



Meeting: GHTF-SG2 **Place:** Toronto, Canada

Dates: 3-5 June 1998

Host: MEDEC/Kevin Murray

Chaired by: Larry Kessler (LGK) FDA/US

SG2 Members Present:

Carl Wallroth EUROM VI/EC - Step-In Chair

Deb Blum FDA/US - Exec Sec

Kevin Murray MEDEC/Canada

Roland Gerard IAPM/EUCOMED/EC

Robert Virefléau European CEC

John Worroll MDA/UK

Werner Schönbühler COCIR/Germany

Ekkehard Stosslein BfArM/Germany

Larry Kroger (LK) NEMA/US

Ben Khosravi NEMA/US

Mike Flood TGA/Australia

Masaaki Naito JFMDA/Japan

Kazuhisa Kenmotsu MHW/Japan

Kim Dix TPP/Canada

Ken Kopesky (KK)HIMA/US

Rich Farb ISO TC 210/US

Vivian Coates ECRI/US

Ian Campbell IAPM/Switzerland

SG2 Members Not Present:

Kazuhisa Hasebe MHW/Japan

Jacob Nordan NBH/Norway

Martin Bayreuther COCIR/Germany

Gisela Inninger BfArM/Germany

Jan Michalíček Státní ústav pro kontrolu léčiv/Czech Rep

Observers:

Gillian Mandel Health Canada

Pat Robinson Health Canada

Brenda Murphy SC1Canada

The following documents were disseminated at the meeting:

- 1) Revised Toronto Agenda
- 2) Fax to LGK dated 1 June 1998, from Michiko Takei: feedback on SG2 documents (LGK)
- 3) Harmonizing Postmarket Reporting and Surveillance, by DB, published in MDDI, May 1998 edition (DB)
- 4) Guidant letter of 16 March 1998 from Michael Gropp: feedback on SG2 documents (DB)
- 5) Risk Management Model for Summary Reporting: FDA Draft (DB)
- 6) FDA Definitions of terms from Code of Federal Regulations (DB)
- 7) Fax to KK from St. Jude Medical, dated 22 May 1998: feedback on SG2 documents (KK)
- 8) BMDN Project: 1st Progress report to CEN TC/257 SC1, dated Sept 97- Apr 98 (RF)
- 9) Vigilance Case Exchange Criteria SG2 N20 R3 dated 1 June 1998 (KD)
- 10) Guidance on Medical Device Vigilance Systems for CE Marked Artificial Heart Valves, IAPM Draft, dated 3

June 1998, Version V (RG)

- 11) FDA Definitions of Recalls, Class 1-2-3 (DB)
- 12) MDA/ERA; Organizational tree (JW)
- 13) EU File No. 95/0013 (COD) Dated 23 March 1998: Directives on IVDs (RV)
- 14) MDR Prioritization Questionnaire: FDA Draft
- 15) Bern Hotels Maps (IC)
- 16) Action Items List resulting from Toronto SG2 meeting (DB)
- 17) Toronto SG2 meeting attendance sheet
- 18) CW's notes of Toronto SG2 meeting
- 19) MDD Reports by device category:1996 and 1997
- 20) Draft SG2 Communiqué for Toronto meeting
- 21) Preliminary Flier on Post-Market Surveillance and Medical Device Vigilance for Medical Devices in Europe (JW)

ACTION ITEMS SUBSEQUENT TO THE TORONTO SG2 MEETING:

