



GHTF SG2 Meeting

Location: St. Vincent's Hospital, Melbourne, Australia

Date: 30 January – 1 February 2007

Attendance:

| Name | Organization | Email | 30/1 | 31/1 | 1/2 |
|-------------------------|---------------|---------------------------------|------|------|-----|
| Penny Adams | MIAA | padams@miaa.org.au | | | |
| Miguel Antunes | 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@cdrh.fda.gov | X | X | X |
| Isabelle Demade (ID) | EC | isabelle.demade@ec.europa.eu | X | X | X |
| Jorge Garcia (JG) | TGA | jorge.garcia@health.gov.au | X | X | X |
| Kensuke Ishii | PMDA | ishii-kensuke@pmda.go.jp | 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) | NEMA | larry.kroger@med.ge.com | X | X | X |
| Hideo Eno | MHLW | eno-hideo@mhlw.go.jp | X | X | X |
| Roger Leclerc (RL) | MEDEC | rleclerc@medec.org | | | |
| Tony Sant (TS) | MHRA | tony.sant@mhra.gsi.gov.uk | | | |
| Mark Segstro (MS) | Health Canada | mark_segstro@hc-sc.gc.ca | * | * | * |
| Ekkehard Stösslein (ES) | BfArM | e.stoesslein@bfarm.de | X | X | X |
| Carl Wallroth (CW) | EUROM VI | beate.moeller@draeger.com | X | X | |
| Observers | | | | | |
| Pam Carter | TGA | | X | X | X |
| Roger Chapman | NSRL QA Mgr | | X | | |

* By telephone

Welcome, Introductions, Announcements:

The 32nd meeting of SG2 was held at St. Vincent's Hospital in room 1, St. Vincent's Function Centre, Aikenhead Wing, 27 Victoria Parade, Melbourne, Australia.

Day 1 of the meeting began with a greeting and presentation from Elisabeth Dax, the Director of the National Serology Reference Laboratory (NSRL) in Melbourne. Ms. Dax described the mission and activities of NSRL with PowerPoint slides, which were provided to the participants following the presentation. The SG2 meeting started with introductions of the participants. The meeting was chaired by JG. Observers from TGA and the NSRL were in attendance during the meeting.

There was one new member to the Group:

Mr. Hideo Eno, Ministry of Health, Labour, and Welfare, Japan.

Review meeting goals and agenda; approve old minutes:

The group reviewed the agenda for the meeting. The following items were added to the agenda:

- A discussion on definitions

- A discussion on ISO 19218 developments
- A discussion on the status of implementation of SG2 documents (N73)
- A discussion of previous AdvaMed comments on proposed documents
- A discussion regarding gaps in Sg2 documents and the meaning of 'maintenance phase'

Planned dates for the next SG2 meeting are 30 September to 2 October 2007 in Washington, DC immediately preceding the 11th GHTF Conference on 3-4 October 2007. JG reported that SG2 might need to have materials ready for a training session at that time.

SG2 minutes from the Lübeck meeting were reviewed. Changes were added to modify the document number from N99 to N98 and correct Leighton Hansel's title referenced in the minutes.

The Action Items from the Lübeck meeting were discussed – Most of the actions were completed or are in process. The following actions resulted from the discussion.

Action Items:

1. Clarify with Larry Kessler the meaning and intentions in relation to NCAR training at the GHTF conference in October. JG by end of February 2007.
2. Send training Materials (ex Santiago) to Jean Olson/ Larry Kessler. Make clear that the slides are based on old documents that have now been replaced with N54 N79 etc. LK by 15 February 2007.
3. Implement document/revision numbering for training materials such as Santiago slides. LK ASAP.
4. To suggest to SC that training materials should have document control numbers assigned by the SC secretary. JG/HI by end of February 2007.
5. To put "obsolete cover" to N21, N20 N9 etc - Ask Jean Olson to update these old documents on website. JG to report to the SC that this is what we have done. JG/LK ASAP.

JG & HI Report from Steering Committee

JG reported on the discussions held at the last GHTF Steering Committee. The role of WHO was one of the topics of discussion at the SC meeting. There was further consideration regarding WHO participation in the NCAR program. It was proposed that WHO be a promoter of the NCAR program to their member countries rather than an active participant in the program. There was also discussion regarding the SC concept of 'maintenance mode'. The SC now considers SG2 to be in a 'maintenance mode'. The initial impact is fewer meetings and fewer new work items.

Report on AHWP meeting in Korea

JG summarized SG2 activities related to the Asia Harmonization Working Party meeting in Korea during September 2006. JG and PA gave presentations on government and industry perspectives, respectively. It was reported that AHWP is considering setting up a separate NCAR program. This would be instead of participating in the SG2 NCAR program. The consensus was that SG2 should engage AHWP on this issue before a new system is created.

Action Items:

6. Send to SG2 copies of presentations at AHWP Korea 2006. JG/PA by end of February 2007.
7. To invite AHWP and WHO to participate in SG2 meetings as liaison members. JG ASAP/March 2007.

