NAC (IVD – MD) meeting

17th – 18th May 2018, Prague

Minutes

Agenda 17th May: Part I "IVD Specific"

16.00 **Introductions, Meeting Purpose and Outcomes**

- Attendance/Apologies register
- Competition Law compliance reminder
- Adoption of the minutes of previous meeting
- Agenda approval
- Opening Address from the IVD Chair

16.15 **Regulatory and Industrial Policies**

- Labelling: Symbols
- IVDR: Roundtable on latest national activities

16.45 **Market Access and Economic Policy**

- Value of Diagnostic Information project
  - Short update (10min)
  - Discussion
    - ➔ Agreement on communication and outreach plan presented
      - On MTE level
      - On country level and what is the MTE support
    - ➔ Common projects on the topic
    - ➔ What are the tools and support NA need

17.30 **External affairs**

- Building a new narrative for the value of IVDs
- Leveraging LTO

19.00 **AOB and closing remarks**

19.15 End of IVD NAC Meeting

20.00 Networking Dinner with all NAC MD-IVD

Agenda 18th May: Part II "Common MD-IVD"

08.30 **Introductions, Meeting Purpose and Outcomes**

- Attendance/Apologies register
- Competition Law compliance reminder
- Adoption of the minutes of previous meeting
- Agenda approval
- Report of the last Board meeting from the IVD/MD Chairs

08.45 **Hot topics of the moment**:

- Notified Bodies: Round table on national activities
- Brexit: National Outreach Plan

10.15 *Pause*

10.30 **HealthTech TAB**

- Guidance and support to make innovations available for patients

11.15 **Legal and Compliance**

- Q&A on GDPR

11.45 **Market Access and Economic Policy**

- HTA update and NAs involvement

12.15 **External affairs**

- MedTech Week 2018: Round table on NAs activities
- Value Project update

12.45 **AOB**

- MedTech Forum 2019 and future
- What from the NAs to the next Board?
- Future meetings 2018 meetings

13.15 Closing Address from the IVD/MD Chairs

13.30 Lunch

Agenda 18th May: Part III "MD Specific"

14.15 **Introductions, Meeting Purpose and Outcomes**

- Attendance/Apologies register
- Competition Law compliance reminder
- Adoption of the minutes of previous meeting
- Agenda approval
- Opening Address from the MD Chair

14.30 **Regulatory and Industrial Policies**

- Labelling: Symbols
- E-labelling

15.00 **Environmental**

- MDR: Obligations for manufacturers regarding hazardous substances

15.15 **AOB & Closing Remarks**

15.30 End of the meeting

Attendance

Name	Organisation
Adam Schuman	HIVDA
Andrea Ollari	AMDM
Anna Lefevre Skjoldebrand	Swedish MedTech
Bernhard Schilling	Sterile Barrier Association
Carlos Sisternas Suris (CS)	FENIN
Carmen Aldez	FENIN
Marnix Denys	beMedTech
Fernanda Gellona	Assobiomedica
Henrik Christensen	DiaLab
Istvan Sarandi	HIVDA
Joachim M. Schmitt	BVMED
Jozef Jakubiec	IPDDL
Justin Carty	IMSTA
Krisztin Tibély	AMDM
Laura Simik	SAILAB MedTech Finland
Marcus Kuhlmann	Spectaris
Mihaly Kramer	HIVDA
Miroslav Palat	CZECHMED
Orlando Antunes	IPQ
Peter Ellingworth	ABHI (By Phone)
Petr Smidl	CZEDMA
Philipp Lindinger (PL)	AUSTROMED
Rami Rajab	Mecomed
Richard Philipps	ABHI
Roelf A. van Run	NEFEMED
Sinead Keogh	Irish Medtech
Witold Wlodarczyk	POLMED
Rui Sousa	NOBEL
Christopher Breyel (CB)	MedTech Europe
Diana Kanecka (DK)	MedTech Europe
Jean-Noël Bouillon (JNB)	MedTech Europe
Jerick Parrone (JP)	MedTech Europe
Jessica Imbert (JI)	MedTech Europe
Merlin Rietschel (MR)	MedTech Europe
Oliver Bisazza (OB)	MedTech Europe
Shannon Ziegler (SZ)	MedTech Europe
Tanja Valentin (TV)	MedTech Europe

Welcome and introduction

- The rules related to competition law and attendance to MedTech Europe meetings have been introduced and all participants signed the "Guidelines on participation in MedTech Europe meetings / Do and Don'ts" document.
- The groups approved the agenda.
- Minutes of last NAC (IVD) meeting have been approved at the NAC (IVD) specific part of this meeting.
- Minutes of last NAC (IVD-MD) meeting have been approved at the NAC (IVD-MD) common part of this meeting.
- Minutes of last NAC (MD) meeting have been approved at the NAC (MD) specific part of this meeting.