- 1) REMINDER: FDA Code Blue report is NOT to be disseminated beyond SG2 members
- 2) RF and LK will develop a draft work scope on MEDDRA regarding medical devices problems nomenclature
- 3) KD and LK will review discussion points and make revisions to CA reporting criteria. Two documents will be generated:
 - 3A) Revision to N20: criteria document
 - 3B) New document to define protocol for methods of exchanging CA reports (active vs. passive)
- 4) MF and BK to generate additional text for clarification of "clinically foreseeable" within the N21 document- Completed during Toronto meeting.
- 5) IC to send SG2 members a letter of invitation to Bern meeting. The letter to include business letter, needed by some for travel funding. Hotel maps made available during meeting. About 5 extra copies given to DB.
- 6) DB will continue to lead task group on defining well characterized events. CA members encouraged to look at most frequently reported products. Industry members may use other rationale for items to be considered, outcomes being more the focus perhaps, than the device. Persons wishing to give input to SG2 definition of "well characterized", or to submit related topics for discussion, should send written comments to DB, providing suggestions as well as rationale.
- 7) DB will send out flow chart that accompanies the disseminated text of the FDA questionnaire for summary reporting.
- 8) LGK and K.Trautman discussed possibility of having a one-day joint SG2/SG3 meeting. Tentative agreement set for 25 **OR** 26 **OR** 27 January 1998. One of these dates will be designated for a joint meeting. Anticipated due date: 30 June 1998
- 9) All CA members are to evaluate the Manufacturer Rules for Reporting, and identify consistencies or inconsistencies with current regulations.
 - 9A) JW and RV will evaluate SG2 recommendations vs. The EU directives and guidelines
- 10) All CA members will identify items in the reporting rules guidance which need additional clarification and send feedback in writing to DB.
- 11) KM will lead industry groups in testing manufacturers reporting rules. Members include: KM/MEDEC: lead, KK/HIMA, RG&IC/IAPM, LK&BK/NEMA, MN/JFMDA, WS/COCIR.
- 12) LGK to contact SG3 and SG4 regarding field training as relates to harmonized changes in reportability of adverse events.
- 13) Retire the Use Error document. DB & RV& MB to draft statement on use error to be incorporated into current SG2 guidance on reporting. This submission will be in writing and compiled with other recommendations to be reviewed by SG2.
- 14) VC will compile data from the ECRI database to help with #6 above:
 - 14A) Data on reports related to devices based on literature or manufacturer submissions.
 - 14B) Data on reports related to devices based on user facility submissions.
- 15) DB to contact MDDI (re: article on harmonization) to emphasize that SG2 documents are still evolving, and to request MDDI to publish web address for readers to stay current with the changes in SG2.
- 16) Industry members requested to provide data on timeframes needed for evaluation of various reported problems. LGK to check with Industry members to get status report of findings. Anticipated due date: 31 July 1998.

- 17) Members should anticipate SG2 meeting for 25-27 January in Irvine, California. Hosted by Baxter/RF.
- 18) RF, CW and DB to meet in Rockville, MD on 16 July 1998 to compile and consolidate written feedback to SG2 documents.

Toronto
Meeting Minutes:

1.1 General Announcements

Members were welcomed by LGK. Self introductions conducted around the table. LGK clarified that SG2 now needs to work on the small details, having established consensus around major issues concerning reporting adverse events.

FYI:

Robert Allen, UK/MDA is taking over TC 210 following the departure of Gordon Higson.

Norbert Anselmann is changing positions. It is not known, at this time, who will assume his previous duties.

1.2 Canberra Minutes

Hard copy of the highlights of the Canberra meeting had been previously sent to all SG2 members and interested persons. DB noted that no comments for clarification have been received to date. Thanks expressed to CW for taking his usual comprehensive notes on this meeting, as DB was not able to attend. Minutes considered final.

1.3 Meeting Details

KM provided information about use of meeting room and available support for copying, faxing, etc. The previously disseminated tentative Toronto Agenda (N23A) was revised, (ref: N23B) and changes were briefly discussed.

1.4 Nomenclature Update- RF

RF provided update from recent ISO TC 210 WG3/CEN TC 257 SC1 meeting of 29 May 1998 in London. There are currently approximately 14,000 terms which need to be reduced to 9-10,000. Robert Allen is the new manager of the project. Reports are filed by TC 210 and TC 257, and input should come through these sources.

Nomenclature may become a standard. In the interim, information is provided via technical reports. New proposals, electronic formats, etc., need to be studied more. It was noted that there are few device problem codes in the current project. The issue has been debated, but no one has volunteered to take on this issue. SG2 supports a link between the nomenclature project and MEDDRA. RF has agreed to explore this. (Action item #2) RF reminded SG2 that MEDDRA is not a standard, it is a database, and is independent, much like ECRI's universal Medical Device Nomenclature.

