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Adress
Centre de Conference A. Borschette - CCAB
Rue Froissart, 36
B-1040 Bruxelles

Place / Date
Brussels / 6 and 7 July 2005

Subject
EU Medical Devices Expert Group Meeting

President: Mrs. Georgette Lalis, CEC, Dr. Antonio Lacerda, CEC
Secretary: Mr. John Brennan, CEC DG ENT.
Place/Date: Brussels / 6 and 7 July 2005
Participants: 67 delegates from AT, BE, CH, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU[0], LV[0], MT, NL, NO, PL, PT, SE, SI[0], SK, SL, TR[0], TW[0], UK, CEN, CENELEC, COCIR, NB-MED, EAAR, EUCOMED, EUROMCONTACT[0], FIDE, EUROM VI

Executive Summary
The Medical Devices Expert Group met 6 and 7 July 2005 in Brussels with the following results:

- **General**
  Mrs. Georgette Lalis, director consumer goods introduced herself being responsible for medical devices since January 2005, apologized for not being present before but meetings were set without consulting her agenda. Her directorate is responsible for cars, pharmaceuticals, cosmetics, bio technology, medical devices, and food.
  More coordinated approach with these groups than the case before. No option to change the legal frameworks of those industries.
  Borderline products, surveillance, safeguard clause to be addressed. Efficient working measures intended, more harmonized market for MDs, disparities throughout EU recognized when going through the dossiers, our task to bring to convergence.
  Late arrival of documents will not happen again, new approach discussion on next MDEG, ditto EUDAMED.

- **Review of MD Directives, state of play-public discussion**
  Jack McMillan to provide outcome of discussion with other industry sectors.
  Full text of the MDD was put on the web for comments by mistake, normally only amendments, but very good feedback received on full text received which might be helpful for further clarification.
  Full text good for the public understanding and commenting.
  Adoption expected in October by the Commission, UK to take active role in the Council.

  J.B.: 25 June 2005 deadline plus late comments received, only one comment from the public, the rest from federations etc., more than 80 submissions, over 300 line items.

  Substantial: reuse of single use - ban or control process. Class IIa almost identical with class IIb - not intended.
  E-labelling; software; AR clarification; scope of the MDD, gap when read against human tissue engineering directive.
  AIMD changes are not planned, only alignment.

  D.P./chair: no written answers to submission are planned, covered by impact assessment.
  MDD revision into public domain by October.
  Registration of class I devices under examination, cumbersome.

- **CETF**
  J.C.G., FR: work output into MDD reviews.

- **MSOG**
  M.J.N., PT: 26 June 2005, 20 MS present, revision of directive class II MP registration, single annex for AR...

- **NBOG**
  S.O., UK: NB-MED group to comment on several papers; system of peer review to be established by September, annual report under preparation, NBOG to deliver against the work programme.
  Chair: NB hopping prevented? S.O.: no ...

- **New and emerging technologies NET**
  J.K.: workshop on 5 July 2005. Conclusion: legislation is able to deal with those products, e.g. from nanotechnologies.
  Chair: report from the group if legal framework is sufficient or to provide suggested changes.

Chair: we have too many subgroups, leave it to this group, no need for nanotechnology subgroup ... no, Dario you will not have the floor.

- **Vigilance**
  No report.

- **Standardization issues**
  M.N., DE: proposal of WG at MDEG level to allow CAs from USs to actively participate in the development of standards, to support Commission on mandates, advice article 6 committee, support Commission decisions, inform authorities, industry; work with industry, membership limited to CAs only.

  M.F.: at CEN level BTS existed, disappeared, we all regretted that, brought together all stakeholders including industry and national standards body.
  Chair: no need for a committee to advise this committee (?)
  Cyprus: welcomes DE suggestion for small countries.
  EUCOMED: industry feels a little bit orphaned when BTS3 disappeared.
  Non-appropriate if industry is kept out.
  P.V., EUCOMED: ... special issue.
  W.E., AT: create division of labour.
  PT: support. NL: ...

  Chair: cooperation can take place outside MDEG.
  S.O., UK: examine initially cooperation between CAs.
  EE: EE so small.
  P.L., COCIR: consensus process, revitalize CEN Healthcare forum, relationship between industry and CAs is a relatively good one, only the exceptions need to be discussed.
  D.P.: no need of this group.
  M.F.: CA responsibility to have contact through their national standards authority. EU has 25 votes on ISO level while USA only has 1 vote, BTS3 should be revitalized.
  Chair: will have discussion with CEN on the nomenclature, maybe she will add this point (BTS3 revitalization) to the discussion.

