GLOBAL HARMONIZATION TASK FORCE

Working Towards Harmonization in Medical Device Regulation

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NOTE: These Minutes incorporate comments on the Draft Minutes provided by Steering Committee Members during April 2001; and will be endorsed at the Committee's 2nd Meeting on 12 -13 June 2001.

MINUTES

STEERING COMMITTEE - 1ST MEETING

TRAINING ROOM
AUSTRALIAN HEARING SERVICES BUILDING
CHATSWOOD, SYDNEY
AUSTRALIA

WEDNESDAY, 28 FEBRUARY 2001 -

FRIDAY, 2 MARCH 2001

AGENDA **PAGE NO.**

The 1st Meeting of the Global Harmonisation Task Force (GHTF) Steering Committee was held in the Training Room at the Australian Hearing Services Building, Chatswood, Sydney, Australia from Wednesday, 28 February to Friday, 2 March 2001.

Those present were –

Steering Committee Members:

Australia: Ms Rita Maclachlan (Chair) - Therapeutic Goods Administration
Mr Terry Slater - Therapeutic Goods Administration
Mr Brian Vale (Vice Chair) - Medical Industry Association of Australia
Mr Barry Evers-Buckland - Medical Industry Association of Australia

Japan: Dr Soichiro Isobe - Ministry for Health, Labor and Welfare
Mr Masato Yoshida - Japanese Federation of Medical Device Associations
Mr Kenichi Matsumoto- Japanese Federation of Medical Device Associations

Canada: Ms Beth Pieterson - Health Canada
Mr Kevin Murray - MEDEC

United States: Dr David Feigal Jr - Food and Drug Administration
Dr Lillian Gill - Food and Drug Administration
Mr Dennis Baker - Food and Drug Administration
Mr Robert Britain - National Electrical Manufacturers' Association
Mr James Benson - Advanced Medical Technology Association
Mr Michael Gropp - Advanced Medical Technology Association

Europe: Mr Cornelis Brekelmans - European Commission
Mr Hanz-George Will - Federal Department for Health, Germany
Mr Rainer Voelksen - Swiss Federal Office of Public Health
Dr Egid Hilz - Coordinating Committee of the Radiological and Electromedical Industry

Secretary: Mr Craig Davies - Therapeutic Goods Administration

Observers: Dr Daisaku Sato - Ministry for Health, Labor and Welfare - Japan
Ms Jocelyn Kula - Health Canada

Guest: Mr Tom Hayes AO – Consultant

LIST OF ACTION ITEMS

Action Item	Status
1.2: Adoption of Agenda	
GHTF Secretary to ensure Members receive agenda papers at least four weeks prior to Steering Committee meetings.	Noted by GHTF Secretary for future meetings
To facilitate the above, Members and Study Group Chairs to provide agenda papers to the Secretariat at least six weeks prior to a Steering Committee meeting.	Referred to Members for noting - 11 April 2001
GHTF Chair to advise Study Group Chairs of the above time-lines and suggest that Study Group meetings be scheduled at least seven weeks prior to Steering Committee meetings.	Completed - 11 April 2001
1.3: Minutes from the 3rd Meeting of the GHTF Ad Hoc Procedures Group - 19 September 2000	
GHTF Secretary to incorporate the above amendments into the final Minutes from the 3rd Meeting of the GHTF Ad Hoc Procedures Group, re-title the document as "Final (Amended)" and arrange to have the new, amended version of the Minutes posted on the GHTF website.	Completed - 14 March 2001
1.4: GHTF Steering Committee Membership List and Contact Details	
Members to review Membership List and advise any changes to the GHTF Secretary.	Referred to Members for noting/action - 11 April 2001
2.1: Review and Approval of two SG2 Documents from Working Draft to Proposed Document status	
GHTF Chair to advise Dr Kessler of the above outcome.	Completed - 11 April 2001
GHTF Secretary arrange to have the SG2 document, *"Manufacturer's Trend Reporting of Adverse Events"* posted on the GHTF website as a "Proposed Document".	Completed - 6 April 2001
The Chair to seek verification that all SG2 Members have agreed to the version of the *"Competent Authority Reporting Criteria"* document dated 22 February 2001; and refer any new information to the Steering Committee for further consideration out-of-session.	Dr Kessler's advice requested - 11 April 2001
2.2: Discussion on the SG4 document - *"Estimation of Audit Duration"*	
GHTF Chair to advise Mr Allen of the outcome.	Completed - 11 April 2001
2.4: Global Medical Devices Nomenclature (GMDN) Maintenance Agency	Report requested from Dr Kessler - 11 April 2001,
GHTF Secretary to add this item (including a report from Dr Larry Kessler) to the agenda for the second Steering Committee Meeting.	GHTF Secretary to include in 2nd Steering Committee agenda

