# Regulatory update / Notified Bodies

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# Overview of this presentation

- **Update of the Regulatory environment of NBs:**
  - Commission Implementing **Regulation** (EU) No 920/2013
  - Commission **Recommendation** (2013/473/EU)

- **Update on the amended *draft* Regulations after the voting at the ENVI group Sept. 25:**
  - Focus on requirements / issues for NBs:
  - Various concerns from **TEAM-NB** on the current proposals

- **Way forward / concerns and expectations**

# Update of the Regulatory environment of NBs (1)

- **On Sept. 24, 2013 adopted and Sept. 25 published in the Official Journal of the Eur.Union:**
  - Commission Implementing **Regulation** (EU) No 920/2013 on the designation and the supervision of notified bodies
  - Commission **Recommendation** (2013/473/EU) on the audits and assessments performed by notified bodies in the field of medical devices

Both were on the Joint Action Plan by former EU commissioner John Dalli as agreed between Eur. Commission and Member States.

=> an overall progress report is expected in October 2013.

# Update of the Regulatory environment of NBs (2)

- Commission Implementing **Regulation** (EU) No 920/2013 on the designation and the supervision of notified bodies:
  - it details the designation responsibilities of the National Authorities and the need for much greater cooperation between Designating Authorities (DA) and the National Authorities.
  - it identifies rules that *in practice are already in place* for the current audits by Competent Authorities … (*but were differently applied in daily life* by some CAs in some Member States …)

# Update of the Regulatory environment of NBs (3)

- The“joint audits” by CAs in a voluntary program of NBs of this year  have shown to be very serious indepth critical assessments => and have *resulted so far* in:

  2 removals of designation,  2 suspensions and 2 voluntary NBs withdrawals

- The Assiocation of NBs **TEAM-NB** (now 29 members) supports this strong increase in supervision as we see that it greatly will enhance / harmonize the performance of NBs in practice

- It is clear and transparent and it shows that the CAs are able to increase their level of control in a concerted manner

# Update of the Regulatory environment of NBs (4)

- Commission Commission **Recommendation** (2013/473/EU) on the audits and assessments performed by notified bodies in the field of medical devices:

  - this is a new tool in the EU medical device world; *although gently phrased* as “a request to Member States to use the details in identifying their expectations on notified bodies”;

  => effectively it can be seen as “soft Legislation” with significant status

  - at this stage most of the MSs have already confirmed they will endorse the document and follow it as part of their duty to oversee the work of their NBs.

# Update of the Regulatory environment of NBs (5)

- a critical element is seen as expected unannounced audits; that are to be added on top of the existing audit structure

- to be early prepared **TEAM-NB** has in the last 12 months followed / participated closely on the requirements in earlier drafts of the **Recommendation** as to harmonize interpretation and asap implementation

  and

- moreover, in support of that effort and, as requested by individual MSs, a number of unannounced audits have been performed

=> this has resulted in a common provisionally interpretation in our Code of Conduct (CoC); *this will be updated now* based on the recent publication of the **Recommendation**

# Update of the Regulatory environment of NBs (6)

- Unannounced audits:
  - really unannounced !
  - at locations of manufacturers / critical subcontractors and suppliers
  - worldwide (see arrangements for contracts / use of visa !)
  - at least for one day with two auditors
  - NB will take a Risk based approach to define suitable frequency
  - will have both a product as well as production focus

# Update of the Regulatory environment of NBs (7)

- recently produced products will be verified for conformity with the Technical Documentation and Legal requirements
- evaluation also can be done with products being produces or are undergoing quality testing during the audit on site
- on top of a Technical File review and comparison, the auditors may request specific test(s) to be performed by the manufacturer during the audit on site
- such ad hoc test(s) can be witnessed by the auditor on site, as well as tests performed outside of the audit by or on behalf of the NB; these will be undertaken in accordance with testing procedure(s) definedby the manufacturer (in TD or QMS)

# Update of the Regulatory environment of NBs (8)

- check of the conformity of the medical device should include verification of traceability of critical components and materials used in the production

- as for the functioning of the QMS: NBs are expected to verify at least two critical processes among processes such as:
  - Design control
  - Establishment of material specifications
  - Purchasing and control of incoming materials or components
  - Assembling
  - Software validation

# Update of the Regulatory environment of NBs (9)

- Sterilization process
- Batch-release
- Packaging
- Product quality control

- where needed NBs have been changing details of their contracts, or terms and conditions;

- also manufacturers need to look whether the possibility of having unannounced audits at their critical subcontractors or suppliers is covered appropriately !