  M.N., DE: disappointed, repeat of arguments, e.g. 20 people burned to death over three years unless corrective actions had been taken (on the bed standard). WG needed ...
  Chair: Mr. Neumann you might realize that what you are saying you are digging in the new approach; if you tell me that MDEG an informal group creates an informal group to help article 6 work better is needed who will have the resources?

  Malta/chair/M.F.: ISO has adapted essential principle concept for standards.
  Chair: extremely interesting meeting, will leave the rest to Abraao and Antonio, see you at the next MDEG meeting, the date has not yet been fixed.

Lunch break from 13:00 to 14:45 pm 6 July 2005 while London was chosen for the 2012 Olympics.

M.N.: astonished about pre-made position of the chair.
A.L.: will not go into the minutes because he had the opportunity to say it into her face.

- **IVDs**
  IVD technical group
  J.B.: genetic test expert opinion sought.
  A.L.: documents can only be circulated when internal discussions are completed and cleared.
  C.T., EDMA: we can send document to you, you do not need to read it.
  A.L.: IVD technical group might meet in September or not.

  Definition of Health Institute
  Comments to M.N., DE on proposal by 10 September for the Commission by end of September. National definitions if they exist to be sent to the Commission.

- **GHTF**

  Steering Committee meeting - Sevilla meeting

  A.L.: first SC after restructuring within the Commission. Informal SC meeting on 7 and 8 February 2005 on Ottawa rules from 2000.
  Over 80% of MD trade within founding members.
  SC meetings so far only as closed sessions, plus SG chairs and invited experts.

  GHTF 2006 Conference in Lübeck

  A.L.: recognition to the organization by C.F.W. EUROM VI host, M.W. GHTF vice-chair, Peter Linders et al. red carpet treatment in Lübeck.

  J.C.G., FR: good work on the GHTF documents, very useful meeting in Sevilla.
  A.L.: good news - Susanne Hoeke recovered former position as political secretary for GHTF.

  Listing of adop... (?)
  - definition of MD
  - labelling
  - essential principles
  - NCAR application requirements
  - implementation of risk mgt principles in QMS

  Thanks for M.F. SG1 chair for 9 to 10 years, leaving.
  Dr. Alain Prat to take over SG3.
  J.K., NL: thanks to Kim Dix leaving SG2 chair.
  M.W.: very good climate.

  C.F.W.: presentation of the GHTF 2006 Lübeck Conference, sponsored by EUROM the European umbrella federation of fine mechanic and optical equipment including medical technology (EUROM VI)

fee structure	300 € / 250 €	industry
	200 € / 150 €	regulators, NBs, faculty
	100 € / 75 €	spouses

  early bird specials until 15 February 2006.

  Information to be posted on GHTF website www.ghtf.org

  GHTF Training seminar on risk management - 24 June 2005 in Lübeck

  Organized by Horst Frankenberger and sponsored by EUROM VI, 130 attendees including 40 students who showed a high level of engagement and interest in the topics.
  Good turn-out for a regional GHTF Conference. Dr. Larry Kessler, FDA was one of the speakers.

  GHTF, APEC meeting 13-17 June 2005

  Report by A.L.: 204 participants - Asian Pacific Economic Council.

  GHTF meeting of study groups

  SG1: Maurice Freeman report
  - definition of MD
  - classification rules, pending, awaiting conformity assessment guidance
  - STED worked on since the last millennium

  J.B.: role of type testing, only 6% of Europe and Australia use it, not in the GHTF conformity assessment draft, comments requested seems to be a sticky point for FDA; SG1 subgroup met last week in Vancouver and made significant progress on the conformity assessment guidance.

  SG2: Carl Wallroth report
  - met in Milwaukee early June 2005 at GE training and QM systems / one of the 4 key focus elements: customer satisfaction
  - N54 adverse event reporting rules, merging of N21, N31, N32, N36 on rules and exemptions, use errors,

trending, timing
- recall notices
- sun setting / maintenance consideration for new chair Dr. Jorge Garcia

Adverse nomenclature task by ISO TC WG3 by request of SG2.