17th May - Part I "IVD Specific"

Introductions, Meeting Purpose and Outcomes

- **Competition Law compliance reminder**
- **Adoption of the minutes of previous meeting**
- **Agenda approval**
- **Welcome introduction from Czedma (Petr Smidl)**
- **Opening Address from the IVD Chair Carlos Sisternas**

  See attached presentation of CS (*20180517 Carlos Siternas Intro*)

  CS presented an update of what he considers as being the key topics to be important for IVDs in the year to come.

Regulatory and Industrial Policies

- **Labelling: Symbols (DK)**

  See attached presentation of MTE secretariat (*20180517_Regulations and Industrial Policy (IVD)*).

  A question arises on copyright consideration for using part of a standard for sensitisation campaign.

  Labelling will be one of the cost drivers in IVDR.

  Symbols used by industry will have to be explained in the "instruction for use".

  All steps to be fully explained in a Regulatory communication on development of new symbols (by industry). To follow soon.

  To do:

  Diana will double check if national competent authorities can request translation of NB documents coming from another country and if so, if they can impose that the costs will be covered by the manufacturer.

  All NAMs to check also on national level with local NB.

- **IVDR: Roundtable on latest national activities**

  Some regions in Spain are requesting documents in regional languages. This doesn't seem to be the case in other countries.

The Netherlands expressed a couple of concerns on in house testing (see email in attachment) : Belgium and Norway seem to face the same problem.

Market Access and Economic Policy

- **Value of Diagnostic Information project - VODI (CS on behalf of Zuzana Pisano)**
  - ➔ Short update. See attached presentation of MTE secretariat (*20180517_VODI project*).
  - ➔ Discussion
    - Agreement on communication and outreach plan presented
      - On MTE level
      - On country level and what is the MTE support
  - ➔ Italy and Spain have a very useful document on obsolescence of MDs
  - ➔ Common projects on the topic
    - What are the tools and support NA need
    - It is important to define who would be the primary audience and primary message.
    - Importance of a good collaboration with scientific community has been emphasized.
    - Use of specific "languages" for different types of stakeholders
    - Coming soon we will organize a specific webinar on VODI

External affairs

- **Building a new narrative for the value of IVDs (JNB / TV)**

  See attached presentation of MTE secretariat (*20180517 IVD Values Story*) and documentation (*20180517 IVD Values Country Guide* / *20180517 IVD Draft Narrative*).

  The group agreed on the interest of the proposed strategy for basic communication on the value of IVDs.

  The draft narrative must be improved, eg. The Future of IVDs narrative is too long

  Media support and target audiences must be defined.

  Define convergence between a communication plan on IVDs and VODI.

- **Leveraging LTO (JNB)**

  See attached presentation of MTE secretariat (*20180517 LTO*).

  MTE to organise before the end of the year a 1-day workshop with NAs involved in LTO to allow best practice exchange.

AOB and closing remarks

18th May - Part II "Common MD-IVD"

Introductions, Meeting Purpose and Outcomes

- **Competition Law compliance reminder**
- **Adoption of the minutes of previous meeting**
- **Agenda approval**
- **Welcome introduction from CzechMed (Miroslav Palat)**

Hot topics of the moment

- **Notified Bodies: Round table on national activities (MR/OB)**

  See attached presentation of MTE secretariat (*20180518 Notified Bodies*).

  Before the discussion on Notified Bodies, OB presents the result of the election of the new executive group of CAMD. The new Chair is Paul van Zeijst from the Dutch inspectorate (IGJ), replacing John Wilkinson (MHRA). The Competent Authorities for Medical Devices Vice-Chairs are still to be elected. The rest of the newly elected Competent Authorities for Medical Devices Executive Group is made up of Croatia (Suzana Oštarčević), Denmark (Thomas Wejs Møller), Ireland (Niall MacAleenan), Sweden (Helena Dzojic), Switzerland (Bernhard Bichsel) and the UK (John Wilkinson).

  On Notified Bodies:

  - For the **European Commission:** at the present time there is no concrete reason to be alarmed about NB applications under IVDR/ MDR. They are fully committed and there is enough resources.
    - ➔ Plan B: nothing planned before European election of May 2019 but thing could change. It is important to continue to raise awareness at European Commission, Member State, Parliament and stakeholder level.
  - Transparency **of Notified Bodies:** some are very transparent, others not due to the competitive nature of the information.
    - ➔ Companies should engage now with NBs to obtain clear and transparent information
  - **National Ministries:** awareness is growing.
    - ➔ Increase awareness to have Members States knocking at the door of the European Commission on this subject.
  - **Stakeholders:** only starting to be aware of the issues.
    - ➔ We must use them as allies by making them aware of possible disruption.
  - **EU Parliament:** identical - limited contacts so far

  What type of messaging should MedTech Europe adopt? Do we consider to move from a collaborative to an aggressive messaging? This point was discussed by the Board in March. To be more aggressive we need more data. The subject will be discussed once again during the Board on June 21st.