1.5 & 1.6 ~~Vigilance Reports~~ - Competent Authority (CA) Reports - KD

During the meeting it became evident that the term "vigilance reports" was confusing for EC states. To avoid further confusion, it was agreed that reports between competent authorities be called "Competent Authority Reports" or "CA Reports".

Re: electronic data

KD presented a concept of electronic data management. This approach incorporates both a "passive" exchange and an "active" exchange of information. The "passive" exchange is so called because the user send for information. The data "passively" exists on a dedicated server, available at the users convenience, with password protection. Such data would include CA reports that are of lower risk, or otherwise do not necessitate immediate attention by the reader(s). The "active" exchange is named to reflect that the data will be intentionally forwarded to the designated CA representative, via some form of electronic mail system (email). This email would include a mechanism to confirm that the message has been received by the intended parties. It is anticipated that this "active" delivery of information will more readily assure that the recipient(s) receives the needed information and can take appropriate action on a more timely basis than is likely in the "passive" system.

It was recommended that a pilot project for the exchange of CA reports be conducted. It is anticipated that many things may be clarified during the pilot. Concurrently, the reports may be evaluated, by recipients, for their value.

During discussion of what types of events would be included, KD referenced SG2 N20, R2 dated 1 June 1998, which was redistributed during the meeting for convenience.

Decisions re: CA Report Exchange

1. Flow chart for CA Report
2. Criteria for CA Report
3. Lead CA
4. Pilot project
 - a. who is involved
 - b. method of communication (fax, email, etc.)
 - c. evaluation
 - d. manufacturer exemptions/variances
 - e. echo reporting
5. Implementation by manufacturers/CA - SG2 reporting guidance
 - a. changes in regulation
 - b. definitions
 - c. auditing guidelines
 - d. periodic reporting
 - e. confidence building and training
6. Begin defining the boundary between postmarket vigilance and quality systems requirements

Discussion points included:

- Why capture events where there was not resultant action? (Answer: Action may be initiated at later time. Additionally, database helpful to others who later experience similar problems.)
- Pilot needs to assess appropriateness of data
- Database needs to be high risk/ high profile
- Need to define "Action Contemplated" by whom? CA or Mfr? (Answer: EITHER)
- "Action" should be related only to products already cleared to market in at least one participating CA's region (consensus: agreed)
- Regarding the decision to file CA report concepts such as-if investigation is complete OR there is lack of scientific data- are the same and should be considered equally.
- Decisions must include risk/benefit AND regional state of the art options (therapeutic alternatives available in a given region)
- Reminder given that CA Report gives guidance to recipients on how to use the information
- How should we handle device problems that tend to recur?
 - Is this covered under Quality Systems?
 - Will this become an issue for the CA based on the numbers of reports, or increase in frequency of reports?
 - Is there a better way to intervene than through vigilance? Where?
 - CA is obligated to intervene when the problem is device specific
- Need to clarify where industry fits into this process
 - Clarify in appropriate SG2 documents
 - CA to inform Mfr. when compiling data that will be shared in CA report

Suggested considerations for action:

- Seriousness - Have actual documented cases of death or serious injury or serious consequences
- Unexpectedness
- Vulnerable population - e.g., pediatric or geriatric
- Preventability - goal of SG2 is to prevent recurrence of similar events in various locations. Action should include useful recommendations
- Public concern (sometimes called "outrage") - e.g., lead aprons emitting radiation
- Lack of scientific data that could address the issue, especially long term effects
- Are product warnings sufficient and effectively translated?

It was noted that not all of the above elements will exist at one time, but that each is significant on its own to merit consideration of a CA report. It was emphasized several times by various participants that seriousness should always be a component in taking action, i.e., one would not initiate action because an adverse event is preventable,

but that it is serious and preventable.

