The European Association Medical devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Phone: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: secretary@team-nb.org
Web: http://www.team-nb.org
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

Editor : Francoise SCHLEMMER	Date : 28 May 2015

REPORT
MEDICAL DEVICE EXPERT GROUP MEETING

1. Welcome and approval of agenda

Erik Hansson welcomes the participants to the open part of the meeting.
They are some new persons who join the unit.
They are also some changes as the unit joined the DG GROW.
DG GROW is a merger from the DG enterprise and DG internal market.
The new organisation will enter into force next week.
There will be only 11 directorates (13 before) and 47 units (before 53).
The new head of unit is Mr D'Acunto who was formerly Directorate-General for Mobility and Transport.
The staff will be reduced from now on until 2018 following political decisions.
Mrs Lecrenier take the opportunity of this meeting to thanks for the dialog that took place in these last years.
Mrs Lecrenier will take in charge spatial European politic.
MDEG will become MDCG in the framework of a modernised way to work on the revision of the legislation.

2. Approval of minutes

2.1. MDEG meeting 17 November 2014 – 'Plenary'
The minutes are approved.

3. Documents for approval

3.1 MEDDEV 2.7.2 Rev. 2 – Guidelines for competent authorities in making an assessment of a clinical investigation application (endorsed by the Clinical Investigation and Evaluation (CIE) Working Group)

This document proposes indications to the CA when they assess clinical investigations reviewed by Notified Bodies.
The work was done to harmonize the guidance with the new harmonized standard. The aim is to harmonize procedures with the help of checklists but also to allow better exchange of information between CAs.
Some changes have been made with regards of the former document. The new one will be circulated.
The definitions contained in this document will be reopened for clarification.

This morning it was decided to have a procedure to have it adopted as soon as possible.
The timing for validation will be around a few weeks.
The launch of the written procedure to adopt the document will be probably made by end of June or beginning of July.

3.2 MEDDEV 2.7.3 Rev. 3 – Guidelines on clinical investigations: serious adverse events reporting (endorsed by the Clinical Investigation and Evaluation (CIE) Working Group)

This document on reporting was worked in the working group in presence of representatives of Industry.
One of the aim has not been achieved. This was possible to find an agreement to harmonize the forms especially with the 3 German speaking countries.
The changes was made to the summary tabulation in order to process them electronically.
One question remained open on the transition period. This was decided this morning 1 year of transition period because the CAs wanted to get only one electronic form for all studies whatever on-going or new.
The validation of this document is proposed for adoption to this meeting. This document approved with the aspects of transition to be taken into consideration.
Wolfgang Eckert states that all regulators are busy reading thousands of paper for the new MDR meeting on June 19th, but shooting to finish before the start of the holiday season

4. Regulatory issues

4.1 Revision of MDD, AIMDD and of the IVD Directive – State of Play

The state of play history began with the 1st reading in Parliament on 2nd April 2014.
Once the council has finished their comments negotiations between Commission, Council and Parliament will start trilogy.
There are still some controversial topics to be discussed such as designation of NBs for high risk devices.
The Council is working hard to come with a proposal as soon as possible. The Council should be ready by June 19, 2015.
The presidency has come with compromises with some of the controversial issues as well as the technical issues.
In the remaining controversial issues, there is still among others single use devices, scrutiny procedure and in house IVD/MD.
A lot of progress have been made and now the main remaining issue is the "scrutiny".
Before the health Ministry meeting on June 19th, there will probably still be a meeting at the level of “attaché” which could be held on June 10th. The objective is to try to come with a final proposal to be presented at the Health Ministry level.
The discussions are on-going in the Council and could not be disclosed at this level. Anyway, the Commission had not yet access to the final document discussed at the Council level.

It is not known whether the document will be circulated before the beginning of the trialog.
Question by COCIR: Moreover a new concept was proposed regarding "Common specifications" which could replace the CTS. What could be the status?
Answer: The idea is not to replace harmonized standards but to propose specifications in areas not covered in standards.

4.2 Harmonised Standards and Mandates – information on recent developments

New lists will be published with 7 new entries very soon states Manfred Kohler.
The CEN/CENELEC pilot in order to work of the standards come with 3 issues although a good work have been made.
5 standards will be hopefully available on the July dispatch.
On the side of CENELEC, some of the ISO 60601 series will be available shortly.
CENELEC pilot started, basically agreed on final text fro 60601-1 agreement, 60601-1-1, -6, -8, - 32

One more important result which is a step forward to work on the agreed Annex Z is as the kind of form for the future.