3: Founding Members' Reports: Update on the Adoption of GHTF Documents	
GHTF Steering Committee regulators to complete their Founding Member reports in tabular form (as per the template presented at Item 3.2, Paper C of the agenda papers, which is available electronically from the GHTF Secretary) and forward to the Secretary prior to the next Steering Committee meeting; and	Referred to Members for action - 11 April 2001
GHTF Secretary to add the tabular reports to the GHTF website and amend the existing 'status' tables on each of the Study Group Final Document pages of the GHTF website in order to provide a 'country-by-country update' on the implementation of each Final Document.	To progress when reports from above action item are provided
Founding Members' updates to be retained as a standing item for future Steering Committee meetings.	Noted by GHTF Secretary for future meetings
4: Regional Harmonisation Group Updates	
Updates from the regional groups be retained as 'standing items' for future Steering Committee meetings.	Noted by GHTF Secretary for future meetings
5: GHTF Study Group Matters	
5.1: Processes/Format for Reporting to the Steering Committee	
GHTF Secretary to- update the Study Group Work Plan 'template' developed by the former Secretariat;	Completed - 9 March 2001
circulate the document to the Steering Committee for any further comments; and	Completed - 9 March 2001
distribute a final, amended version to each Study Group Chair for completion to enable further consideration of this matter at the second Steering Committee meeting.	Referred to Study Group Chairs - 11 April 2001
5.2: Study Group 1 Proposed Document - *"Medical Devices Classification"*	
GHTF Secretary to post the revised version of the SG1 Proposed Document entitled, *"Medical Devices Classification"* on the GHTF website, over-writing the version which currently exists.	Completed - 21 March 2001
6: GHTF Strategic Review	
GHTF Secretary to arrange for the establishment of a private, password-protected page within the GHTF website for use by the Steering Committee Working Groups carrying out work on the six GHTF Strategic Themes.	Completed - 15 March 2001
Working Group co-convenors to provide reports on the key issues and specific proposals under each Strategic Theme to the GHTF Secretary by Tuesday 1 May 2001, for inclusion in the agenda papers for the Steering Committee's second meeting.	Referred to Members for action - 11 April 2001

7: GHTF Training Program	
The concept of a GHTF Training Program be re-considered at the 2nd Meeting of the GHTF Steering Committee, in conjunction with the GHTF Strategic Review.	GHTF Secretary to include in 2nd Steering Committee agenda
Ms Maclachlan to update the Steering Committee on progress of the AUSAID funding proposal at the next meeting.	GHTF Secretary to include in 2nd Steering Committee agenda
8: Planning for the 9th GHTF Conference	
GHTF Chair/Secretary to further refine the draft program for the 9th GHTF Conference, circulate to the Steering Committee for information or any further comment, finalise and post on the GHTF website.	Referred to Members for action - 11 April 2001
9: Establishment of a Permanent Secretariat	
GHTF Secretary to include this item in the agenda for the 2nd Steering Committee meeting.	GHTF Secretary to include in 2nd Steering Committee agenda
11.1: Request for GHTF Representation on the Chairman's Advisory Group of IEC Technical Committee No.62	
The GHTF Chair to seek further details from the IEC TC62 Secretariat concerning the meeting date, venue and the exact type of GHTF involvement being sought, noting that GHTF involvement will have to be consistent with its liaison strategy which is currently under development.	Advice sought from IEC TC62 Secretariat - 11 April 2001
GHTF Chair to provide a report on this matter at the next Steering Committee Meeting.	GHTF Secretary to include in 2nd Steering Committee agenda
11.3: Approval of Two Study Group 4 Documents as "Final Documents"	
Members to review the two SG4 documents, *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplements Nos.4 and 6"*; out-of-session and refer any comments to the GHTF Chair by Friday 27 April 2001.	Referred to Members for action - 11 April 2001
11.4: Timetable for Future GHTF Meetings	
GHTF Secretary to include this item in the agenda for the 2nd Steering Committee meeting.	GHTF Secretary to include in 2nd Steering Committee agenda
12: Next Meeting	
GHTF Secretary to confirm the venue for the second Steering Committee meeting.	In progress - April 2001