Discussion on draft plan for pilot of N87PD

JG started the discussion by diagramming process for electronic reporting. An FDA program is also underway for electronic reporting using HL7 format rather than the XML format that SG2 is planning to use. If agreement cannot be reached on a reporting format, one alternative would be for each NCA to create its own electronic reporting form. This however would defeat the efforts of SG2.

ES proposed reopening N32 to expand data fields to include NCA-specific information requirements.

ES expressed willingness to create the electronic data form that manufacturers would use to convert their event information into a XML file for submission to NCAs. The SG2 NCAs were asked about their capability to participate in the electronic reporting pilot. EU authorities indicated they were prepared. U.S. FDA indicated that it would be possible if all the fields required satisfying their data needs were present. Japan MHLW indicated that significant obstacles existed for them including the language issue. Australia and Canada indicated that they had limited capability to participate. JG stated that since Japan has developed electronic reporting using XML already, that perhaps their previous experience is sufficient, and participation in the SG2 pilot may not be required. LK asked about the language issue. It was indicated that the pilot trial would be in English only.

Everyone was asked to provide comments to ES on the TS protocol document N100R1 by 9 March 2007. NCAs will need to be prepared to receive and display data in a data form or database format by the end of April. NCAs were asked to send a statement of readiness to JG.

Action Items:

8. To forward to ES the difference between their reporting requirement and N32R5.2. All NCAs by 15 February 2007.
9. To use responses from NCAs above to compile an E-form that can be used by manufacturers to submit reports in XML that complies with all member state requirements for the purposes of participating in the N87 pilot. ES by 15 March 2007.
10. To prepare either E forms or Database import routines that will enable them to receive N87 XML reports during the pilot. All NCAs by 30 April 2007.

Applications for joining the NCAR Program

The World Health Organization (WHO) and Cuba have submitted applications to join the SG2 NCAR program as members. JG reviewed the recent past discussions with WHO including a conference call held on 9 January 2007. It was suggested to WHO that their role be more of a facilitator rather than participant in the NCAR program in part due to the fact that they did not

qualify under the provisions of the SG2 NCAR guidance as a NCA. In accordance with that guidance it is preferred that the national authority of each country apply on their own for participation in the NCAR program.

The facilitator role for WHO was endorsed by SG2 members rather than actual membership in the NCAR program. It was discussed whether WHO should received copies of reports that go to their participating countries. SG2 membership opinion was divided on this matter.

Action Items:

11. Respond to WHO: 1)- WHO can join as associate member and receive training and reports. 2) Emphasize that WHO cannot pass on the reports received in this way to anybody. 3) WHO to facilitate and encourage training by SG2 full members so that WHO member MoH's can join the NCAR program in their own right. JG by 1 March 2007.

Discussion on AHWP proposal for vigilance exchange

JG reported that the Asian Harmonization Working Party is expected to submit an application letter on behalf of several of the AHWP members. Each AHWP country will be evaluated on its individual qualifications. No time frame was specified as to when the application may be submitted.

New work item proposal SG2 N96R1

A new work item proposal to revise 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) guidance documents was implemented. A major objective of the revision is to clarify that NCAR participants must not redistribute NCAR reports, especially to non-members. It was also emphasized to reevaluate paragraph 4 in Section 4 of N38 regarding non-NCA applicants. MS will lead the revision project. The first draft is scheduled to be available by the end of April 2007. NCAs were asked to provide inputs to MS by the end of March 2007. All NCAs are encouraged to participate in the revisions.

Action Items:

12. To provide comments to MS in relation to changes to N79 and N38 – especially in relation to confidential information and in relation to the fact that reports should not be passed on outside NCAR participants. All, especially NCAs by end of March 2007.
13. Review N79 and N38 – especially clauses on how to handle and label confidential information, and whether there are other changes required. MS by end of April 2007.

Confidentiality of NCAR reports

MWB reported that NCAR reports marked confidential had been released by both an NCAR member and an NCAR non-member. These actions were not consistent with the SG2 guidances for managing report exchange. LK suggested that perhaps the NCAR program needs some type of CAPA process to deal with process breakdowns.

It was suggested the SG2 might need to provide a definition for 'confidential'. Discussion during the meeting indicated that there is disagreement among SG2 NCAs about what should be marked confidential. A question was raised regarding 'confidential to whom, manufacturers or other NCAs'. It was also suggested that it might be useful for a retraining program or a refresher exercise on N79 content and requirements.

Some NCAs may be restricted by law or other agreements regarding how confidentiality is used. JG suggested creating a document regarding retraining and corrective action for NCAR program issues.

Action Items:

14. Strategic document dealing with retraining, dealing with problems that come up with NCAR program etc. JG by June 2007.
15. To prepare discussion paper on public access to information and distribute to SG2 to consider as NWI. ID by July 2007.

Joint SG work on definition of 'Manufacturer'

SG2 has collected definitions of 'Manufacturer' from each participating NCA. SG1 has been tasked to establish a final definition for use by GHTF. There is concern as to the impact that the final definition may have on SG2 guidance documents. It was decided that JG should communicate that concern to the chair of SG1.

