GHTF SG2 Meeting
Location: 45 Avenue Auderghem Breydel building Room 12A
1040 Brussels -BELGIUM
Date: 11-13 February, 2009

Attendance:

Name	Organization	Email	11/02	12/02	13/02
Isabelle Demade (ID)	EC	isabelle.demade@ec.europa.eu	X	X	X
Philippe Auclair (PA)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MWB)	FDA	mwb@fda.hhs.gov	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com	X	X	
Klaus Stitz (KS)	MEDEC	kstitz@medec.org	X	X	X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X	X	X
Miang Tanakasemsub (MT)	AHWP	miang.tanakasemsub@bausch.com	X	X	X
Hiroyuki Tamishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X
Yoshihiko Sano ("Yoshi")	MHLW	sano-yoshihiko@mhlw.go.jp	X	X	X
Takehiko Arima	JFMDA	tarima@its.jnj.com	X	X	X
Barbara Mills	MITA	Barbara.Mills@ge.com	X	X	X
By phone					
Jorge Garcia (JG)	TGA	jorge.garcia@tga.gov.au	X	X	X
Barbara Harrison (BH)	Health Canada	barbara_harrison@hc-sc.gc.ca	X		
Observers / visitors					
Takuya Noro	PMDA	noro-takuya@mhlw.go.jp	X	X	X
Carmen Ruiz Villar	AGEMES Spain	cruizv@agemed.es	X	X	X
Hannu Seitsonen	laakelaitos Finland	hannu.seitsonen@laakelaitos.fi	X	X	
Invited experts					
Leighton Hansel	ISO TC 210	leighton.hansel@abbott.com		X	
G. LeBlanc	SG5	gregleblanc@cookcanada.com			X
S. Ludgate	SG5	Susanne.Ludgate@mhra.gsi.gov.uk			X

DAY 1: FEBRUARY 11, 2009

Welcome, Introductions, Announcements

The 36th meeting of GHTF Study Group 2 was hosted by the European Commission 45 Avenue Auderghem, Breydel building, Room 12A, 1040 Brussels - Belgium.
Day 1 of the meeting began at 9:00 AM on February 11, with a greeting from the new Chair, **Mrs. Isabelle Demade**, (DG Enterprise and Industry) SG2 Chair and **Philippe Auclair** (Abbot Vascular /Eucomed) Secretary who welcomed the participants.

Laurent Selles, Deputy Head medical devices at DG Enterprise made the opening address. Mr. Selles gave a short history of the European Commission, emphasizing that unification is sustained by diversity and detailed the "subsidarity principle". Mr. Selles reinforced and confirmed the involvement of the European Commission in the Global Harmonization process.
There are two new members in the group. **Sano Yoshihiko** ("Yoshi"), Deputy Director, Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (MHLW), and **Barbara Mills** (GE Healthcare) representing MITA.
I Demade proposed that Takehiko Arima, Senior Director Vigilance/Safety & Quality Assurance Division, Medical Company, Johnson & Johnson KK, representing JFMDA becomes SG2 Vice Chair. The proposal was endorsed by the Group.

Jorge Garcia joined by phone for part of the three days, B. Harrison joined on the first day. Unfortunately, technical polycom difficulties prevented her to connect on the 2nd and 3rd day.
The Brazilian representatives who attended the Toronto meeting were excused. The interest in having representatives from South America was confirmed. It is mentioned that PAHO has been solicited to identify permanent observers representing South America.
The European observers were **Hannu Seitsonen**, Senior Officer medical devices, National Agency for Medicines, Finland and **Carmen Ruiz -Villar**, Spanish Agency for Medical Devices, AGEMED.

Review meeting agenda

The first order of business was a review of the agenda for the meeting. Accommodation was made - considering the time difference - to allow **J. Garcia** (TGA) to participate by phone from Australia to the Day 2 discussion on the work item "Definition and Classification of Product Safety Corrective Actions including recalls". The agenda was adopted.

