GHTF SG2 Meeting
Location: INFARMED, Av. do Brasil, 53, 1749-004, LISBOA, PORTUGAL
Date: 27-29 February 2008

Attendance:

Name	Organization	Email	27/2	28/2	29/2
Miguel Antunes (MA)	INFARMED	miguel.antunes@infarmed.pt	X	X	X
Takehiko Arima (AT)	JFMDA	tarima@jjmkk.jnj.com	X	X	X
Philippe Auclair (PAu)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MWB)	FDA	mwb@fda.hhs.gov	X	X	X
Isabelle Demade (ID)	EC	isabelle.demade@ec.europa.eu	X	X	X
Jorge Garcia (JG)	TGA	jorge.garcia@tga.gov.au	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com	X	X	X
Larry Kroger (LK)	MITA/NEMA	larry.kroger@med.ge.com	X	X	X
Tetsuya Kusakabe (TK)	MHLW	kusakabe-tetsuya@mhlw.go.jp	X	X	X
Mark Segstro (MS)	Health Canada	mark_segstro@hc-sc.gc.ca	X	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 Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com	X	X	X
Observers					
Takuya Noro	MHLW		X	X	X
Hideto Yokoi	PMDA Advisor		X	X	X
Adriana Gamboa	INFARMED		X	X	X
Luisa Carvalho	Vice-President INFARMED				
Judite Neves	Health Products Dep. Director INFARMED				

Welcome, Introductions, Announcements:

The 34th meeting of SG2 was held at the Portuguese Competent Authority, INFARMED, offices in Lisbon, Portugal. There were no new members to the group, but two observers from Japan and three observers from INFARMED were in attendance.

Day 1 of the meeting began with introductions of the participants. Miguel Antunes welcomed the SG2 members to Lisbon on behalf of INFARMED and reviewed the local arrangements for the 3-day meeting.

Review meeting goals and agenda; approve old minutes:

The first order of business was a review of the agenda for the meeting. There were no major additions or changes to the agenda.

JG gave a report from the last Steering Committee meeting. SG2 was asked to prepare a new work item proposal to define the term 'adverse event' for the GHTF glossary. Previous SG2 guidances describe what the term means but did not include a formal definition. The GHTF Steering committee also made a request to SG2 to develop and submit a new work item proposal (WIP) on the definition and classification of recalls.

The minutes from the previous SG2 meeting in Washington, DC were reviewed. MWB suggested the minutes be revised to report the FDA translation of SG2 requirements to the HL7 format. Since this activity was completed following the Washington, DC meeting, the item will be noted in the minutes for the next meeting. The minutes will be posted to the GHTF website as document SG2 N106R3.

The action items from the previous SG2 meeting in Washington, DC were reviewed. A number of the actions are still in progress and will be included with the actions from the Lisbon meeting.

Discussion of N61: PMS Harmonization Chart

The SG2 document entitled PMS Harmonization Chart which is an internal SG2 working document was discussed and reviewed. It lists topics considered for harmonization by SG2 and provides rationale where it has been decided that harmonization is not required at this time. The study group decided to revise its previous position and undertake a project to develop guidance around 'public access to information' due the expanding availability of regulatory information on public websites and in other media. Clarification was added to two items: 1) Technical File Reviews and 2) Condition of Approval Studies, PMS Studies, and re-evaluation re-examination schemes. The conclusion section of the document was also edited to reflect the changes. The document revision number was changed to N61R6.

Event Coding and ISO 19218: Discussion developments:

Further discussion was held on a project involving adverse event coding. The standard ISO 19218 which defines event codes is currently being revised and SG2 has been asked to review the planned changes. In addition, FDA is developing its own coding scheme and SG2 is working to facilitate harmonization of event coding.

MWB discussed her work to convert FDA level three codes to ISO level two codes. She presented a number of new ISO level two terms. ISO has selected approximately 60 new terms. The current ISO scheme uses about 20 level one terms and 60-70 proposed level two terms. MWB will continue to work on reducing and simplifying the table of proposed ISO 19218 codes.

Action Items:
1. Coding Chart (ISO 19218 Type table) – simplify and distribute to all via LK: – MWB - Mar 08

2. Provide comments on Coding Chart to MWB via LK - MWB will send to L Hansel – All SG2 - May 08

Discussion on plan for pilot of N87PD

ES gave an update on a pilot project for electronic adverse event reporting using the XML format. The project expected to begin January 1 is experiencing some delays due to some required changes to the protocol. The European reporting form uses a PDF form that can be attached to an email. Another electronic reporting project is underway at FDA using the HL7 format. FDA is working on translating the GHTF required fields to HL7 format. There has been considerable discussion as to how to best converge the two approaches.