It was recommended that CA to CA reports be exchanged when:

- ⇒ there are new hazards
- ⇒ there are long term effects
- ⇒ there are recalls

Re: Lead CA

There was much discussion about the function of a lead CA in cases where multiple CAs are involved. The European CAs have recognized some difficulties arise when the event occurs in a location different from where the device is manufactured and other difficulties when the injury needs reporting to a CA different from where the event occurred and also different from where the device is manufactured. If you add that perhaps several CAs need to get the report, it becomes difficult to determine which CA should have the lead. It doesn't work out well to assume that the first CA to get a report will have the lead, because language differences might play a role. Additionally, motivation of the CA factors in to the consideration of which CA should or will agree to take the lead. It was suggested that the manufacturer may be the best source for providing guidance on which CAs may have an interest, based on where the device is known to be marketed. CAs also face difficulties in meeting their own obligations while trying to work through another CA who might have the lead. Manufacturers expressed concern that they will receive more phone calls about problems as a result of the exchange of CA reports. Evaluation of the various aspects of the CA report exchange will be conducted during the pilot phase. It was noted that the EU vigilance working group is scheduled to meet in September 1998. Aspects of the pilot study may be shared there, with recommendation that the EU participation during the pilot be limited to those EU states who are currently participating in SG2. It was also noted that designation of a lead CA does not negate the individual obligations of the other CAs involved.

Re: European Database of CA reports

It was noted that a central database of all EC CA reports does not presently exist. EUROMEDIES is built around the SG2 N8 CA report form. Separately, individual adverse event reports can be transferred electronically via the internet. Access is granted for CAs only. DIMDI is the contractor. English is the required universal language, though the report may *also* be in the native language of the reporting CA. DIMDI has two standard forms, one for the initial report, a second for the final report. EUROMEDIES and DIMDI have been asked to combine reporting efforts. Contractor tender is being extended by the European Commission.

Re: Pilot Exchange of CA Reports- also called CARPS (CA Report Pilot Study)

The following points were recommended for the CA report pilot study:

- Need to clearly define criteria for CA report: with sub-clarification for "active" exchange and "passive" exchange
- Pilot to be conducted for at least six (6) months, to commence in 1998. Anticipate start by September 1998.
- Pilot participants to include: BfArM, CMH&W, Norway, FDA, JMH&W, MDA and TGA
- When CA begins consideration of sending CA report, assure that Mfr. has been informed.
- Manufacturers will identify all CAs known to have device marketed.
- CAs will discuss and determine by consensus who will take the lead; in absence of consensus, use EU guidelines approach
- Possibilities of electronic data interface will be further explored. KD will continue in the lead.
- Each CA Report will need to have a unique identification number so that evaluation forms may be properly linked.
- Each CA receiving a CA report during the pilot is to complete an evaluation of the CA report. These evaluations will be compiled and reviewed at the end of the pilot study.
- Manufacturer exemptions and variances must be taken into account

Suggested evaluation questions

The following three questions were posed as those which should be applied to each CA report received. It is anticipated that each CA report will have a unique identification number on it, and the evaluation forms will contain

that number, so the evaluations can be matched to the report.

- 1) Was this CA report useful? No Yes
- 2) Do you believe this information needed to be brought to your attention via email (active exchange), or do you think it would be appropriate to place the report in an electronic file where you could access the information at your convenience (passive exchange)? Active exchange preferred Passive exchange preferred
- 3) Did this report result in your initiation of corrective action? No Yes
If "Yes" please mark all that apply:
 CA report forwarded to other CAs - specify: _____
 Notice sent to Health Care Professionals
 Notice forwarded to general public
 Recall initiated by Mfr CA
 Device correction initiated by Mfr CA
 Other: defined as _____

Re: Sample CA reports

Several CA reports were presented for consideration as to how they would fit into the SG2 proposed model. It was expressed that using the two tiered system of "active" and "passive" reporting, only the most serious reports would demand the time and attention of the CA recipients, which seemed mutually agreeable.

1.7 Reporting and Non-Reporting Examples- deferred to Day 2

1.8 Criteria for well-characterized events- DB

DB presented project goal to identify situations or adverse event outcomes that may be globally recognized as well-characterized events, thus affecting reporting requirements. In order to know what is universally understood, the first task of the group was to have CAs identify a list of the most frequently reported products. Australia and MDA have provided these data to date. The intent is to note if any products appear on several different CA lists, and then engage in further discussion about the products, to determine if there is universal knowledge about the device(s) and common reporting problems.