Minutes from the previous SG2 meeting in Ottawa, Canada

Minor corrections related to the section FDA Coding Project on page 3 ; EU AE system on page 4 and N87 on page 5 were introduced . N112 R1 will be sent for posting on the web site.

Action 1. PA. See that minutes from Ottawa N112R1 are on the web site

Review of the actions items from the last meeting

Action items from the previous SG2 meeting in Ottawa, Canada, were reviewed. The Chair noted the excellent progress. A few actions are still in progress and will be included with the Action Items List from the Brussels meeting.

Review of the functioning of the group

The Chair explained her intention to establish, for key projects, sub groups in charge of preparing document in between meetings. The subgroup leaders will be responsible to report to the whole group on the progress. The proposal was endorsed by the group.

Steering Committee Report

HI and ID reported on the last SC teleconference.
ID agreed to update the SG2 group on any SC discussion arising from the teleconference that impact SG2.
Question was raised about the availability of the minutes from the SC minutes and teleconference. Minutes are available on the web site.

- Action 2.ID to Report to SG2 group on the SC discussions

IH presented document GHTF AHWPN1 R4 from the adhoc group on defining a regulatory model. ID will circulate in view of obtaining comments from the group.

- Action 3. ID to circulate GHTF/AHWG N1 R4 ad hoc group regulatory model.
- Action 4. ALL to comment to ID on GHTF/AHWG N1 R4 ad hoc group regulatory model

Toronto GHTF Conference (May 12-14)

- A presentation during the main meeting on "Adverse events reporting / traceability of concerned devices" is on the draft conference agenda.
  - Action 5. A call for SG2 speaker is organized. Selection of one (1) speaker for the GHTF conference May 12-14th 2009 - Candidates to be identified by SG2 members and to contact ID / PA

- Discussion about the need for training for Latin America countries. MWB will check with APEC what their plan is for satellite meeting (tentatively May 14-16). Program was later circulated on day 2.
  - Action 6. MWB and PA to clarify what SG2 presentations are required and suggest speakers

- SG2 will organize a meeting (May 10-12 morning) prior to the main conference. The group reinforced the suggestion to disconnect SG2 meetings from the conference as this may affect the focus and dedication of the group. Going further, it is recommended for SG2 meetings to be organized separately from the conference (e.g. after) to avoid any overlap.

➢ National Competent Authorities Reports (NCARs) related documents

◙ **N38 R16 (revised by L. Kroger):**
Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

Review of the document. All editorial changes accepted. Definition of confidential; the word "unfairly" was deleted.
Application process: the flow of the text appeared not to match the diagram. It was agreed that the Chair of SG2 has the prerogative to identify trainers based on their qualification criteria and the geographical region of the trainer and of the applicant . The wording was adjusted to fit the diagram
The conditions for the redistribution of received NCARs by the recipients have been modified for full and associated participants.

The final text will be re-circulated for approval and then presented to the SC.

- Action 7. MWB-ES Identify criteria for NCAR trainers for the purpose of the NCAR application process described under N38

- Action8.
  Revised N38R18 Application requirements for participation in GHTF NCAR program final :
  - clean version to be circulated by PA
  - all to comment before presentation to the Steering Committee

- Action 9. PA to circulate "Official slides" SG2 training on criteria for exchange of NCAR in view of ad hoc retraining of NCAs.

- Action 10. Updated training of documents for current NCAR participants- example of confidential / non confidential reports.- to be on the next SG2 meeting agenda .(PA/ID)

◙ **N79 R9 (revised by L. Kroger)**
Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.

Review of the document. Editorial comments. The confidentiality section is reworded. Section 4, Criteria of distribution of NCAR report is polished, with addition of geographical consideration for wide circulation. (2 or more regions affected). Section 6, Instructions for filling NCAR is supplemented based on the NCA group comments.

