The European Association Medical Devices - Notified Bodies

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53RD MEETING OF NB-MED, 13-14 OCTOBER 2015 REPORT

Notified Bodies Meeting Tuesday 13 October 10.00- 17.30

1. WELCOME

Guy Buijzen is welcoming the participants.
He thanks the chairmanship of Gert Bos and Hans-Heiner Junker during his unavailability.
Nevertheless, he informs that following his accident the recovery is still on-going and that he will step down from the NB-Med chairmanship.
There is a call for candidates to the chairmanship.
Hans-Heiner Junker is candidate.

On the next day as there is no other candidate and Hans-Heiner Junker is elected by applause.

2. GENERAL AND ORGANISATIONAL MATTERS

2.1 Roll call of the participants — Gert Bos

Collection of email addresses from participants for circulation of NB only minutes

A document is circulated among the present to allow the circulation of the notes among the present NBs.

2.2. Draft agenda for Notified Body session — Gert Bos

A new agenda with added point is available and will be sent shortly by the technical secretariat.

2.3. Notes from Previous NB only session — H-H Junker

The notes of the last meeting are accepted.

3. NOTIFIED BODY DISCUSSION TOPICS

3.1. Unannounced Audits (UAV) - exchange of experiences — Gert Bos

It looks that although the Manufacturers are not too happy to receive the auditors for an unannounced audit, the audit are done without reel problem.
Some of the audits came to the suspension of the Manufacturers.
It looks although it is an unfair way to deal with very small or big companies with the same numbers of day.
In Germany, when a NB has no internal test laboratory, he needs to contract with an accredited test laboratory which will be perform the tests on the production samples took during the UAV.

There is very few refusal of UAVs. The most number of refusals came from subcontractors.
The refusal of 1 manufacturer lead to an immediate withdrawal of their certificate.
There are examples where some legal manufacturers have had more than 2 men-days with probably a maximum of 10 days a year on several sites.
On the contrary with very small company or very restricted scope a 1 day is very much. In this case the NBs proposal is to let some "opening". It could be decide to go ahead with a normal surveillance and to skip the one surveillance to be held in the coming months.
As far as the cost is concerned, the main objections came from small manufacturers.

Improvement effects:
The experience has been very positive with among others the focus on the products. The auditors like to go on production. The detection of fraud is nevertheless difficult.
Some NBs make the balance on materials bought, used,... but it is not straightforward. It is very time consuming and in this case some other aspect should be neglected.

What about the unannounced auditor arrive on site and there is already on site audit? That could be situation that arises. A possibility could be that the second NB arrived will left the company. But then what about the travel costs. Probably that will be difficult solution when the audit team made a long travel.

3.2. Status update legal position paper German Notified Bodies — H-H Junker

There is not 1 German position on that paper.
It looks that this paper is not legally enforceable.
This paper try to set up how the German NBs have to deal with unannounced audit.
The problem come from pharmaceutical companies who are afraid that the unannounced audits could became a way of auditing the pharmaceutical industry.
The fact it that for political reasons there is no way back regarding unannounced audits realisations.
There is a need of rule guidance on a European level

3.3. Improving documentation (Regulations, Directives, MEDDEVs, NBOG BPG, NB-MED doc etc) to reduce ambiguities, contradictions, and difficult language. Explanations of terminology and rationales behind the requirements should exist.

MedDevs requirements have shown their interest.
Although it looks that there is a trend not to do this kind of documents in the future<<;
There are definitely a need of guidance's.
It is to notice that the NBs influences of the MedDevs is less important than is the past.

A possibility to get guidance's is to try to set up simple document among NBs to try to help harmonization.
There is a willingness among the NBs to produce guidance documents to help NBs in their work.
Today there 56 guidance documents. What are the priorities for modifications?
The list is asked to the NBRG in order to be shared in an objective to point out the most prioritize documents.

A possible improvements in the writing of those types of document is to take in mind a harmonization of structure of the documents.