The NBRG proposed a revision in order to do a more general document mapping different standards. The idea is the possibility of having one cross reference document instead of having annex Z for each standard. Although it could be a valuable document but it could be difficult to manage with such a document. A meeting will take place between Commission representatives and NBRG ones to discuss this proposal. The CEN/CENELEC would like to be included in the discussions.

ISO 14971
The Commission was not happy with the draft guidance proposed by NBs. Some deficiencies were pointed out by the Commission to the NBs with request to improve it. However, the Commission is diving in deeper and may come with new comments to the Notified Bodies.
CENELEC opposed that they were not informed about the meeting with NBRG, because they are responsible for annex z
Hans-Heiner Junker comments that this document was prepared by Michael Bothe / VDE, but not circulated for discussion, therefore it was not approved by NBRG, but it may help the situation as it suggest to have one document explaining the relationship between the chapters of the IEC 60601-1 family instead of having Annex Z in every single IEC document

Materials with “0” (zero) risks.
Assuming that such a materials exists what is the possibility to reduce the use with technological solution.
Manfred Köhler asked the group to give him feedback on this situation:
There are 2 similar devices. One has a material which could cause allergic reactions, the other one has a different material not causing allergic reaction.

Can the product which could cause allergic reaction still be placed on the market? The risk is not mitigate as low as possible as there is a device that does not contain this risk.

Dr. Neumann/BMG said such a question cannot be answered. Give us a good question, and you will get a good answer. But such a simplified questions cannot be answered.

Basically it is to be seen in a way that taking into consideration the risks links with materials have to be reduced taking into consideration the difference basic risks of materials.
Although we do need to keep in mind that the important is the overall remaining risks with the best overall solution which has to be preferred. The best technical choice cannot be imposed on manufacturer. It is up to the manufacturer to make his choice based on a risk/benefit analysis.
It is pointed out that we may first ask the good question to get a good response. One cannot consider a material on only one such a specification.

5. PIP Action Plan – Update

5.1 Joint assessments of notified bodies – update

We moved on from a voluntary stage to a mandatory one.
For each Joint Assessment there are representatives from Commission (FVO) and from 2 members' states.
To date 26 Joint Assessment from 14 countries took place. It was 23 re-designation and 3 new designations
Only 9 reports are uploaded on CIRCA (available to DA only).
No feedback to the nine uploaded reports.
In 8 of 9 cases has let to new designation. In one case the outcome was negative, too many problems, a company wanted to become a NB
It is due to the fact that the national CA has to verify the corrective and preventive action plan produces by the NB raised in response to the NCs. Verify its implementation can take up to 1 year.
Therefore the scheduling of the on-site assessment has not to be too close of the expiry date. Otherwise designation will expire, responsibility of both parties, examples that gaps occurred,
Joint Assessment Team report lists the NCs identified during the audit and make a recommendation on designation (or not).
Up to now, there was mainly no disagreements between the designating authority and Joint Assessment Team.
There was no case where unconditional approval was given.

In 2015, up to date, there were 12 Joint Assessment done/ 15 remaining. Some of them are already postponed to 2016.
Until now, 10 NBs have decided not to undergo Joint Assessment and withdraw from MDD field.

Team-NB asked on how the Joint Assessment Team will take in charge the de-designation and the transfer of the business and of the auditors to others NBs.

The Commission answered that situation has 2 aspects:

- 1st is the dropping out with the information to be available as publicly as possible. NBOG has a work item with the objectives to clarify this item.
- 2nd is the management of the transition by the CAs and/or Joint Assessment Team. This will be managed in 2 steps. The today one with the introduction of principles in the existing regulation framework. There is a need to find solutions in this transition period. There is also a continuous task in order to address this issue in the MDR.

It is clear that there is a request for the information to be as easily accessible as possible to all manufacturers. Moreover there is a request for the CAs to control that the de-designated NBs inform directly their clients about the de-designation.

Industry associations point out that some SME manufacturers informed them that they had no answer for request of quotations and also some delays in the surveillance audits.
It is clear that the situation is quite turbulent in the moment.
On one hand, it is true that NBs are facing resources staffing issues taking into consideration the new tasks they have to perform (unannounced audits) and the difficulty to find competent staff on the market.
On another hand, some NBs had been asked not to accept new clients until they close some open issues identified during Joint Assessment.