ITEM 1: INTRODUCTION

ITEM 1.1: WELCOME AND APOLOGIES

1.1.1 The new GHTF Chair, Ms Rita Maclachlan opened the Meeting and welcomed all Members to Sydney, Australia for the first meeting of the GHTF Steering Committee. Ms Maclachlan noted the significance of the occasion, that being the inaugural meeting of the Steering Committee and rotation of the GHTF Chair from North America to the Asia-Pacific (with Australia assuming the role of Chair for 18 months from 1 January 2001 - 30 June 2002).

1.1.2 Ms Maclachlan acknowledged the efforts of the immediate past GHTF Chair and Secretary - Health Canada's Ms Beth Pieterson and Ms Jocelyn Kula respectively; and expressed her appreciation for their assistance with the transition of the Chair and Secretariat from Canada to Australia.

1.1.3 Apologies were received from Mr Michael Baker (and subsequently Mr Zeger Vercouteren) (EUCOMED), Dr David Jefferys (UK Medical Devices Agency) and Dr Souichi Ikegaya (Ministry for Health, Labor and Welfare - Japan). Mr Michael Gropp advised that in addition to representing US industry, he would also be speaking on behalf of EUCOMED at this Meeting. Dr Soichiro Isobe advised Dr Daisaku Sato was attending this Meeting as an observer (in place of Dr Ikegaya).

1.1.4 The Chair asked all Members to introduce themselves and also welcomed Mr Tom Hayes AO to the Meeting as a Guest who has been asked as an independent non-member, to facilitate discussion under Agenda Item 6 - "GHTF Strategic Review". The Chair also advised of a visit to the Meeting on Friday 2 March 2001 by Senator the Hon Grant Tambling, Parliamentary Secretary to Australia's Federal Minister for Health and Aged Care. Mr Slater noted Senator Tambling's visit represents a significant statement on behalf of the Australian Government with regard to recognising the GHTF, its various activities and providing support to industry in relation to facilitating international trade and harmonised regulatory practices.

1.1.5 At the outset, the Chair noted the role of the Steering Committee as specified in the *Roles and Responsibilities* procedural document ie. to provide policy direction, strategic planning; and to assign and provide oversight of technical work initiatives. Additionally, Ms Maclachlan also noted the Chair's responsibility includes management oversight of the Steering Committee and the provision of general supervision and guidance to the Secretariat.

ITEM 1.2: ADOPTION OF AGENDA

1.2.1 Members accepted the agenda as presented and no new agenda items were brought forward from the floor.

1.2.2 With regard to the distribution of agenda papers, Members requested that papers be received four weeks prior to the meeting date to allow adequate time for consultation within their own organisations.

1.2.3 With this timeframe, Members acknowledged the possible impact upon the timing of GHTF Study Group meetings; but believed Study Group Chairs would be willing to schedule their meetings accordingly. It was suggested that Study Group meetings would need to be scheduled at least seven weeks prior to a Steering Committee meeting to ensure timely consideration of any Study Group matters.

Action:

1. GHTF Secretary to ensure Members receive agenda papers at least four weeks prior to Steering Committee meetings.

2. To facilitate the above, Members and Study Group Chairs to provide agenda papers to the Secretariat at least six weeks prior to a Steering Committee meeting.

