRCA new is quite useless (not self-explaining)

There were a 2 day meeting in June.

Focus was on draft Commission implementing Recommendation and Regulation.

Ongoing projects were mainly delayed following the focus on Commission documents.

Joint plan for immediate actions on designation and monitoring of NBs

They consider legal basis partially unclear (review of class III NB by MS & class III NB will be assessed by a team of national and Commission staff as from 2013 & reception by NBs of vigilance reports)

Member States are reasonably unhappy with the Commission proposal.

Commission recommendation

A few comments were submitted:

- checklist of items to be verified by the NB during audit;
- perform unannounced audits/inspections;
- check of adequate product samples;
- not legally binding.

The MBs considers this recommendation different from a reel law.

The Designation process has been endorsed by CMC.

Document on Review of NB activities on file reviews relating to clinical evaluations agreed.

6.2. NB-Recommendations

e Labelling HH Junker

Commission has concerned about this document.

One of the concerns is that eIFU and Technical documentation design dossier sampling check by NBs are mixed.
The revised document will be sent to the Commission and NBOG for comments.

Technical Documentation L S

IVD Revision John Andrews

Systems and procedure Packs John Andrews
Commission has concerned about this document.
The document will be sent to NBOG for comments.

List of Consensus Documents Gero Viola

Vote for approval for completed draft documents Chair

6.3. Other NBRG matters Gero Viola
There will be a call for volunteers to attend working groups.

7. TECHNICAL ISSUES RELATED TO DEVICES

7.1. None notified at this time

8. GLOBAL HARMONIZATION

8.1. Status and Activities of IMDRF Vice Chair

8.2. Status of Asian Harmonisation Working party (AHWP) Vice Chair

9. INTERNATIONAL RELATIONSHIP

Progress in MRA discussions:

9.1. MRA EU/AUSTRALIA and NEW ZEALAND Commission
For Australia, they could restrict the MRA to class 1 or 2A

9.2. ROC Taiwan TCP II John Howlett/Gert Bos

9.3. FDA Voluntary Audit report Submission program Vice Chair

10. STANDARDIZATION AND NOMENCLATURE

10.1. New Work Items

10.2. TC210 ISO 13485 revision Discussion of draft

NBOG has been asked to have an official representative at the TC 210 meetings.

11. REPORT FROM WORKGROUPS

MDEG *Vice Chair*

ATM Products *Vice Chair*

It looks that there is only 1 assessment ongoing.

Emerging technologies *Guy Buijzen*

There is a request of expertise in the field of new radiotherapy technologies.

Borderlines and classification *Michel Binar*

A meeting took place last week.

They are reviewing definitions.

There are looking to improve the decision process.

Clinical investigation and evaluation *Vice Chair*

IVD *?*

Animal tissue *Vice Chair*

MRA's *Vice Chair*

Software *?*

ISO 62304 has been reviewed and 80 questions were raised.

There is a request to set up a WG under NBRG umbrella.

Vigilance *Mr Rentschler*

e-labelling

MDEG	Vice Chair
ATM Products	Vice Chair
Borderlines and classification	Michel Binard
Clinical investigation and evaluation	Vice Chair
IVD	?
Animal tissue	Vice Chair
MRA's	Vice Chair
Software	?
Vigilance	Mr Rentschler

12. Any other business

Arrangements for next meeting (ie sessions, timings)