- **Brexit: National Outreach Plan (TV)**

See attached presentation of MTE secretariat (*20180518 Brexit*) and documentation (*MedTechEurope_Brexit_question_checklist_for_members and 20180411 Brexit - MedTech Europe update to members*).

MedTech Europe will continue advocating for:

- **A formal agreement on an extension of the transition period** which lasts to at least through December 31st, 2020 taking into consideration the current "notify body re-certification" challenge in the colluding implementation of the new IVDR and MDR.
- **A mutual recognition agreement for all CE marked** medical technologies granted by a UK based notified body (for EU) or granted by an EU continent based notified body (for UK).
- **A trade agreement for healthcare** to prevent development of trade barriers which would decrease industry investment capacity in innovation and industrial development.
- **A convergence of regulatory framework**, particularly the implementation of the new IVDR and MDR for market access to both EU and UK.

Key advocacy/outreach activities:

- **Letter to national governments** to raise awareness about the huge potential impact of Brexit on the MedTech sector
- **EU Chief Negotiator Barnier as keynote speaker** at MTE CEO Summit
- **Meeting with key MEPs 1:1**
- **Council** (Health Attaches) **roundtable on** 12 September
- **Call with National Associations** to discuss how to ensure that Brexit becomes a national priority
- **'Brexit advocacy package'** for national/EU outreach

- NAs who are not closely involved into Brexit discussion would appreciate information (MedTech toolkit should provide that):
  - Why should their members care (especially if they are mainly distributors)?
  - What should they say to governments why they should care, including also key milestones/timeline/decision making information
  - SNITEM/ABHI letter could be relevant
  - MTE questionnaire for company preparedness could be relevant
  - There is another need to have a short summary about the different areas of impact of Brexit

    = for that IBEC has an excellent Brexit resource webpage:

    http://www.ibec.ie/Ibec/Brexit.nsf/vPages/Home~Brexit?OpenDocument
- Actions:
  - MTE to share the tool kit and assess if further material where needed.
  - Interested NAs to address a letter to their Governments / relevant, active MPs
  - Interested NAs to address a 'due diligence' call for action to their members
  - Interested NAs, ABHI ready to collaborate at bilateral level

Peter Ellingworth makes a point on the recent meetings of ABHI with UK authorities.
For Irish MedTech Brexit is a top priority of the association, a team is working on it in alignment with ABHI.

HealthTech TAB (Rui Sousa)

See attached presentation (*20180518 HealthtechTAB*).
The HealthTechTAB is a unique one-stop-shop to boost the translation of medical innovation to the market. It offers custom mentoring, product characterization and GMP manufacturing. It removes the specific roadblocks identified in health technologies development. It is open to all: entrepreneurs, SMEs, industry, academic labs, etc. It is a PREMIUM service, sponsored by Europe & 100% FREE OF CHARGE.
For more information on the HealthTech TAB and the application process see: http://healthtechtab.eu/

Legal and Compliance

- **Q&A on GDPR (SZ)**

See attached presentation of MTE secretariat (*20180518_Data Protection Committtee Update*) and documentation (*20180327_GDPR_NA_OnePager*).

- After final validation, the updated One Pager for NAs will be sent to the NAs and attached in the meeting documentation in Sharepoint. Compared to the previous version new references has been added by the Data Protection Committee.
- The UK Information Commissioner's office (ICO.) and the French Commission Nationale Informatique et Liberté (CNIL) offer a lot of tools and templates:

https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/
https://www.cnil.fr/en/home

- MedTech Europe Member's only Newsletter (re)subscription: The GDPR sets forth the concept of 'legitimate interest' to use someone's contact details which is an alternative to 'consent'. The general interpretation is that if someone's contacts is already there as being your member, it falls under the legitimate interest of your membership relationship to use their email address to send them news/newsletter. So, we could do that without having to get an explicit consent.

Market Access and Economic Policy

- **HTA update and NAs involvement (JI)**

See attached presentation of MTE secretariat (*20180518 HTA*).

Engagement opportunities for National Associations

- Towards the political level:
  Raise awareness on concerns on the Proposal (& **the specific national HTA situations)**
  Advocate at national level on HTA and HTA cooperation

Refer to the available materials: is there any need of translation?

- Towards MedTech Europe:
  Share with MedTech Europe any relevant information: examples / contact persons / recent developments / ongoing initiatives / your members' feedback.
- With MedTech Europe:
  Combined actions as appropriate

AUSTROMED (PL) met Mrs Wild who is leading EUnetHTA. She is sure that HTA regulation will be implemented but probably in a weaker form due to strong opposition. She and is not happy with the position of MedTech Europe and would appreciate more constructive meetings and discussions.