3. GHTF Chair to advise Study Group Chairs of the above time-lines and suggest that Study Group meetings be scheduled at least seven weeks prior to Steering Committee meetings.

ITEM 1.3: MINUTES FROM THE 3RD MEETING OF THE GHTF AD HOC PROCEDURES GROUP - 19 SEPTEMBER 2000

1.3.1 The final Minutes from the 3rd Meeting of the GHTF Ad Hoc Procedures Group (19 September 2000) were included in the agenda papers and incorporated all comments received on the draft Minutes that were circulated on 16 October 2000 by Ms J Kula (GHTF Secretariat, Canada).

1.3.2 The following additional amendments to the Minutes were requested -

1. Page 1, Meeting Attendees - Dr Hilz advised the first word in the name of his organisation should read, "Coordinating";

2. Page 6, Item 5, Paragraph 4 - Dr Isobe requested the paragraph be amended to read, "Mr Yoshida and Dr Isobe stated that they had no comment on the document."; and

3. Page 11, Item 14, Paragraph 3, 2nd Sentence - further to concerns expressed by the European Commission (the fact that Europe's participation reflects three different constituents - the European Union, EFTA countries and applicant countries; that the Union has precise procedural rules to take international commitments; that competences in the health policy area are partly Union and partly national competence), it was agreed to amend the sentence to read, "Taking note of Europe's concerns, the group endorsed the three procedural documents for presentation at the Plenary Session".

1.3.3 The Steering Committee agreed to the above changes to the final Minutes from the 3rd Meeting of the GHTF Ad Hoc Procedures Group; and also agreed that the document be re-titled as "Final (Amended)".

Action:

GHTF Secretary to incorporate the above amendments into the final Minutes from the 3rd Meeting of the GHTF Ad Hoc Procedures Group, re-title the document as "Final (Amended)" and arrange to have the new, amended version of the Minutes posted on the GHTF website.

ITEM 1.4: GHTF STEERING COMMITTEE MEMBERSHIP LIST AND CONTACT DETAILS

1.4.1 The Meeting's attention was drawn to the Steering Committee's membership list and contact details which were included among the agenda papers. The Chair asked all Members to review the list and advise the Secretary of any amendments or corrections which may be required. Mr Brekelmans advised the Committee that France would act as a substitute for the European regulators. The Committee took note of this statement, while agreeing that the most stable membership is in the best interests of the Steering Committee's continuity.

Action:

Members to review Membership List and advise any changes to the GHTF Secretary.

1.4.2 The Meeting was asked whether observers or advisers are permitted to attend Steering Committee meetings. Mr Brekelmans indicated the European Commission has received such requests from the Governments of Slovenia, Malta and Latvia. Members were advised that paragraph 6.1 of the *Roles and Responsibilities* procedural document outlines that observers and advisers from the Founding Members may attend Steering Committee meetings.

1.4.3 The Meeting was also asked whether observers from non-Founding Member countries are entitled to attend Steering Committee meetings. Ms Pieterson advised the reference to 'observers' attending Steering Committee meetings is focused towards observers from Founding Member countries as attendance by a large number of countries may make the Steering Committee too unwieldy.

1.4.4 Under the heading, "5.0 Membership" of the *Roles and Responsibilities* procedural document, paragraph 5.4 states, "Observer status can be granted on a case-by-case basis, at the discretion of the GHTF Chair or Study Group as appropriate".

1.4.5 Consistent with this provision, the Meeting agreed that any requests to attend Steering Committee meetings as observers should be referred to the Chair for consideration in conjunction with Steering Committee Members.

ITEM 2: MATTERS ARISING FROM PREVIOUS MEETINGS

ITEM 2.1: REVIEW AND APPROVAL OF TWO SG2 DOCUMENTS FROM WORKING DRAFT TO PROPOSED DOCUMENT STATUS

2.1.1 At the 3rd Meeting of the Ad Hoc Procedures Group, SG2 Chairman, Dr Larry Kessler presented the documents - *"Manufacturer's Trend Reporting of Adverse Events"* and *"Competent Authority Reporting Criteria"*, proposing advancement from Working Draft to Proposed Document status. A revised copy of the first document was included among the agenda papers and the latest version of the second document (issued by SG2 on 22 February 2001) was tabled at the Meeting.