An issue was also raised that SG5 has defined the term 'adverse event' in a manner that is different from that used by SG2 in N54. It was decided that HI should add the definition of 'adverse event' taken from N54 to the GHTF glossary of terms.

Action Items:

16. Respond to SG1 chair regarding concerns on definition of manufacturer – ensure that they meet SG2 guidance requirements. JG by 5 February 2007.
17. Send to HI definition of adverse event from N54. HI to include definition in Glossary. JG/HI by end of February 2007.

ISO 19218: Discussion developments

MWB distributed updated FDA coding at the SG2 meeting. The FDA coding scheme has been reduced from 800 terms to 500 terms. There are 5 levels to the scheme. Search on level 3 for example will shown children terms on levels 4 and 5.

MWB met with Leighton Hansel, who is the convener of ISO TC210 WG3 to discuss the revised FDA scheme. Leighton Hansel believes the FDA scheme can be largely harmonized with ISO 19218. Six codes could not be matched to ISO 19218.

SG2 has established a small working subgroup to work on the coding for ISO 19218. Homework for the subgroup is to look at levels 4 and 5 in the FDA scheme and perhaps pull them to a higher level. MWB, JG, ES, HI, and PA will work with Leighton and a subgroup from TC210 to create the next iteration of ISO 19218. The first draft of the harmonized ISO 19218 is schedule to be available by 1 May 2007.

MWB reported that FDA is not currently working on a cause table to go with the event codes. The cause table will be developed after the event list is completed. There are 32 event codes in level 1 and 2 of the FDA list. There are 22 event codes in ISO 10218.

Action Items:

18. Distribute FDA code table to all SG2. MWB by end of February 2007.
19. To coordinate teleconference and the work on the subgroup on ISO 19218. Send names/emails to Leighton Hansel. Coordinate an agenda expectations of teleconference with Leighton. MWB by 28 February 2007.

NCAR performance and statistics

MS presented all NCAR data through the end of 2006 for review and comment by SG2 members. It was suggested that MS provide further details such as the number of reports marked confidential and perhaps categorize the NCAR statistics by action type in future reports. MS with investigate the feasibility of including such detail.

Action Items:

20. To break down NCAR stats. Confidential, action type, etc. MS by October 2007.

Discussion of N73: status of implementation

N73, which tracks the implementation of SG2 guidances by member NCAs, was reviewed for any updates. EU NCAs reported that there were minor changes to the planned implementation schedule, but no other changes. Information for other NCAs was unchanged.

It was suggested to create a similar implementation-tracking document for non-founding member NCAs. Inputs would be provided by groups such as WHO, AHWP, etc. Action on this suggestion was tabled for future consideration.

Discussion of gaps in SG2 guidance

JG opened a review of N61 which is the PMS Harmonization Chart containing those postmarket surveillance activities that SG2 has identified for potential harmonization efforts. N61 also identifies those PMS activities, which SG2 members concluded it would not be useful to attempt to harmonize. This analysis was presented at the GHTF meeting in Gaithersburg in September 2005.

The 2005 presentation also contained proposed activities for the maintenance phase of SG2.

A bullet was added to the proposed maintenance phase activities to monitor ongoing events and developments in medical devices. It was suggested to rename 'maintenance phase' to 'monitoring and improvement phase'.

Previous discussions on recalls were revisited as well as the identified obstacles to harmonization. It was suggested that JG locate the previous new work item proposal (NWIP) on field safety corrections (recalls) and circulate to SG2 members for review. All members were asked to provide comments and indicate their willingness to work on guidance for recalls. The NWIP will be discussed at the next meeting in Washington prior to submission to the Steering Committee.

Action Items:

21. Locate old NWI on definition and classification of field safety corrective action. Review/Amend and distribute to all SG2. ALL SG2- to review and consider working on this as a NWI. JG to distribute amended NWI by end April. All provide feedback by August 2007 – Discuss in October
22. Watching brief on developments at other SG's on IVD's and Combination products include in the discussion of the next meeting if necessary. All by October 2007.

Other Business:

SG2 members were invited to participate in a one-hour tour of the National Serology Reference Laboratory starting at 11:30 AM on 1 February 2007. The tour was conducted by Elisabeth Dax, the Director of Laboratory, who showed SG2 members around the facility and described the activities carried out there.

There was a discussion regarding AdvaMed comments on N57 and N79, which were received after the comment deadline. SG2 members decided not to reopen the affected guidances but to ask AdvaMed to resubmit at the next revision.

The meeting closed at approximately 2 pm on Thursday, 1 February 2007 after an update of the SG2 Work Plan N49R15 and a review of the action items.

Action Items:

23. To reply to AdvaMed that their comments on N57 and N79 were received too late and that they could not be considered. If they wish to have their comments considered they should resubmit at the next revision. JG ASAP.

Future SG2 meetings:

October 2007: Washington, DC before 11th GHTF conference on 3-4 October 2007
1-3 April 2008: Possible location Portugal (alt. location Brussels)