External affairs

- **MedTech Week 2018: Round table on NAs activities (JP)**
- **Value Project update (JP)**
  See attached presentation of MTE secretariat (*20180507 Value MTW*).

AOB

- **AMR and Patient-Medtech workshops (TV)**
  See attached documentation of MTE secretariat (*20180518 MTE_AMR HCAI_Health Attache Roundtable_outcome_03 May 2018*)
  - **AMR/HCAI: continuous successful work is happening through the working group in MTE.**
    - ➔ Recent Roundtable with Member States Health Attaches (03 May) to raise awareness about the role of MDs and diagnostics to address AMR & HCAI: 40 participants from 17 member states and patients/HCP groups = TV to share outcome and country representatives (SLIDES attached)
    - ➔ AMR/HCAI group in MTE has an open call for one of the 2 Vice-Chair positions = it is very desirable to have a nat ass to fill this position!
    - ➔ Deadline for Vice-Chair application: end June / next AMR-HCAI meeting: 17 September 2018
    - ➔ For more information please contact Timea Rezi-Kato who manages the AMR/HCAI group: t.rezi-kato@medtecheurope.org
  - **Regular workshops with patient organisations: Open invitation to Nat Ass & nat patient groups**
    - ➔ MTE repeats an open invitation to all NAs to join the regular Patient-Medtech Dialogue workshops with patient groups
    - ➔ Next workshops are 24th May (on HTA) and 25th May (on community care) 2018
    - ➔ This invite can also be extended to national patient groups. For more info please contact Timea Rezi-Kato: t.rezi-kato@medtecheurope.org
- **MEAT VBP Initiative (CB on behalf of Sophie Koettlitz)**
  See attached documentation of MTE secretariat (*20180518 MEAT VBP initiative*).
  - **MedTech Europe procurement and competition law guidelines for NAs and their members participating in the MEAT VBP initiative**
    Final version of the guidance in development and to be circulated to the NAs before the summer
  - **MedTech Europe MEAT VBP training session for NA members**

3rd July 2018 in Brussels. To register: Sophie Koettlitz - s.koettlitz@medtecheurope.org

- **MedTech Forum 2019 and future (CB)**
- **Report of the last Board meeting from the IVD/MD Chairs**
  - **Intervention of CS:** see attached presentation (*20180517 Carlos Sisternas Intro*), slides 11 to 13.
  - **Intervention of PL:** SMEs / Membership / Representativeness

Currently MTE has access to SMEs through NAs. SMEs direct membership at MTE has been discussed and rejected. The Board decided that SMEs are not considered as top target for direct MTE membership as SMEs are members of the NAMs and via them represented at MTE.
To properly represent the SMEs towards the European institutions, MTE needs to know from the NAs how many SMEs/Start-ups are part of their membership, what kind of economic operators they are and what is the potential of each country.
Within the SMEs member of NAM it is also important to know who would be ready for engagement for SMEs representativeness towards European institutions.

- **What from the NAs to the next Board?**

The new regulations make obligation to the manufacturers to give access their Technical Documentation to their providers (eg. Label manufacturer). This create an important Intellectual Property issue. Board should push regulatory teams on this subject.

- **Future meetings 2018 meetings**
  - **6th – 7th September, Brussels**
  - **29th – 30th November, Brussels**

18th May - Part III "MD Specific"

Introductions, Meeting Purpose and Outcomes

- **Competition Law compliance reminder**
- **Adoption of the minutes of previous meeting**
- **Agenda approval**
- **Opening Address from the MD Chair (PL)**

  PL salutes the great job done by SNITEM and MedTech Europe for the cancellation of French Decree on "Summary of Device Characteristics".

  PL emphasis on the difficulties to find the right persons to talk with in period of political changes.

Regulatory and Industrial Policies

- **Labelling: Symbols / E-labelling (DK)**

  See attached presentation of MTE secretariat (*20180518 Update on Labelling MD*) and documentation (*180302_eIFU Reg revision_MTE comments_final*).

  - MedTech Europe calls for information on members interested in symbols or having their own symbols.
  - ISO doesn't recognise "word in a box" as a symbol anymore: what about the "word in a box" symbols used presently?

Environmental

- **MDR: Obligations for manufacturers regarding hazardous substances (OB on behalf of Nathalie Buyjs)**

  See attached presentation of MTE secretariat (*20180518 MDR hazardous substances*).

AOB & Closing Remarks (CB / PL)

- **Possible delay in EUDAMED availability**
- **COCIR:** Collaboration

  Code of Ethic update (banishment of direct sponsorship)