# Update of the Regulatory environment of NBs (10)

- to be able to host such unannounced audits the manufacturers will need thorough preparation as the results are key for the continuation of the CE certification of their medical devices !

- in smoothly moving into a system supported by the unannounced audits, the medical devices industry will be able to improve its reputation towards the public; recovering from the effects of some recent scandals

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# Regulatory update after the voting at the ENVI (1)

- **TEAM-NB** has closely followed the development of compromises in the ENVI group on the MDR and IVDD updated Draft Regulations.

- We have worked with the Rapporteurs for the Draft MDR/IVDD Regulations as well as the Shadow Rapporteurs of other Political Fractions in the Eur. Parlaiment to comment, make suggestions / proposals for amendments.

We are pleased *to see a number of our previous concerns addressed in detail*:

- qualification requirements for CA inspectors supervising NB work
- the need for fast borderline and delineation decisions,
- streamlining of relevant data from Eudamed to NBs
- increased transparency with respect to suspension and de-designation
- electronic implant cards
- facilitation of professional data minng in Eudamed
- some requirements on Authorities to run public assessment from its data

# Regulatory update after the voting at the ENVI (2)

- Focus on requirements / issues for NBs:
  - Key in house competence: permanent: adminstrative , technical and scientific personnel with medical, technical and where needed pharmacological knowledge
  - But NBs mey hire external experts on ad hoc and temporary basis as and when needed
  - NB shall publish a list of its staff responsible for the conformity assessment and certification of medical devices
  - Details of the organizational structure to be made public
  - Can continue to work for various manufacturers making competitive products

# Regulatory update after the voting at the ENVI (3)

- Declaration of interest for all staff to be made public
- Impartiality of subcontractors to be guaranteed
- Justification needed on individual cases were NB treat information and data as confidential
- NB to keep og of information provided to their staff
- External experts on ad hoc and temporary basis: NB makes publiicly available the list of these expert as well as their declarations of interest and their specific tasks they are responsible for
- Unannounced audits at least once per year in ALL manufacturing sites

# Regulatory update after the voting at the ENVI (4)

- NB to report findings on annual inspections to ALL MSs
- Audit report to be automatically forwaded to responsible National Authority
- Much more detail on subcontracotr requirements throughout
- MDCG to set criteria and procedures for qualification of NB staff
- Certification panel requirements (as per CoC)
- NB will have in house staf with expertise in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. On top of that external experts may be used.

# Regulatory update after the voting at the ENVI (5)

- Clinical evaluation plans potentially to be reviewed by specialists
- Early debate of clinical evaluation stimulated
- Qualification product assessors (as per CoC)
- Qualification auditor (as per CoC)
- Subcontracting:
  - most clinical experts to be in house in NB
  - annual performance evaluation report on NB subcontractor to CA
  - annual supervisory audits at NB over sucontractor compliance
  - Subcontractors of NB to be centrally registered before being used

# Regulatory update after the voting at the ENVI (6)

- Subcontracting *continued*:
  - one week for change notification; details publicly available
  - NB to have own expertise on treatments and medical specialty of their designation
  - Policy and procedures for NB subcontracting to be approved by CA

- Process requirements: NB procedures including calculations of audit days (*) and status of Certificates to publicly available

  (*): in line with CoC but less detailed.

- Assessment of the application of NBs / notification procedure / monitoring requirements

- Special NBs: (SNBs): will be designated by EMA; they will review high risk medical devices (this is replacing the “scrutiny procedure”)

# Regulatory update after the voting at the ENVI (7)

- Special NBs: (SNBs): these will be designated by Eur. Medical Agency (EMA); these SNBs will review high risk medical devices (this is replacing the “scrutiny procedure” in the Eur. Commission’s Draft MDR Regulation)

Various concerns from **TEAM-NB** on the current proposals:

- involvement of EMA in an unclear selection process of designating SNBs.
  It is noted that involving EMA does not bring any additional safety assurances (they don’t have the needed expertise).

  Also the Commission **Regulation** (EU) No 920/2013 provides a better solution to address the differences in quality between NBs and will be applicable shortly !