3.4. Open discussion on any other issue — Gert Bos

3.5. Workshops — Gert Bos

3.5.1. OEM/OBL — H-H Junker

Specific rules only in France, UK, Germany.
All other countries do not have special rules and NBs are acting according to the recommendation.
That mean that no Technical Documentation available on the OBL site should lead to suspension of the certificates.
Until now no suspension was operated.

If the requirement stays to keep the full Technical Documentation -> The problem and OBL sector will go away.

Of course that is too simple and not fully true as far as different legal entities within one corporation may have OEM/OBL solutions and other solutions could come.

Can we provide solutions to replace the Commission requirements?
- The NB can keep the Technical Documentation and allow other NB to assess this Technical Documentation
-> This solution is not wanted by NBs.

- The Technical Documentation can be kept within EUDAMED allowing other NB to assess this Technical Documentation
-> This solution cannot be envisage at short term (perhaps in 15 years)

- Official database finalized by ??? to be organised.
-> This solution should envisage a funding, eventually through of industry associations???

Supply chain
Even if there is a contract between OBL and OEM, changes of critical supplier to the OEM will not be reported to the NB of the OBL
For information, a chain of several OBL is not accepted by German authority.

3.5.2. UAV – queries from industry via Commission — Gert Bos

Costs for UAVs
- Impact on small companies
- Problem of travel costs

Problems:
- How to deal with Manufacturers under more than 1 directive (several UAVs?)
- How to perform UAVs for large companies?
- How to organise UAVs at supplier / subcontractors premises?

Testing:
- Selection of tests performed
- Tests to be done in accredited lab
- No witness testing for class III devices

Feedback to NBOG to improve the joint assessments:
- collect open issues/ unclear requirements
- Via a form?
- WG will be set up to categorize and send to NBOG.

3.5.3. Harmonization of standards — Thomas Feldmann

Under Michael Bothe, there is a proposal of harmonization of Annex Z.
Today there are 274 harmonized and 292 non-harmonized standards related to MD sector.
The establishment of a matrix could presents a column with the EE and the standards.

3.5.4. Guidance on estimation risk/benefit ratio (in the framework of ISO 14971).UAV — Françoise Schlemmer

There are difficulties is setting the risks / benefit ratio.
Although the risks estimation is described in guidance's, there are some findings on the subject identified during the audits with scales not reasonably established. The proposal is to keep in mind a link with the product and the potential harm to patients.

On the benefit scale it is even more difficult, there is no guidance's.
Than the risks/benefit ratio could not be adequately estimated.
The question is could we come with a guidance on benefit scale criteria?

3.5.5. Expectations of CA on qualification of clinicians — Nick Baker

MHRA requires inn house clinician but that must stay MD practitioner (MD part-time employee)
There seem to be inconsistency in when a MD needs to be involved
Independence criteria for medical specialists are a challenge
Training of MD experts should lead to a general approach on how to do the job for NB

4 . ANY OTHER BUSINESS

EC COMMISSION AND NBOG CHAIR JOINS MEETING (APPROX 15.00)

5. NOTIFIED BODY + COMMISSION TOPICS 15.00 hr

5.1 Commission review of implementation of Implementing Regulation and Recommendation

Manfred Kohler

Manfred Kohler stated the state of play on those 2 documents.

The NBOG is informed of the importance to start early to work on guidance's documents when the new regulations will be voted.

The priorities of the stakeholders of the "Trilog" are confidential and could not be shared with the participants of this meeting.

A working group is going to meet in a next future (November 25) to work on the EUDAMED data base project.

UAA: industry seems to be happy about the application, concerned about additional workload and money. Industry will most likely approach the NB to take the results of UAA into the regulatory audit planning.
Idea from industry about audit of critical supplier: NBs should get a mapping from the industry so the NBs can jointly plan UAA; joint audit teams.
American chamber of commerce: many comments demonstrate that the instruments are working, sometimes some minor technical aspects that need discussion – but more on our side, COM will not much intervene
DG Grow has been increased by merger, to make promise, now the number of staff will be reduced to the old enterprise but with bigger scope, MD unit needs to refocus on interpretation, less feedback, slower feedback from MD department, they will withdraw back from das-to-day advice.
Priority list for implementing acts was already established in August of last year.
NBOG is aware to start quite early with this work
7 subgroups for EUDAMED database, working on future structure, some underrepresentation in some subgroups
We should connect to people working on EUDAMED, especially subgroups with a link to NBs.