- Action 11. PA to circulate revised document
- Action 12. ALL to comment in view of presentation to the Steering Committee

◙ **NCAR performance and statistics**

ID mentioned that Thailand has applied to the NCAR Exchange Program. JG is the trainer.
Report from P. Carter was tabled. (no number allocated). NCAR stats 2008. P. Carter. The document was circulated 2 days before the meeting.
The report updates M. Segstro's previous slides in a simplified version. The report gives an accurate 10 years overview. The switch from a majority of reports marked confidential to a majority of reports marked non confidential was noted.

Concerns were raised about the predominance of reports originating from EU. It is reported that during 2008, only 2 reports have been issued by non EU countries. (1 FDA / 1 MHLW) This is not visible on the slides update as the data from originating country are only given in a 10 years consolidated overview. It is suggested to refine the data by comparing the last year period vs. the previous 2-3 years and versus the overall 10 years.

This EU related predominance signals difference is circulation criteria. Non EU participation is very reduced

Action 13.
Group of regulators (1 regulator from each region AU /CA/ US/EU/JP /HK as associated participants) to review difficulties and to propose solutions – And to define which consolidated data are needed from the NCAR Exchange Program secretariat. MWB to coordinate. Report to be presented at next SG2 meeting.

➢ **GHTF training**

Presentation by PA of N115 (summary of SG2 trainings for 2008). The group noted the increase in requests of SG2 trainings.
It was agreed that each request received by a member would have to be clarified as to the scope and audience and transmitted to the Chair for possible allocation of trainers.

This stimulated a general discussion about the various training types e.g.

- NCAR certification related trainings – as per N38 - ;
- basic N54 trainings for the public or NCAs;
- case studies;
- general SG2 and GHTF training.

The possible need of advanced training was mentioned. Funding was also discussed as being a source of limitation.

J. G was given the lead in compiling all trainings documents and to produce a "Core" training slide deck to be updated and supplemented by case studies for advanced trainings. These presentations should be referenced and document controlled.
PA mentioned recent request from India DGCI. He will seek clarification from DGCI on what kind of training is sought. Also AHWP is seeking training for their November 09 meeting. MT will liaise with the organizers. The APEC training in May 09 was discussed under the GHTF Conference item. See above.

MWB gave an update on the SC ad hoc group on training. The group is now led by Jean Welch, FDA. MWB and PA to follow up.
All requests of general training to be forwarded to the Chair for trainer selection

- Action 14. **Training Log**
  PA to Review N115 log of training. Training to be reformatted. Monitor going forward.

- Action 15. **SG2 general training materials.**
  Collect all training materials to prepare the core SG2 documents for revision and control.
  J.G to take the lead with input of MWB/ PA/ ES/ MT
  To be presented at next meeting

➢ Update on AHWP

MT presented. (Documents were not circulated prior to the meeting).
- Overview of the AHWP SG2 progresses; including the SADS program.
- New regulation proposals (China / India). Suggestion is made that SG2 should prepare consolidated comment when new adverse event regulations are proposed for public consultation. Members are asked to forward all proposal received or formulated to the Chair.
- N54 implementation status (so called Asian N73), including KHG / S Arabia / Singapore / Taiwan). The group recognizes progress made by the Asian countries. A more complete picture will be prepared and presented at the May 09 SG2 meeting .

- Action 16. AHWP presentation (from MT) to be circulated by PA
- Action 17. MT to complete the AHWP harmonization chart of implementation N54.

DAY 2: FEBRUARY 12, 2009

➢ Electronic reporting program / Device Nomenclature

- **HL7. events codes- compatibility with N87 (MWB)**

MWB reported on the SG2 request to HL7 for addition of the seven (7) missing fields

required to map with document N87. This issue was not raised at the HL7 meeting. HL7 links with ISO (and CEN) via ISO/CEN TC 215 WG 6 . This ISO group will release in late February its document prEN 27953 part 1 & 2 for public comments. These document will NOT include the 7 missing codes .
SG2 Chair will seek endorsement by the SC to have SG2 representative(s) in the ISO/CEN TC 215 WG6 . ES volunteered to represent SG2 at the next ISO TC 215 WG6 meeting is in Edinburgh on April 26, 2009

- Action 18. MWB to circulate prEN27953 part 1 and part 2
- Action 19. ID to obtain endorsement by the SC to have a representative from SG2 in the HL7/ISO/CEN Committee
- Action 20. ES to prepare a letter to be sent to the lead of the executive secretary ISO TC 215 committee with cc: HL7/CEN. The letter will request the addition of 7 new codes and the attendance of SG2 representatives at HL7 meetings. Letter to be sent by SG Chair.