ES reviewed the changes that have been made to the N87 protocol document. The changes include 1) trend reports deleted and 2) clarification re the use of ISO 19218. ES is looking for three NCA's to participate in the pilot. Likely candidates are Germany and UK. ES is currently reconciling the German and UK XML versions and will launch the pilot as soon as possible.

JG asked the SG2 NCA's to consider whether they could develop and accept a common form. The current form is only acceptable in Europe.

Action Items:

3. N87 pilot – ES to get final XML schema from TS – then send final draft protocol to all SG2 – ES – Mar 08

4. Provide comments on revised protocol to ES via LK – All – May 08

Definition of Adverse Event

The study group discussed the request from the Steering Committee to prepare a definition for the term 'adverse event'. There was a brief debate on whether it was necessary to first prepare a new work item request and submit to the Steering Committee before the work was done. Since this did not seem to be a big project and much of the basic information was already in SG2 guidance, it was decided to proceed based only on the request.

SG2 members drafted a definition using information in the previously published SG2 guidances. The agreed definition was submitted to the member of the Steering Committee responsible for maintaining the GHTF glossary. All study group members were asked to review the glossary for any other gaps or discrepancies prior to the next meeting.

Action Items:

5. Send definition of AE drafted in Lisbon to HI / Steering committee. Copy to all SG2 – JG – Mar 08

6. Distribute Glossary to all SG2 – LK – Mar 08

7. Review Glossary especially duplicate definitions for a single term/concept – Prepare comments in comment template – and provide to LK – July 08 – All

8. Compile comments on Glossary into a single document and distribute for discussion at next meeting - LK – Aug 08

NWIP – Definition and Classification of Recalls

A draft version of the new WIP was discussed and revised during the meeting. The proposed WIP will be presented to the Steering Committee at a meeting in Malaysia in early March by the SG2 Chair. The use of the term recall has been controversial in some jurisdictions and may require the development of alternate terms. Therefore, the scope of the document will state that the work involves developing terms alternate to the word 'recall'. It was also decided to broaden the scope to include all types of product corrective actions.

The timeline for the project was discussed and it was decided that it should be extended due to the many anticipated difficulties that will need to be addressed and agreed upon during development of the guidance. The planned date for the first draft is Q3 2008.

The title was changed to 'Definition and Classification of Product Safety Corrective Actions including Recalls'. The WIP document number is SG2 N108R1.

Washington, DC SG2 Training

A training session on SG2 guidances was held and taped at the last meeting in Washington, DC. The participant feedback from that training was reviewed and discussed. There were differing opinions regarding how the taped materials might be used for future training especially related to its use for NCAR training. NCAR is the National Competent Authority Reporting program that SG2 developed to facilitate and manage the exchange of product issue information among regulators. Countries not currently members of GHTF can apply to participate in the NCAR program, however, one condition is that applicants receive training on the system before being accepted as participants because of confidentiality issues and other sensitive matters. It was generally agreed that the Washington, DC training tapes should not replace face-to-face NCAR training. Past group training in Chendu, China and Washington, DC was considered the equivalent of face-to-face training. The nominated trainer will take this into consideration when working with applicants to the NCAR program.

The training was recorded on two CDs that are available to SG2 members. It was proposed to advertise the training on the GHTF website or alternatively post the training files on the GHTF website for anyone to view. It was requested that the slides used in the training be reviewed by the full SG2 membership before being posted to the GHTF website.

The training discussion next changed to how to evaluate the effectiveness of the training. A decision was made that trainers can use various means including questionnaires to determine training effectiveness.

Action Items:

9. Washington DC training slides: distribute to SG2 members for comments – LK – Mar 08

10. Provide comments to LK on Washington DC training slides– All – June 08
11. Once any comments are resolved slides to be given document number and posted on website – LK – June 08

NCAR performance and statistics

MS presented NCAR data for the period from January 1, 1999 through December 31, 2007 for review and comment by SG2 members. The presentation included data on 1220 NCAR reports. There are 23 NCAs in Europe, North America and Asia-Pacific who participate in the program. The data analysis included trends by product sector. The number of NCARs dropped from 185 in 2006 to 174 in 2007. The largest contribution by product type still involves cardiovascular products (22%). Software related issues accounted for about 13% of NCARs in 2007. The NCAR slides were assigned a document number SG2 N76R9.

It was announced that the secretariat for the NCAR program would be moving from Canada to Australia within the next year, as the Canada regulatory member will be leaving SG2. The Canada replacement is not yet determined.