This effort does include industry perspective. In order to identify specific outcomes which may be globally understood, industry members are invited to evaluate complaint files to identify adverse event outcomes which have been well investigated and frequently reported to CAs. Such outcomes may have been well-characterized in scientific or medical literature. Suggestions for designation of specific outcomes as globally well-characterized should include data and rationale. Suggestions should be in writing, sent to DYB@CDRH.FDA.GOV.

It was noted that knowledge is affected by available technology and by device labeling. The FDA criteria for summary reporting is being used as a model for this taskgroup.

---end Day 1---

2.1 Reporting/Non-reporting examples -LGK

Concern was expressed that the current tree gives false guidance. It was further expressed that the boxes needed either more complete text-so that the full considerations are clear- or less text-so that one was forced to refer to the complete guidance. Ultimately it was determined that clear guidance was needed at the top of the tree to reinforce the need for users to have full knowledge and understanding of the full guidance, and not to use the tree independent of that more comprehensive guidance.

There was also return of old discussion about definitions. FDA definitions were distributed, and discussion was conducted. It was realized that users to the SG2 documents will want to know what SG2 intends various terms to mean. Some members felt definitions should be intuitive, others felt that "intuition" equals subjective definitions which lead to considerable inconsistencies.

Question was raised if question 4 (of the tree) should lead to question 8 instead of question 7. This is one of the questions that may be better addressed after industry volunteers test out the tree.

It was noted that the EC has expressed concern over the concept of periodic reporting under the vigilance system. Issue debated.

KK/JMH&W noted that general guidance states that “don’t know” should routinely lead towards reporting, yet there is an inconsistency at question 3, and should be adjusted.

BK and MF offer the following additional definition of “clinical foreseeable” to be included in the reporting guidance about question 8 of the N21 document:

Foreseeable also includes the situation where a manufacturer becomes aware of new information related to a device which indicates there is a reasonable risk of death or serious injury (e.g., extended life cycle testing contradicts previously published data). It does not include device changes brought about by normal quality system improvements which do not impact safe use or application of the device.

RF noted that there were many suggestions about the documents, and we are soliciting comments, so it is best if we compile all input into one document for review and comment. The minutes of the Toronto meeting may serve as a reference to some suggestions, but may not be complete. SG2 members are encouraged to provide feedback on documents in writing to DB. RF, CW and DB will meet on 16 July 1998 to compile and organize all input received. Comment period for documents will conclude on 1 July 1998.

No determinations were made about any specific examples presented.

2.2 Definitions, Interpretation, Guidance - LGK

FDA definitions discussed as provided detailed inclusion or exclusion criteria. EC guidelines are expressed in more general terms. Industry expressed concern that interpretation varies widely.

Exploration of terminology might include conducting workshops which will help identify what concepts need to be included, and compile collective wisdom. Such an effort will include sensitive information and confidentiality must be protected.

In discussing implementation, the major question was: Do the reporting rules satisfy the CA’s requirements?

LGK asked CAs to look at the reporting rules for any inconsistencies with current regulations, and to identify which areas require more clarification or guidance.

Pilot studies will be the first phase of implementation.

Manufacturers are asked to take complaint files and apply adverse events to the reporting rules to test the clarity of the guidance and the appropriateness of the flow of the tree. The added value of using manufacturers not directly involved with SG2 is that it provides a better test of the system. This is a voluntary exercise, but SG2 industry reps are encouraged to solicit participation by their peers. KM/MEDEC agreed to take the lead in this project. Other participants include KK/HIMA, , BK& LK/NEMA, MN/JFMDA, IC&RG/IAPM, WS/COCIR. KM will generate a procedure document for consistency in conducting this evaluation.

Another concern expressed was the training of auditors and inspectors. Will they be familiar with harmonized processes? Can an amnesty period be declared so that no penalties are applied during transition? It was noted that the roles of the Notified Bodies (NBs) is ever expanding.

Industry expressed that the ultimate desire is to file only one universal incident report that will meet the needs of all appropriate CAs.