◙ **Pilot program e-reporting N87 (ES)**
The program started in January 09 in EU and includes Germany , France , UK and Ireland . Based on Germany early feedback , minor changes will have to be made in the data entry form. Industry should increase its participation. Eucomed will forward this message to members. An update on the pilot results will be made in June 09. ES mentioned that Germany intended to modify its law to make e-reporting mandatory under its jurisdiction on January 1, 2010 .

◙ **ISO TC210 WG3 report (Leighton Hansel-LH)**
LH updated the group on the ISO group progresses on the **event code nomenclature**. The content and format of the final document was discussed at the December 2008 meeting of TC210 WG3. The document will include an appendix explaining the mapping with the FDA Codes . WG3 will meet during the annual meeting of Technical Committee 210 in May 2009.

The likely calendar is that the Technical Report will be reviewed and approved during the WG meeting and then submitted to public consultation for international input requiring a 3 Months (90 days review) public comment period . Assuming validation at the comment/ vote process, the final Technical Report should be published by ISO early in 2010. FDA agreed to have the document posted in its web site. The group congratulated LH for progress.

- Action 21. L. Hansel to inform SG2 when document 19218 released for public comments.

◙ **FDA coding project (MWB)**
MWB reported orally on the FDA draft evaluation codes and draft conclusion codes.

These are for information only. A draft will be transmitted to SG2 as the document is reviewed by ISO TC 210 WG3.

Mrs. Sabine Lecrenier, Head of Medical Devices and Cosmetics at DG Enterprise, visited the group. She reinforced the importance of the work of SG2 for public safety, including the NCAR Exchange Program. She emphasized the need to foster harmonization of corrective actions and their timely adoption across geographies to improve public health.

➢ Definition and classification of Product Safety Corrective Actions, including recalls

J. Garcia joined by phone and presented document N111R2. Definition and Classification of Product Safety Corrective Actions, Including Recalls. The definition of a Field Safety Corrective Action, per N57, was reexamined.
The work focused on the schematic of definition of field action, as described in N111. This schematic was used as a start for a brainstorming session. The diagram was completed by introducing description of each type actions described. (i.e. recalls / product corrections / hazard alerts / safety alerts / product notifications/ withdrawals / improvements / recovery).
It was decided that a sub group will work on providing examples and offering a more refine set of definitions.

- Action 22. PA to circulate the brainstorming document on FSCA
- Action 23. Task Force created. JG taking the lead. (With MWB / ID / BH / Arima-san/ MT / HS) to review, including examples output for the next meeting.

➢ Unique Device Identifier (UDI) HI

IH reported on progress of the ad hoc Steering Committee Work Group. (February 11, 2009 conference call). A questionnaire has been completed by each jurisdiction. Analyses of results are ongoing. Next step is to define the minimum (“Core”) info to be included in the database and the bar codlings.

➢ Map on SG2 guidance N80 R9 (provided by JG)

The document was circulated for endorsement before being placed on the Web site.
IH raised some questions and the group reviewed the document. Decision was taken modify N80 R9 and not to place it on the web site until a revised version is agreed.
Slide 2: Reference of the definition of post market surveillance is erroneous.
Slide 5: refers to documents no longer available on the GHTF web site. The group recommends removing it.
Reference to N63 R8 to be deleted.
Generally take out all references which are not referring to a guidance document.