Action Items:

12. Distribute N76R9 (NCAR stats) to SG2 – LK – Mar 08

Public Access to Information

A draft of a planned paper on 'Public Access to Information' was not yet ready for discussion at the Lisbon meeting. See the previous discussion on document N61. This is the area that SG2 has determined to require further consideration in view of all the information now available on public websites and in other media.

Action Items:

13. NCA members to provide reference materials related to "Public Access to Post Market Information – taken/reported to NCAs" – ALL SG2 NCA members – June 08
14. Prepare draft discussion paper on "Public Access to Post Market Information – taken/reported to NCAs" – done on NWI template distribute to SG2 via LK – PA/ID – by Aug 08

Confidentiality of NCAR reports

MS reviewed proposed revisions to N79 (National Competent Authority Report Exchange Criteria and Report Form) and N38 (Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program) and the issues related to the confidentiality of reports. A clarification on the definition of confidentiality was discussed. It was recommended to update N79 and N38 to ensure consistency in the use of the term in the two documents.

Action Items:

15. Update N79/N38 with revised definition of confidential & send to GHTF secretary with new rev # to update the website (copy LK) – MS/JG – Apr 08

Discussion of N73: status of implementation

PA reviewed the changes that have been implemented in the EU Guidance MEDDEV 2.12/1 rev 5. An updated version of the implementation chart in N73 with references to the MEDDEV changes was presented to SG2 members. The SG2 document number was updated to SG2 N73R9.

Action Items:

16. Distribute N73R9 to all SG2 – LK – Mar 08

Report on Asia Harmonization Working Party

MT, the Asian Harmonization Working Party liaison to SG2, presented an update of AHWP harmonization activities related to adverse event reporting and the AHWP SADS program (similar to the SG2 NCAR program). Currently only Hong Kong and Saudi Arabia have signed up for the SADS program and no reports have yet been exchanged. It is expected that the AHWP SADS system will evolve to NCAR when all SADS members are members of NCAR. It was reported that seven AHWP members have mandatory adverse reporting systems and four have voluntary reporting systems. A list of those countries and their status will be sent as a follow-up to the SG2 secretary.

Action Items:

17. Provide update on AHWP slides presented in Lisbon to all SG2 members – MT via LK – Mar 08

18. Update N73 with information from AHWP member economies – MT – Aug 08

Emerging Technologies/Plug & Play

CW proposed that SG2 monitor activities in the areas of emerging technologies and the establishment of industry guidance re plug and play for medical devices. CW offered to provide periodic updates to SG2 members. There are expected to be some important regulatory and technology challenges related to these activities. CW suggested that regulatory relief might be required for changes that fall into the area of continuous improvement. Current regulatory rules do not recognize continuous improvement in the quality system requirements.

Action Items:

19. Provide update on interoperability/plug and play – include case studies for discussion at Next SG2 meeting – CW – Oct 2008

Other Business:

There was a brief discussion on the need for periodic retraining for NCAR participants. It was reaffirmed that SG2 guidance needs to be developed to define the scope of this activity.

JG reported that SG1 had issued another draft on the definition of 'manufacturer' and the proposal will be distributed for comment. SG2 members were encouraged to review the latest version.

A suggestion was made to check the SG2 documents on the GHTF website to determine if any have passed the 3-year review period and now require an update.

ID requested time (~15 min) on the next SG2 meeting agenda to discuss the EU adverse event system.

The meeting adjourned at approximately 2:30 pm on Friday, 29 February 2008 after an update of the SG2 Work Plan N49R17 and a review of the action items.

Action Items:

20. Prepare NCAR retraining Discussion paper before next meeting distribute to ALL via LK – JG - Aug 08
21. Forward latest draft of SG1 work on definition of manufacturer – All to provide comments to SG1 via LK – ALL – March 20 2008
22. Finish N12 – JG – Aug 08
23. Consider Impact of SG1 work on Listing and Registration on SG2 work – All – Aug 08 for discussion at next meeting
24. Review N6R3, N8R4 and N16R5, N38R15 and N68R3 on the website (> 3 years old) consider whether they need revision – discuss at next meeting – All

SG2 Announcements:

Mark Segstro from Canada announced that he will leave SG2 after Lisbon. The Canada regulatory authority will appoint a replacement representative to SG2. Thanks to MS for his contributions to the NCAR program.

Jorge Garcia, the SG2 chair, announced that he is planning leave his position on SG2. No date was given. Thanks to JG for his very hard work and contributions for many years. A search will be started for a new chairperson for SG2.

Future SG2 meetings:

October 2008:   Either Mexico or West Coast USA – exact dates will depend on arrangements for the 5-6 Oct meeting of Steering Committee in Mexico
10-13 May 2009: GHTF Conference - Toronto, Canada.