2.3 Use Error and Single Fault Issues -LGK

The document originated by MB defined all events as either common or uncommon. It was noted that the term

“misuse” is not universally defined nor clearly understood. Some off-label uses may be the effect of evolving medical practice, and not accurately defined as either common/uncommon or misuse. Additionally, there are cases where the device itself contributes to the “misuse”, such as obstructions over visual displays needed to assure accuracy of device function.

After discussion, it was determined that the misuse document will not be further developed, and that the concepts of the consideration of use error will be incorporated into the reporting guidance for manufacturers N21 document. RV had some language which will be forwarded to DB via email, and included in the feedback document.

Likewise, single fault was previously presented by CW. This concept too, can be folded into the N21 document. Further suggestions to be forwarded in writing to DB.

2.4 Timeframe for Reporting- LGK

The new FDA postmarket reporting regulations include changes in reporting timeframes for manufacturers, which includes 5 day report for events that represent significant risk of substantial harm which necessitated remedial action, and includes 30 day reports for other reportable events. FDA notes many reports are submitted as 5 day reports, but do not meet the criteria as defined above. Additionally, data submitted in the 30 day reports appear no more beneficial than that previously submitted in the 15 day reports- despite the added time. Manufacturers report that the device analysis cannot be completed within the 30 day deadline. FDA seeks to received data that will support what timeframes are needed for complete device evaluation of various products. LGK solicited manufacturers to voluntarily compile data to identify how much time is routinely needed to fully evaluate different types of devices. For example- in evaluation of short peripheral IV catheters: ## % of initial reports are finalized within ## days.

Though EU directives also have 30 day reporting period for specified events, the reporting system is a bit different. Each report has two phases, an initial report- which serves notice that a reportable event occurred, and a final report- which is intended to provide data from the manufacturer’s evaluation and subsequent conclusions.

Discussion included recommendation that elements also to be considered include potential for harm and likelihood of recurrence. Such factors may necessitate intervention independent of reporting timeframes.

Action: New pilot to be conducted to identify routine timeframes for device evaluation. LGK will contact industry members by end of July regarding status of data collection. He would appreciate obtaining data from various manufacturers on timeframes for evaluation of various device complaints and problems. It was suggested that each SG2 industry member solicit willing firms to provide data on how much time is generally needed to evaluate reportable events. It is desirable to have a checks and balances system, such as two or three firms reviewing time requirements for similar devices with similar reported events.

2.5 Document Posting and Feedback - DB

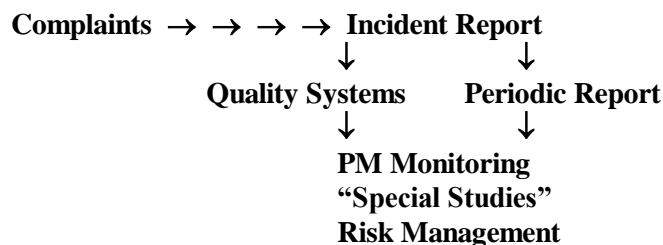
The SG2 documents forwarded to the GHTF and available for public comment have been posted on the FDA web site. Access to the documents may be made by using the address- www.fda.gov/cdrh/harmmain.html
Other SG2 members have been encouraged to make links to the FDA site so that interested persons may have ready access to the documents. The FDA site also provides link to FDA email for immediate and direct comment to documents. To date only one em has been received via this system. Comment period concludes 30 June 1998.
All SG2 members are encouraged to send comments to DB via em at : dyb@cdrh.fda.gov
CW and RF will join DB at CDRH to compile all comments into one document that will then be forwarded to all SG2 members for review. Decisions on how to deal with suggestions and comments will be addressed at the next SG2 meeting (September 1998- Bern Switzerland)

3.1 Postmarket Surveillance (PS)- LGK

EC expressed concern on the terminology of postmarket surveillance. The European Directives are based on the Treaty of Rome (1957) regarding free movement of people, services, capital, and goods. There exist many different regulations which supplement each other.