5.2 Status of Proposals for Regulations on medical devices and IVD Devices

Manfred Kohler

The 2 legislators' part (Council and Parliament) will meet to come to a compromise document.
The 1st reading took place in the Parliament 18 months ago. A 2nd reading is planned.
Probably 6 informal meetings will take place between now and December to try to come to new draft documents.
There is a problem taking into consideration that the Parliament comments are based on the former version of the document.

Here are the main "hard" position topics:

- Parliament tougher on pre-market control,
- Council tougher on nano-materials

Probably there is a need of better understanding of each other position.

The technical specifications are unlikely to be changed for example the designation of NBs.

It is advised not to wait before the documents are adopted because the transition for NBs to be able to apply will be 6 months from the vote which mean something like 2 weeks from the publication in the JOEU. As all the NBs will need to be assess following the new regulations requirements, there will probably still take another year before all the NBs are assessed. The authority will have to struggle to

organize the joint assessment of all the NBs. Regarding the transition period, it is not yet sure that Parliamentarians will accept them. If not we will probably run into serious problem.

As far as risks management is concerned a balance is taking into consideration (no need to reduce the risk related to risk A if that reduction imply an increase of risk B). The risk benefit ratio will become a key topic.

The NBOG representatives pointed out that the designation authorities will need to focus on the re-designation of NBs.
The transition provision will answer the questions concerning the time-lines among others the ones concerning the re-designation of NBs as well as the validity of certificates issued by the today designated NBs.

5.3 Further updates from Commission to NB-closed session — Manfred Kohler

The Commission detected some deficiencies in Technical Files regarding nanomaterials.
Among other nanoparticles were detected in bone fillers.
The vast majority of the Manufacturers had insufficiently demonstrated the safety of their products as far as the presence of these nanoparticles are concerned.

There are 2 cases in Court regarding the NBs liability. This could be an indirect responsibility of NBs regarding Annex II and V certificates issued.
The German position will not be the defended position.
In case the proceedings is being severe in terms of NBs liability that could lead that the insurance cover will become very high and difficult to be paid.

The trialog on October 13th.
The chair is shift by Council or Parliament representatives.
The room is quite small with 4-5 people of each part with some technical people in support.

5.4 NBOG feedback — Rainer Edelhäuser

In September a meeting took place with the presence of more than 20 members' states, Commission representatives and FVO representatives.

The on-going projects are:

- Commission implementing regulation
- Commission implementing recommendation
- Future implementing acts
- Questions from US industry (most are related to NB-Med)
- Falsified certificates
- Certificates for class I non sterile and non-measuring

- IMDRF MDSAP / RPS

The NBOG paper related of Change of NB is still in discussion with diverging opinions. Now the work is stopped taking into consideration the MDR. (Council positions on Art 36 (involuntary change) and Art 46 (voluntary change)).

A lot efforts are made regarding the "mandatory joint assessments"
The objective is to have the whole process described in a

- best practice guide
- a model assessment plan and
- various forms for application review, file review, ...

It is also planned to train the DA and FVO assessors in January 2016.

NBOG requests information regarding the SILIMED breast implant case.
As NBs do we know any SILIMED products used by OBL?
If so, could we let NBOG know about the situation?

5.5 Questions from Notified Bodies — All

5.6 Output of WGs / session shared with Commission — Gert Bos and deputies

PLENARY MEETING Wednesday 14 October 9.00 -16.30

1 WELCOME **Gert Bos**

Gert Bos welcomes the participants and he informs that Guy Buijzen will step down from the NB-Med chairmanship.
There was a call for candidates to the chairmanship and Hans-Heiner Junker is the only candidate.
Hans-Heiner Junker is elected by applause.

2. GENERAL AND ORGANISATIONAL MATTERS

2.1 A word from the resigning NB MED Chair — Guy Buijzen

Guy Buijzen thanks the chairmanship of Gert Bos and Hans-Heiner Junker during his unavailability.
Nevertheless, he informs that following his accident the recovery is still on-going and that he will step down from the NB-Med chairmanship.