On the diagram slide 8, reference to N8 to be removed, as N8 is not a guidance document.
The relevance of slide 10 is questioned. Slide 11 to be deleted.

- Action 24.
  PA to relay comments to JG . JG to revise R9 based on the comments provided. Revised document to be circulated prior to the Toronto SG2 meeting

➢ Drug device Combination

ID is handling a question from the ad hoc group to review the AE reporting in various geographies. Question coming from the SC ad hoc group on drug device combination. The group raised the question if this includes device / biologics combination, as these are regulated differently in some geographies.

- Action 25.
  ID to clarify with the ad hoc group the definition of drug/device combination product for the scope of this survey.

DAY 3. FEBRUARY 13, 2009

➢ Access to public information (N116 PA/ID)

PA presented a revised document in the form of a new work item proposal for discussion by SG2 members. The scope is restricted to communication made by NCA to the public on Field Safety Corrective action.

Group discussion:
Two (2) issues were discussed / 1. Content of the public information for the lay man, including patient and 2. Harmonization of actions taken between geographies.
This is a difficult subject as the patient community is putting pressure on transparency on the safety profile of devices and there is no agreed template by NCA on how to communicate to the public.
It was recommended to review the section on communication to the public included in N8. Based on this review, a decision will be taken to modify N8, or to develop a new WI.

- Action 26. ALL to review N8 section referring to communication to the public and assess suitability.
- Action 27. IH to review of possible incorporation of N8 into N79 and recommend need to maintain or not N8

➢ AE reporting during clinical trials- joint WI with SG5

For this agenda item of the meeting SG2 members were joined by Susan Ludgate, MHRA UK, Chair of SG5, and Greg LeBlanc, MEDEC Canada, Vice-Chair of SG5.

It was clarified that the scope of this WI is reporting of pre market clinical investigation AE, and does not deal at this stage with post market clinical follow up (PMCF) . Greg LeBlanc presented the mapping document of AE terms and definitions prepared by SG5. The group agreed that what is needed is a N54 "like" document for adverse event reporting during clinical investigations, detailing the "what", "when" and "to whom" to report.

Arima-san presented a general comparison of the reporting scope differences pre /post market. This was recognized by the group as worthwhile background documentation.

It was decided that to create a Task Force to assess the possibility of fitting AE reporting during pre market clinical under N54, or the opportunity to develop a parallel document.

The following people tentatively volunteered or were assigned responsibilities.
⇨ SG2: ES / MB or BK / PA / "Yoshi" + consider an Australian representative (not present at the meeting).
⇨ SG5: Greg LeBlanc / S. Ludgate / Advamed and FDA representative.
Greg LeBlanc accepted to take the lead of this sub group, subject to approval by the Steering Committee.
The Task Force to arrange conference call before the Toronto Conference and meet physically in May in conjunction with the conference.

- Action 28. PA to circulate Arima-san's comparison on AE reporting pre /post market
- Action 29. S. Ludgate to communicate identity of the SG5 participants in the pre market reporting group
- Action 30. ID to communicate names for the TF SG2 members
- Action 31. ID and S Ludgate to communicate for approval by R. Rotter at the next SC conf call the proposal of creation of this task force for SG2-SG5

Review of actions and work plan

◙ **N49- Work plan** was reviewed.
- Action 32. PA to circulate N49 R20 after review with ID

◙ **N 144- Actions items** were reviewed and agreed.
- Action 33. PA to circulate action items to the group ASAP

In order to facilitate the review of documents, the Chair requested that document for review at the meeting are circulated at minimum 7 working days before the date of the SG2 meeting.

Future SG2 meetings

- 10-12 May 2009: 37th SG2 meeting in Toronto, Canada
- 11/12/13 November, 2009 in Hong-Kong (Tentative)
  - 34. MT to consider SG2 meeting in Asia in November 11/12/13, 2009 in conjunction with AHWP meeting.

ID closed the meeting, recognizing all participants' engagement and positive input.

End of minutes (PA/ID)