2.1.2 There was general discussion concerning the level of comment the Steering Committee should be providing on Proposed Documents. Ms Pieterson cautioned against extensive comment at this stage until all other stakeholders had had sufficient opportunity to comment on the documents. Members reinforced the notion that any comments they may have on Working Drafts or Proposed Documents should be referred directly to their Study Group representatives. Additionally, the Meeting agreed with a suggestion from Mr Gropp that the Steering Committee must adhere to its mandate of ensuring 'due process' is followed, rather than attempting to focus on technical detail.

2.1.3 The Meeting then considered a request from Mr Brekelmans to extend the comment period from 3 months to 6 months for the *"Manufacturer's Trend Reporting of Adverse Events"* document. The Meeting subsequently discussed the need to adhere to the processes outlined in the Procedural Documents and the current frustration by some stakeholders that these SG2 documents have not significantly progressed since September 2000.

2.1.4 The Meeting agreed to -

1. Retain the 'three month comment period' outlined at paragraph 7.5 of the *Operating Procedures* procedural document; and
2. Advance this document to "Proposed Document" status, allowing a six month comment period in this case (noting the procedural document allows Study Group Chairs to extend the comment period).

Action:

1. GHTF Chair to advise Dr Larry Kessler of the above outcome; and
2. GHTF Secretary arrange to have the SG2 document, *"Manufacturer's Trend Reporting of Adverse Events"* posted on the GHTF website as a "Proposed Document".

2.1.5 With regard to the tabled document, *"Competent Authority Reporting Criteria"*, concern was expressed by several Members as to whether the content had been agreed to by ALL SG2 Members on, or after the date included on the document - 22/2/2001.

2.1.6 In view of these concerns, the Steering Committee did not agree to advance the document to "Proposed Document" status, but agreed that the Chair would seek to clarify Members' concerns with the SG2 Chairman.

Action:

The Chair to seek verification that all SG2 Members have agreed to the version of the *"Competent Authority Reporting Criteria"* document dated 22 February 2001; and refer any new information to the Steering Committee for further consideration out-of-session.

ITEM 2.2: DISCUSSION ON THE SG4 DOCUMENT - *"ESTIMATION OF AUDIT DURATION"*

2.2.1 At the 3rd Meeting of the Ad Hoc Procedures Group (19 September 2000), it was recommended the document, *"Estimation of Audit Duration"* be incorporated into the *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers"*.

2.2.2 Subsequent to this recommendation, SG4 Chair, Mr Robert Allen has asked the Steering Committee to advise whether the Study Group should develop guidance on audit strategy in order to address the Ad Hoc Procedures Group recommendation.

2.2.3 The Meeting noted industry concerns regarding the balance of representation on SG4, while the regulatory authorities from Australia, USA and Canada believed the *"Estimation of Audit Duration"* was a sound document. Further industry concerns were that the document appeared to bias the duration of audits in the direction of longer rather than shorter audits (which may not be desirable in all cases).

2.2.4 The Steering Committee agreed with Mr Allen's suggestion that the document be incorporated into a new, broader document on audit strategy; and referred back to the Steering Committee for further consideration when appropriate.

Action:

GHTF Chair to advise Mr Robert Allen of the above outcome.

ITEM 2.3: GHTF RECOGNITION AWARDS

2.3.1 At the 3rd Meeting of the Ad Hoc Procedures Group (19 September 2000), it was suggested the Steering Committee discuss a proposal from the Study Group 3 Chair (Ms Kimberley Trautman) that the GHTF distribute recognition awards. A draft document entitled, *"GHTF Recognition Awards Scheme"* was included among the agenda papers for consideration and comment.

2.3.2 The Chair raised for discussion the appropriateness of an organisation such as the GHTF having a Recognition Awards Scheme and asked each member for their comments. Members' comments ranged from being very supportive (that it is sound management practice to recognise consistent and dedicated effort) to ambivalent (suggesting this is currently a low priority issue for the Steering Committee and questioning the notion of rewarding people for 'doing their jobs' and rewarding individuals where much of the GHTF's achievements are based on team efforts).