2.2 Roll call of the participants + Apologies — Gert Bos

Gert Bos apologies for the late distribution of some documents.

2.3 Adoption of the draft agenda — Gert Bos

The new draft agenda was circulated yesterday.
It is approved.

2.4 Approval of the minutes of the 52nd NB-MED meeting — H-H Junker

The minutes were distributed through CIRCA.
They are approved.
Today, Agnes Horvath agreed to take the notes of this meeting.

2.5 Date and place of the next meetings of NB MED — Gert Bos

- 12/13 April 2016
- 11/12 October 2016
- 11/12 April 2017
- 10/11 October 2017

These dates are confirmed and the meetings will take place in the Metropole.

2.6 Election of new chair and of selected WG delegates — Gert Bos

There is only 1 candidate at the chairmanship of NB-Med, namely Hans-Heiner Junker.
The candidate is elected by applause.

It is also make a call to candidates from NBs to attend the different working groups.

3. FEEDBACK FROM NOTIFIED BODY SESSIONS

3.1 See Notified Body agenda for topics.

Where the topic has a specific agenda item the feedback will be incorporated into that debate.

A short summary from yesterday close session NB-Med meeting.
It is fair to say that the room was quite filled.
On UAVs, the report is quite good with no real problems.
Some SMEs claim on the price of those UAVS
The question regarding multiple days unannounced visits is that the consecutives days are no more unannounced. Than should we go to multiple visit with the problem of a lot of travel costs in this case?

3.2 From TEAM NB meeting

The General Assembly meeting of the association took place yesterday.

NBs are reducing from 25 to 23, following 2 mergers.

CoC 1st cycle audit has just ended and 2nd cycle which will be in 2 years is launched.

In 2016, Team-NB will celebrate his 15th anniversary. You are invited to attend our event which will take place on Monday April 11th, from 4.00 to 8.00 PM at the Metropole.

4. INFORMATION FROM COMMISSION AND OTHER LEGAL ISSUES

4.1 Implementing Regulation on Designation of Notified Bodies — Commission

The Commission says as ALAP (As Low As Possible).
In the new regulation, the Commission pointed that the risks reduction must be balanced by the efforts made to reach it.

That clarify and in a way come a bit backward on the requirements in the ISO 14971 concerning risk reduction "as far as possible" versus "as low as reasonably practicable". In is clear that the ALARP concept contains an element of economic consideration. Although the Essential Requirements require risks to be reduced "as far as possible" without there being room for economic considerations.

4.2 Recommendation on Dossier reviews, audits and UAVs — Commission

4.3 New draft regulations — Commission

The informal “trialog” meetings started yesterday.
In same case there are even informal meetings to prepare these informal “trialog” meetings.
They are reasonably optimistic on the fact that could come to a compromise for early next year.
Some topics are already decided and among other the NBs designations. The Commission advised the NBs to go ahead along the draft process.
The transitional requirements are largely debated.

It has been told that nothing will take place in the 1st 6 months.
In the period from 6 to 18 months, main of the re-designation should take place.
It is anticipated that 40 to 60 NBs will fulfil applications to become NBs against the MDR. Probably the whole applications of NBs will not be audited in the 18 1st months. Key issue is the resources fringe in the CAs to assess NBs to do their work.

The Industry is very concerned about the potential backlog of NBs re-designation. It is clear that the NBs not designed against the MDR will not be able to deliver certificates against the new MDR.

The Commission also pointed that in the past they were confronted to deficiencies into technical files for nanomaterials. Risks management has been lacking or very insufficient and that will need to be corrected.

In the framework of the cases actually in justice. The ruling decision will probably not be available before 2020. The Commission wanted to address the liability question earlier. There is a need to respond "where the liability is to be put?" by the legal Manufacturers and/or in the supply chain, and/or by AR and/or by NBs.

4.4 Harmonised Standards — H-H Junker

- State of play — Commission

It looks that some standards are published since a long time.
The question: Is there a process to review the standards that are on the OJEU (Official Journal of the European Union).