# Regulatory update after the voting at the ENVI (8)

- a concern is the direct suspension mode of NBs when a MS requests so;
  - we believe that prior to suspension a critical objective review of the NB and its work need to be performed
  - given the extreme consequences for those manufacturers certified by that NB and thus:
    - ⇒ invalidation of possible large numbers of certificates and
    - ⇒ wholesale removal of products from the market
    - ⇒ which could negatively impact continuity of patient care

# Regulatory update after the voting at the ENVI (9)

- <u>reprocessing of medical devices:</u>

  - of great concern to the patient safety remains the risk of re-using medical devices *unless* the manufacturer *can prove* they *can not* be reprocessed !

  - this is in direct conflict with the key established Risk Management principles currently applied in the medical devices sector

  - a list of “devices / types of devices” that are unsuitable for reprocessing will be hard to maintain and keep up to date … creating confusion / uncertainty !

  - also it is unsound scientifically to use the difficulty in demonstrating reprocessing cannot be done … to justify the acceptance of the risk of cross infection between patients.

# Regulatory update after the voting at the ENVI (10)

- the involvement of EMA in the clinical review will not be an improvement:
  - the additional double assessment of high risk products, that are already assessed by the SNBs (with sufficient clinical expertise and designated by the MSs) will not improve patient safety

  and

  - will, even worse, delay time to the market of new life saving technologies

- Assessing of the Post Market Clinical Follow up plans:

  it is proposed that a 3rd party needs to get involved in evaluating PMCF plans for products.

  => *IF* NBs are well equipped as intended to be the result of the Regulatory improvements; they should be able to review this on appropriateness themselves !

# Regulatory update after the voting at the ENVI (11)

- the reduction of the transition period **from 5 to 3 years** for application of **IVD Regulation** after entry into force will produce tremendous problems due to the huge impact of the change in the Classification System for IVD Devices on the amount of products to be assessed.

  As Article 78 on EU Reference Laboratories shall apply 24 months:

  => this means that all Class D products need to be assessed within one year; very challening to the NBs and other organizations involved !

- Additional concerns relate to the proposal on the apporval of IVD clinial trials through an Ethics Committee which really needs further tekst clarification

- Also it is not clear whether the Ethics Committee approvals are required in the performance evaluation of IVDs with regard to use of clinically characterized specimens left over from specimens previously collected.

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# Way forward / concerns and expectations (1)

- the MDR contains many new proposals compared with the previous document; also many novelties which even have not been discussed during the many public meetings that took place at the Eur. Parlaiment in the first half of 2013 !
  - it is a relief that the ENVI has rejected the Pre Market Approval system as was initially proposed …
  - on the other hand … the alternative system proposed now is a complex structure with four “players”: the ACMD / MDCG / MDAC and Reference Laboratories => possibly leading to an unworkable situation

- The IVDR has less criticized areas; but some issues need attention !

- Although the amended texts of the MDR and IVDR have been accepted by the ENVI => there is still a lot of concern on the exact texts and impact of various articles at the Members of the Eur. Parlaiment (MEPs)

# Way forward / concerns and expectations (2)

- Also it became apparent that for the “political game” it was deemed wiser to wait for the Plenary Eur. Parlaiment general discussion (of late October) to bring forward new amendments / proposals …

- MEPs are concerned that the innovation is hindered, that affordable care is at stake and access to new devices is delayed for patients.
  And the economy could be hindered, so employment in the medical devices industry reduced...

- As **TEAM-NB** we have been approached for our opinions by the MEPs and will meet representatives of the Political Fractions again.
  And other stakeholders (CAs / Industry / Doctors / Patient groups etc) will take the opportunity again to lobby …

# Way forward / concerns and expectations (3)

- Will more significant changes be made to the current proposals? **OR** will a quite similar (as now agreed) text of Sept. 25 go to the Members of the Council of the Eur. Union ? And what then ?

  => what are their opinions ? What will be the outcome?

  => will it give a compromise “that is not liked at / by all” ?

  => will we move into an untested / bureaucratic system ?

  => with unforseen problems ?

  => and no guarantee of improving patient safety?

  => and especially no patient access to innovative products ?

- And what if there is a failure in the first reading at the Eur. Parlaiment ? Due to the upcoming Eur. Elections (May 2014); then at least it will take another 1 – 1.5 years before we see progress again …

**Thank you for your attention! Dank U voor Uw aandacht! Tack so mycket! Obrigado! Gracias! Grazie Mille! Tusentack! Tarviseks! Danke schön! Merci Vielmals! Dankie! Merci Beaucoup!**

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