2.3.3 The Meeting also noted that European Commission staff are expressly prohibited from receiving any type of award (including awards with no monetary value). EC staff nominated for any award would be required to undergo a rigorous process of seeking permission; and overall, it is more desirable to avoid being placed in such situations.

2.3.4 The Chair noted the divergence of views from both, a cultural and management perspective. Overall, the Steering Committee supported the notion of recognising people's hard efforts and dedication to their work and the organisation, but agreed that other work programs such as the Strategic Review must take priority at this point in time.

2.3.5 The Steering Committee also agreed to support situations where Study Group Chairs wished to recognise a particular individual. The Steering Committee suggested this recognition occur by formal correspondence between the SG Chair and recipient; and be copied to the GHTF Chair for inclusion in the organisation's records/corporate history.

ITEM 2.4: GLOBAL MEDICAL DEVICES NOMENCLATURE (GMDN) MAINTENANCE AGENCY

2.4.1 Following the 3rd Meeting of the Ad Hoc Procedures Group (19 September 2000), SG2 Chair, Dr Larry Kessler was asked (and subsequently agreed) to attend the first meeting of the GMDN Maintenance Agency Policy Group and to report back as to the future participation of GHTF in its membership.

2.4.2 The Meeting noted correspondence dated 9/11/2000 from Ms Pieterson to SG4 Chair, Mr Robert Allen, acknowledging this action "does not fulfill the desire to have a representative outside the countries already represented on the GMDN Policy Group". Ms Pieterson also indicated she would put forward a recommendation that a representative from the Asian Harmonisation Working Party be considered.

2.4.3 Ms Pieterson advised there has been no activity to date (as the Meeting is likely to be held sometime during the northern hemisphere Spring). The Meeting agreed with Ms Pieterson's suggestion that this matter be re-visited at the next Steering Committee Meeting, following consideration of Dr Kessler's report from the meeting. The Chair noted this should allow the Steering Committee to make a decision with regard to future GHTF participation in the GMDN Maintenance Agency Policy Group.

Action:
GHTF Secretary to add this item (including a report from Dr Larry Kessler) to the agenda for the second Steering Committee Meeting.

ITEM 3: FOUNDING MEMBERS' REPORTS: UPDATE ON THE ADOPTION OF GHTF DOCUMENTS

ITEM 3.1: AUSTRALIA

3.1.1 At the outset of discussion, the Chair asked whether the Committee agrees with having the Founding Members' update on the adoption of final GHTF Guidance Documents as a 'standing item' in Steering Committee meeting agendas.

3.1.2 The Meeting noted and acknowledged it is not always possible to adopt all parts of all Guidance Documents, that such a process is voluntary and that there needs to be a clear commitment to use the documents in order to justify the investment of resources in their development. However, the Meeting agreed it was important for the Founding Member regulatory authorities to provide regular updates on the adoption of GHTF documents into national regulatory systems. The Chair noted this agreement and indicated this would be viewed as a measure of the GHTF's performance and progress towards achieving international harmonisation.

3.1.3 The Chair drew the Meeting's attention to Australia's progress with adopting the 15 final documents into Australia's medical device regulatory framework (as outlined at Item 3.1, Paper B of the agenda papers). Specifically in Australia there has been focus upon the concept of voluntary standards, the Essential Principles, rules of classification, means for assessing conformity, updated vigilance procedures and the SG3 and SG4 auditing documents have been included in a number of the TGA's Standard Operating Procedures. The GHTF Guidance Documents have been very useful for the TGA and their implementation has been supported by the Australian industry.

ITEM 3.2: USA

3.2.1 The Meeting noted correspondence dated 6 June 2000 from the US FDA's Dr Jacobson, concerning the FDA's progress with adopting three final documents into the USA's medical device regulatory framework.

3.2.2 Dr Feigal undertook to identify the FDA's current progress with implementing the final GHTF documents (or parts thereof) into the USA's regulatory system. Dr Feigal noted there is an important need to understand why documents are being developed, how they will be subsequently implemented and any consequences of that implementation.