In order to help publications of standards mainly with regards to the Annexes Z, Michael Bothe proposed a matrix to help the comparison between each Annex Z and The Directive 93/42/EC - Annex 1.

CEN/CENELEC is making a lot efforts to respond the Commission requests as far as Annex Z are concerned. Basically 2 people from the Commission are working in relation with CEN/CENELEC, namely Manfred Kohler and Salvatore Scalzo.

State of the art may not be in line with standards as far as the writing of standards is probably taking 5 years.

CLINICA interviewed Team-NB on their question: What happens with standards?

4.5 Discussion on draft NB-Med documents — Commission / all

Nick Baker (from LRQA) was elected as chair of the NBRG. The former chair was Michel Binard.

WG on UAVs
Concerns of industry regarding time and costs.
Ask for deduction of time for very small companies.

WG on the vigilance
This group will be co-chaired by Corinne Delorme and Michel Binard.

WG Sub-contractors

WG Risk management

WG implementing acts
Will be chair by Agnes Horvath which intended to address the clarifications on existing documents (MEDDEV, regulations ...)
There is a request for volunteers to participate to the above WG.

4.6 NBOG — Gert Bos

There is some frustrations taken into considerations that the fundings were reduced and then there is only resources for 2 meetings a year. It is clear that some of the works is pending.

One of the topics was the attempt to put efforts to improve the communication among the authorities but also between authorities and NBs through a COEN form.

4.7 Revision to MEDDEVs 2.7.1 — Gert Bos

The family of 2.7. MEDDEVs are under revision.
The 2.7.1 has been in revision for 3 years now. It looks that now they are making tremendous progress in order hopefully for an approval at the December MDEG meeting.
The requirements on NBs could disappear.
These guidance's have not been required by Members states.
It looks that the NBs are using those documents.
Eucomed is participate to the revision of the MEDDEV 2.7.1. One of the main concern is doing with the equivalence definition.

5 DISCUSSION TOPICS

5.1 OBL/OEM — H-H Junker

There are several problem with the OEM/OBL.
A WG has taken place yesterday.
The main problem is about the availability of the technical documentation at the OBL site.
Moreover there are 3 countries who have specific requirements.
Other countries are following the recommendation which imply the TD to be at the OBL site. The implication is that if the TD is not at the OBL site, the NB will be obliged to issue a major NC. That will lead to kill the OBL business.
There is probably some legal way to proceed with the OBL business but not yet clear and anyway with fewer actors.

As NB, it is difficult because for example what about changes in critical supplier of the OEM, will the OBL be informed?
Industry say that it is crucial to keep that model.
It is fair to say it not only a model existing in the MD sector.

5.2 UAVs — Gert Bos

Industry would like to discuss time and costs.

They would like to see whether it could be possible to take these UAVs to reduce the scheduled audits. On that point they receive a good acceptance from the Commission.
Industry would like to address the problem of general subcontractors in the supply chain who are providing critical parts or critical services (sterilization) to numbers of Manufac. Those subcontractors could be a position to receive 40 or 50 UAVs a year which is not really reasonable. It is fair that there is no added value for 30 NBs assessing the same critical supplier. There is a need to solve questions such as how to get rid of confidential problems.

5.3 Harmonization of standards — Gert Bos

See above

6. REPORT OF NBRG

6.1 NB-Recommendations and Work Items — Nick Baker

6.2 Other NBRG matters — Nick Baker

7. TECHNICAL ISSUES RELATED TO DEVICES

Technical topics; tbd; depends on input

Repetitive tests when bibliography exists for example on biocompatibility or not. What is the situation? Most of the countries accepts bibliography information on biocompatibility.
There is also a need to prove the competences to understand the biocompatibility requirements within the manufacturer's staff.
It has to be evaluated from case to case as the production process as to be taken into consideration.
In Turkey, the design authorities insist to get have biocompatibility tests on each products.

For example, a spoon is class 1 measuring function short transient term invasive. That could lead to the need to prove some biocompatibility.

Interest of working groups on this subjects with perhaps the setting up of equivalence on biocompatibility as the clinical equivalence.