FDA regulations have changed. In 1997 FDAMA (FDA Modernization Act) removed certain requirements for postmarket surveillance studies, though some of the studies already in existence were to continue. FDA retains the authority to initiate a study for specific timeframe for specific reasons under discretionary postmarket surveillance. FDA is currently generating new criteria for PS, but it has not yet been published. The PS program concentrates on currently marketed products and those coming onto the market through the 510(k) process. The new PS program is not limited to “studies” but includes data, literature, etc.

One proposed flowchart is as follows:



JW noted that there will be a one-day “Postmarket Surveillance and Medical Device Vigilance for Medical Devices in Europe” Conference on 2 July 1998. Preliminary brochure disseminated.

FDA modernization act limits PS studies to Class III and Class II devices, and for limited time. Severe high failure rates might bring a product under PMS. FDA plans to publish a new set of PS criteria. In recent years advisory panels, in pre-market review of devices, recommend PS about 50%. Tracking of devices is changing, and used more frequently as a tool for PS.

Discussion included questions about defining whether PS is a role for SG2, or more appropriate for SG3. Postmarket surveillance is presently specified in the terms of reference for SG2. Recommended further discussion on this at the joint SG2/SG3 meeting.

3.3 Next SG2 Meetings

23-25 (Wed - Fri) September 1998 in Bern, Switzerland. Host: BAG/Sulzer. IC recommended that persons attending the Bern meeting fly into Zurich and then take the train to Bern, enjoying a 1 ¼ hour ride. 20 rooms at Hotel Kreuz, at a cost of 120 Swiss Francs, which includes breakfast and taxes have been set aside for SG2 use. Please reference BAG/Sulzer and SG2 when making reservations. Hotel information was handed out. DB has about 5 extra brochures.

25-27 (Wed - Fri) January 1999 in Irvine, California. Host: Baxter. RF notes that meeting site will be about 1 ½ - 4 hours drive (depending on traffic) from LAX airport, or just a few blocks away from the John Wayne/Orange County airport.

June 1999 (exact dates not yet finalized)- Full GHTF meeting in Rockville Maryland. Host: FDA. Possible FDA presentations include: orientation to FDA databases, demonstration of data entry, report evaluation, summary reports, and recall database. May possibly extend invitation to CA’s beyond those currently participating in SG2.

3.4 EDI Update - JW

EU is currently establishing electronic exchange of CA reports. The ultimate vision includes one database for global access. EUROMEDIES and DIMDI efforts may be combined. There is no global database expected in the near future. Monies and compatibilities are major issues. FYI- EUROMEDIES and EUROMED let you search using nomenclature.

Global CA report pilot needs to use currently available software and provide some basic search functions.

3.5 Procedures for GH Documents - LGK

GHTF is formalizing document handling and dissemination. Exec.Sec. to GHTF to take procedures to Steering Committee for consideration. Linda Horton, FDA, has drafted some recommendations. Each SG will solicit endorsement of their documents by the GHTF. SG representatives will put the documents out for public comment. It has been suggested that documents should be circulated when in draft form so that early feedback may be obtained. Questions remain about when to circulate draft documents, and to whom.

SG2 documents were provided to all SG2 members, and the GHTF prior to the Australia meeting in February 1998. FDA placed the documents on the internet, along with a means for providing comment via email. All SG2 members were charged with assuring that the documents were made widely available for comment within related industry groups and interest groups. RV was requested to make link between EU web site and FDA web site for downloading of SG2 documents.

3.6 Review Action Items - DB

Please reference list at beginning of Toronto meeting minutes.

3.7 Press Inquiries

Several SG2 members noted that they had received similar inquires about SG2. It was noted that each SG2 member serves as an expert and may have a different perspective on the proceedings of the meetings. Members are encouraged to be factual, and clearly identify when providing personal opinions. It is always a good idea to request a copy of the proposed final text before it goes to publication. Draft communiqué for the Toronto meeting was disseminated. Persons receiving press inquiries about SG2 are requested to notify DB for the SG2 files.

3.8 Heart valve guidance - RG

RG disseminated draft guidance on MD vigilance system for CE marked artificial heart valves. This will be presented to MDR, then later shared with other EU CAs. Information shared as means of demonstrating emerging guidance.

Meeting adjourned at 12:30

Minutes prepared by DB 24 June 1998