5.2 Presentation of JRC report on analysis of incident reporting of Medical Devices in the EU, EFTA and Turkey and EU pilot on vigilance and trending

The aim of the JRC (joint research centre) will be to support the Commission on technical issues such as clinical assessments and evaluation and EURLs.
There will be communication between JRC, the Commission and CAs, but very, very limited to manufacturer and NBs
The proposed regulations have as objective to strengthen the medical devices field.
A Central data base is an important tool for the follow up by the administrations.
The JRC is aimed to continue providing technical and scientific positions.
The JRC is working on PON (patience outcome nomenclature).
It will be obviously a powerful tool with statistic investigation to target the potential problems. It will be important to let access as much as possible to all stakeholders.
Team-NB pointed out that NBs are dealing with incidents, and we would like to get access to some data and/or report from this organisation.
The Commission is not yet at the level to know about what information will be available to whom.

6. International issues

6.1 Update on International Medical Device Regulators' Forum (IMDRF)

IMDRF started its activities on GHTF former activities.
Since the last MDEG, some conference and tele-conference took place.
The EU coordination meeting will be probably take place on July. These meetings show there great interest on the following topics:

- Review NCAR (exchange PM information)
- MDSAP (single audit program in order to facilitate 3rd party auditing)
- RPS (regulation product submission) an electronic submission from manufacturer to CA.
- There is a new item on "Adverse event nomenclature"

6.2 EU participation as observer in MDSAP (Medical Device Single Audit Program) pilot

There are currently 4 full members (US, Australia, Canada, Brazil) and 2 observers (EU and Japan).
The program is planned to begin in 2017.
The product approvals are not part of the scope of this program.

6.3 RPS (Regulated Products Submission) IMDRF pilot

The objective is to evaluate the ToC.
The submission types are for IVD the list A & B applications and the Class III design dossier for MD.
There was a request of interest from NBs. Participation will be coordinated by NB-Med.

7. Update on on-going mandates to the Scientific Committee

SCENHIR stated that Bisphenol could be in some way an alternative to the BPE.

The guidance on the use of nano materials in MD has been published on January2015.
A case by case approach will be necessary to evaluate the risks linked to the use.
The main risk is linked to the potential release of free nano materials and thus to the duration of the contact.

MD containing DEHP
The final opinion is not yet available.
According to the information, they are still working on the document but it should be adopted by written procedure before end of June.

Safety of surgical meshes
The written document should be published early June.

8. Written progress reports from Working Groups

Short written overview of main activities and Work Programme for 2015-2016
The documents were put on CIRCA and send to the stakeholders. No presentation will be made, only responses to the questions.

8.1 Borderline and Classification Working Group

There is a request to know the timeline for the new definitions pharmacological, immunological and physiological. The work will be presented at the next meeting which has been postponed to November.

8.2 IVD Technical group

8.3 Notified Body Operations Group (NBOG)

8.4 Clinical Investigation and Evaluation (CIE) Working Group

8.5 MDEG Vigilance

The EN 14 document was adopted in Tokyo. The implementation phase begins.
A pilot with phasing in program will be prepared for the autumn Kyoto meeting.
The EU pilot in trending. The document is available on the Commission web site.
There is a call for Manufacturers participants.

8.6 Eudamed Working Group

There is a need to fulfil the obligations to the current EUDAMED as it will last probably still 3 or 4 years.
The new version of EUDAMED will be present through a "mock up" to the Commission shortly.

8.7 Software Working Group

8.8 UDI Working Group

8.9 MD Compliance and Enforcement Group (COEN)

Contrary at what stated in the report, the document concerning the phthalates has not been sent to MDEG.

8.10 New and Emerging Technologies (N&ET)

8.11 NB-MED

9. Other Commission Initiatives Impacting Medical Devices

9.1 Information on public consultation on the respect of intellectual property in public procurement procedures

The comments could be seen by July 19th.

9.2 Follow up to the green paper on m-health

The report has been circulated.
The major problem was on safety protection of data.
Reliability is also an important topic.

On MD, there was 2 main issues identified. On one hand the risks links to lack of enforcement and on the other hand the need for basic qualification of Apps.
It looks that some companies has no clue that they have some obligations from now on.

10. AOB

11. Future Meetings

IMDRF (EU preparation) could be planned in July.
MDEG: November 12 and 13.