8. GLOBAL HARMONIZATION

8.1 Status and Activities of IMDRF — Gert Bos

- Table of Content pilot
On the MDSAP, there are 6 NBs taking part.
There is a need of 9 millions to set up a database to collect the information.

Software as active medical devices has been removed from the MDR and the software will stay class 1 MD. Although in the rest of the world software are considered as critical components.

- RPS
The process is starting. It is probably a 10 years process.
The participation as NB will mean that you will review the dossier with your usual procedure knowing the structure will follow the RPS table of content.

- New survey on design addition:
How product reviewer could best review technical documentation?

8.2 Status of Asian Harmonisation Working party (AHWP) Gert Bos

8.3 Status of Australian MRA H-H Junker
Last year, TGA observed some audits.
It looks that some NBs report are revised by TGA to review

Team-NB will ask what is the situation of that MRA?

9. INTERNATIONAL RELATIONSHIP
MRA's etc; tbd Commission

The current MRA and/or other types of trade agreement are on-going.

10. STANDARDIZATION AND NOMENCLATURE

There is no new work item.
In a way it is concerning in itself there CEN/CENELEC do not have receive any mandate (which change names and are now called standardization request) on topic such as implantable cosmetics or human tissue.

As far as the old "Common technical specifications" are concerned they also change name to become wider under the name "Common specifications". Probably, it could be good to come up with detailed information in standards which could leave to less need of Common specifications. The idea need to be backed by the high sphere of the Commission.

The role of standards is now put in the light in the Press (interview of Team-NB by CLINICA). That could help to push the decision process.

10.1 New Work Items Commission

No
EDMA submitted a new work item to the TC 212.

There has a suggestion that GMDN will be bought by the Commission which could make it in free of charge access.

10.2 CLC/TC 62 - Substantiating the use of EN 60601-1 or EN 60601-1-6 for presumption of conformity with requirements with the AIMD Gert Bos

The ISO 60601-1-6 is the usability standard.

11. REPORT from WORKGROUPS

MDEG — Gert Bos

It is hoped that document will be approved.
By the way, it looks that the November MDEG meeting will be postponed.

ATM Products — Gert Bos

EMA is upset with the facts that main Manufacturers has move their claim in order to become medical devices and thus do not need to be revised by EMA.

Borderlines and classification — H-H Junker

There is no meetings recently. It is more email flying around.
Nevertheless, there is a new manual 1.17 published in September 2015.
In this manual, there are new items which are highlighted such as fluid collection,...

NET — H-H Junker

The meeting took place in September.

Clinical investigation and evaluation — Gert Bos

The group has been quite active trying to finalize the 2.7. documents (see above)

IVD — Gert Bos for Sue Spencer

A Webbex discussion took place.
The discussions were among others on the CTS, self-tests,
Some work is on-going.
They are some concerns on the facts that NBs will have enough resources against the new IVDR.
NBOG agreed that they will need to dramatically changing the coding system for IVD.
Companion diagnostics should also be discussed in the future.

Software — Gert Bos for Klaus Ostermayer

A pre-meeting will take place tomorrow and a face to face meeting on October 20th.
The group is desperately looking for a NB representative to be present knowing that Klaus Ostermayer is no more a member.
The MEDDEV guidance document is on revision.

Vigilance — Michel Binard

Philippe Auclair from EUCOMED was involved in the working group.
They are several items ongoing.
There is a pilot to report vigilance event under the MHRA supervision with using a coding for reporting.
The pilot was planned to end of 2015 could be prolonged.
Another item is a field safety notice could be as well standardize.

12. ANY OTHER BUSINESS

- Change of AR: info of the NBs
- Status of NB-Med documents

Status of documents

the status of the documents has been discussed with the Commission

There is a clear wish of the Commission that NB-Med documents are not mainly written by Industry with a small review of NBs.

Team-NB kindly published the NB-Med documents

It is clear that those documents are mainly clarifying and/or addressing gaps of the existing current legal framework.
Probably in a near future we will need resources in this forum to start writing documents to explain the meanings of the new legal regulations.