

GHTF Study Group 2 Meeting Summary

LOCATION: Australian Department of Health and Ageing, 1 Oxford Street, Sydney, NSW, Australia

DATES OF MEETING: March 1-3, 2005

SUMMARY:

Fourteen representatives from industry and regulatory bodies met in Sydney Australia, at the NSW State Office of The Australian Department of Health and Ageing from March 1 to 3, 2005.

GHTF SG2 N80 – Map of SG2 guidance.

N80 is used during seminars to explain the relationship and purpose of the large number of SG2 guidance documents. A member presented an alternative map to that which currently appears in the website. The Group agreed to produce a further draft of the schematic with features from both of the versions that were considered

GHTF SG2 N68 Status of GHTF Member regulations in relation to “To Whom to Report”

This document had been produced in lieu of harmonized guidance on the subject after discussions had failed to yield consensus.

The group agreed to change the title to:

“Summary of Current Requirements for Where to Send Adverse Event Reports”

The group agreed that a note was needed to explain that, because of differences between requirements about receiving reports about events that occurred outside national borders, in some cases reports may need to be submitted to more than one regulatory authority.

The Group also agreed this document as a status document like GHTF SG2 N68) on this subject. “ The group also agreed to consider revisiting the discussion on the production of harmonized guidance in addition to the development of this status document (N68).

GHTF SG2 N12 – Précis.

The GHTF SC had asked for an update on SG2 activities, and whether the Group was close to completion of the work that they set out to do. This prompted a review of N12, as this was one of the documents in which the Group had stated what it was setting out to do and how.

On review, the group considered that the SG2 had covered or was in the process of considering all of the issues raised in the Précis document (N12). However N12 needs updating and editing and the Group agreed to do this before the next meeting.

NCAR Statistics

The NCAR statistics showed strong activity in the program during the past year and since the program's inception. There was evidence that participants had been reviewing their criteria for reporting in order to bring them into line with those set down in GHTF SG2 N20 (the exchange criteria for Europe are slightly different to those of the GHTF NCAR Program).

It was agreed that the statistics be presented at future SG2 meetings on a regular basis.

Discussions on ISO DTS 19218

This draft ISO standard stipulates that an event be described by the combined use of the GMDN #, the product name and model number and a two term code. One term relating to the event type (a brief statement about the event as it was manifested at the time of the event, eg fire, electric shock), and the other term relating to the cause of the adverse event (e.g. electrical/electronic malfunction, use error). The standard specifies 22 unique event type codes and 47 unique event cause codes.

AU (TGA), and UK(MHRA) from SG2 had voted against the adoption of the standard citing that the cause table was not complete. Also many event "types" were being mixed up with event "causes" and vice versa. The unit within FDA responsible for coding of AE's is also unhappy with the standard for much the same reasons and are considering developing their own coding system.

ISO 19218 has now received enough positive votes to be accepted and considered final. However there may be an opportunity to comment and make some changes before May 2005. The SG2 will continue to work with the ISO TC 210 WG3 to improve ISO 19218.

N72 – New Work Item Proposal on Electronic Exchange of AE information

This item relates to the submission of adverse event information as agreed in GHTF SG2 N32 in a generally agreed electronic format. This will avoid multiple manual data handling of the same information.

The group discussed several developments that might impinge on this work, but decided to restrict the scope to the electronic coding of the information stipuated in GHTF SG2 R5.2.

The group agreed to present this as a New Work Item (NWI) proposal (as amended in Sydney) to the GHTF SC.

N57: Guidance on the Content of Product Advisory Letters

The main discussion is related to the sorts of information that should be disseminated using the Product Advisory Notice Format described in the draft guidance. It is important that the format is reserved for communication of a certain level of safety risk. The group agreed to discuss in next meeting and to provide feedback to the author regarding the definitions in the document.

GHTF SG2 N73 Status of Implementation

Canada is on the verge of regulatory change. New regulations will be posted for comment possibly summer 2005. All other member states provided input on what steps they could to implement the guidance. The document can now be used to map the success of SG2 guidance and plan any amendments or updates as necessary.

N54 R4.2 Global (consolidated) guidance on Vigilance

The document represents an amalgamation of SG2 guidance on vigilance so that it is presented to the reader in a more user friendly manner than is currently available. The GHTF agreed that Sections 1-4 of the document (those based on N21R8) need to be updated and reconsidered.

The SG2 has collected a lot of feedback. The group decided to gather the comments, and use them to generate a new draft of N54 to be discussed at the next meeting of SG2.

N79 Updating and Combining N20/N9 relating to the NCAR program

The amalgamation of the two documents has proved to be a relatively easy task, but the SG2 is currently discussing whether the criteria for reporting should be tightened or simply left as they have been since N20 was finalised. The issue will be considered again at the next meeting.

GHTF SG2 N38: Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

GHTF SG2 N38 has been in the GHTF website for public comment for some time. The SG2 had received two comments which were addressed. The comments, the SG2's resolution regarding those comments and the final version of GHTF SG2 N38 will be presented to the GHTF Steering Committee for ratification as a final document.

GHTF SG2 N47/61 Post-market Surveillance

N47 is a review of current activities that may be considered to fall under the classification of "Post-Market Surveillance". N61 defines the term for the purposes of SG2 work, and provides a

list of the activities with recommendations on whether harmonization work is useful or necessary. Over the last few meetings the group had decided that there is little for SG2 to do in this area either because it has already been done by other groups or because harmonization work is not considered useful. One work item is currently under way, which is harmonization of the content of safety related product advisory letters.

The group agreed that N47 should be presented to the SC for approval as a Status Document. The group also considered that, while N61 is really only that is primarily of internal value, it may be of interest to individuals outside the SG2 and could be made available. However, there is no mechanism for publishing SG documents of this type. It was decided that N61 would be presented to the SC as a report.

Work Plan, Future Meetings and other Business

The group proceeded to update the work plan and to consider whether the group had achieved the goals stated in the Precis.

Future meetings:

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| 1-3 June 2005: | Milwaukee, Wisconsin, USA |
| 12-16 September 2005: | Geithersburg, Maryland, USA |
| 27-29 February 2006: | London (TO BE CONFIRMED) |
| 25-30 June 2006: | Luebeck, Germany |