SG3: Alain Prat report
- joint meeting with SG4 on risk mgt auditing as part of QMS
- subcontracting guidance under development

A.P. only EU CA member.

SG4: Markus Zobrist report
- joint meeting with SG3 in Boston begin of April
- September meeting in Gaithersburg joint meeting with SG3
- audit report emphasis

EU under presentation, only M.Z. EU regulator and step-in chair.

SG5: Wolfgang Ecker report
- London meeting with good FDA engagement
- definition clinical data in line with MDD definition
- clinical evaluation
- ISO TC 194 liaison, MoU, ISO 14155 revision, technical ISO, political SG5
- SG1 liaison discussed at September Gaithersburg meeting

- **PVC - DEHP working group**
  Report by Isabelle Demade, EC on progress of work on 2002 revision subject to political pressure and special interest group.
  Thanks to EUCOMED on position paper and restart of work contributions in March 2005.

  A.L.: resubmitted of papers, e-mail addresses by special interest groups, formal request of e-mail address(es) of at least one WG member. Data confidentiality issue.
  S.O.: too late, already getting dodged with papers for the last two weeks.
  A.L.: unless you advise us differently we will not release the e-mail addresses.
  Should special interests groups be invited?
  EUCOMED document to be circulated, deadline for comments:
  H.K.A, DK wants to join WGs for efficient reasons for the same country the same people.

- **Mercury Strategy UK**
  I.D.: same situation as in the opening up of the PVC - DEHP.
  R.G., UK: in embarrassing situation, UK interdepartmental letter circulated to this group of the UK environmental department, apologies to AT for a statement in the letter disagreeing wit
  AT without giving details.
  A.L.: apologies for the letter circulated by accident.
  How should we position ourselves.

  W.E., AT: early horizon scanning as standing item on the agenda. New sphygnomanometer on NIBP monitors without mercury seems to be ok. Amalgam issue comes up every 7 years, scientific committee to be ask for an update.

18:00 close of the 1st day on 6 July 2005 to reconvene at 10:00 on 7 July 2005, 14:30 on general product safety directive.

- **MRA Australia**
  State of play, revised sectorial annex, origin statement to remain?

- **International relations**
  China
  State of play.

Chinese Taipei
Workshop planned for August 2005.

10:30 - six bombs went off in London in Metros and busses

- **Workshop EU-accession countries best practices**
  Prague workshop June 2005.
  Oral report.

- **Cyprus workshop**
  Preparational meeting after this meeting in ad-hoc group.
  29 September - 1 October 2005.

12:00 - first alarm without cause.

- **CDM statement - Euapme European Association of Craft, Small and Medium - sized Enterprises**
  Exchange of views, not much sympathy for additional patient informations.

13:00 - Lunch break, to reconvene at 14:30 with 48 attendees.

- **General product safety directive GPSD**
  Erik Hanson, DG SANCO: GPSD deals with the safety of consumer products where no other directives apply, plus safety management requirements for services, importers; RAPEX rapid alert system. 1992 first directive adopted, 2001 revision, transposition ended last year.
  UK, NL, LX are behind, promised by autumn 2005 because of lengthy national procedures.

  2003 November first guidance on borderline issues for cosmetics, low voltage, toys. Second chapter on MD, medicinal products, cars, machinery ... directives. Comments from PT and NO only.
  GR raised some issue in the meeting, e.g. RAPEX does not apply because of the MDD vigilance system, ergo MDs are exempt from the RAPEX system.

  A.C.: our vigilance system is the best of the world, excellent.
  PT proposal considered a very good idea by A.C., now we are leaving (it to Susanne), now IT ...

signed	**present**	**present**	**signed**
Dr. Carl F. Wallroth	***Dr. Peter Linders***	***Benny Ons***	***Dott.ssa Linda Sanin***
Marcus Wenzel		***Karen Howes***	***Gregor Stock***
		Christine Tarrajat	
EUROM VI	**COCIR**	**EDMA**	**FIDE**

present	**signed**	**signed**
Dr. Maurice Wagner		
Dr. Philippe Verdonck	***Bernard Lambert***	***Dr. Dr. Jaap Laufer***
Dott. Dario Pirovano	***Francoise Schlemmer***	***Ludger Möller***
EUCOMED	**NB-MED**	**EAAR**

Attachments
Participation list
First announcement GHTF 2006 Conference
Conference Programme GHTF 2006 Conference