ITEM 3.3: CANADA

3.3.1 Ms Pieterson advised the Meeting of Health Canada's written policy to adopt any final GHTF outcomes on harmonised regulatory practices; and stated the following -

- The SG1 document, *"Labelling for Medical Devices"* has been adopted;
- The SG2 document on adverse event reporting guidance will not be adopted until two apparent global differences on implementation have been resolved;
- All other SG2 documents which are able to be adopted have been incorporated into the Canadian legislation;
- SG3 documents primarily provide guidance for manufacturers; and
- SG4 documents are being adopted into a developing quality system program.

ITEM 3.4: JAPAN

3.4.1 Dr Isobe advised the Meeting the Ministry for Health, Labor and Welfare are currently considering the adoption of a number of GHTF Final Documents. The Ministry has found the SG1 document, *"Essential Principles of Safety and Performance of Medical Devices"* to be particularly beneficial to the Japanese regulatory system.

ITEM 3.5: EUROPE

3.5.1 Mr Brekelmans advised the Meeting there are no specific European procedural rules concerning the implementation of GHTF documents; but will consider developing a reporting system for EU members, the EFTA States and Applicant Members in order to improve the current process. Mr Brekelmans also indicated that he had requested EU Notified Bodies to advise on their use/implementation of GHTF documents.

3.5.2 In summary, Mr Brekelmans advised as follows -

- SG1 documents basically reflect the European approach to medical device regulation;
- SG2 documents are used where applicable;
- More detailed information will be given concerning the use of SG3 documents by EU Notified Bodies; and
- SG4 documents are used where applicable.

3.5.3 Mr Britain noted the expectation from industry that GHTF documents would be implemented; and such outcomes provide justification for continued participation in GHTF processes. Mr Gropp also added this allows governments with existing regulatory systems to measure the value of GHTF documents within their own systems; and provides opportunities for developing countries to improve/implement their own regulatory systems.

3.5.4 The Meeting agreed with a suggestion from Ms Pieterson that Founding Members' reports be added to the GHTF website, which would serve as a powerful tool for the organisation and provide transparency to the rest of the world.

Action:

1. GHTF Steering Committee regulators to complete their Founding Member reports in tabular form (as per the template presented at Item 3.2, Paper C of the agenda papers, which is available electronically from the GHTF Secretary) and forward to the Secretary prior to the next Steering Committee meeting; and

2. GHTF Secretary to add the tabular reports to the GHTF website and amend the existing 'status' tables on each of the Study Group Final Document pages of the GHTF website in order to provide a 'country-by-country update' on the implementation of each Final Document.

3.5.5 In concluding, the Chair noted the importance of the Founding Member regulatory authorities providing regular updates on the adoption of GHTF documents into their national regulatory systems; and that this is an issue for the Steering Committee to continue monitoring.

Action:

Founding Members' updates to be retained as a standing item for future Steering Committee meetings.

ITEM 4: REGIONAL HARMONISATION GROUP UPDATES

ITEM 4.1: ASIAN HARMONISATION WORKING PARTY

4.1.1 The Steering Committee noted a report from the Chair of the Asian Harmonisation Working Party (AHWP), Dr Clarence Tan (Ministry of Health, Singapore), outlining an overview on recent activities of the (AHWP).

4.1.2 The Meeting was advised that Dr Tan has recently indicated there is a possibility the Singapore Minister for Health will acknowledge GHTF principles in forthcoming regulatory changes in that country.

ITEM 4.2: AMERICAS WORKING GROUP

4.2.1 The Steering Committee noted a number of reports provided by Mr Antonio Hernandez of the Pan American Health Organisation (PAHO), outlining an overview on recent activities of the Americas Working Group.

4.2.2 The Steering Committee agreed it was useful to receive updates from the regional groups and to retain these as 'standing items' for future Steering Committee meeting agendas.

ITEM 5: GHTF STUDY GROUP MATTERS

ITEM 5.1: PROCESSES/FORMAT FOR REPORTING TO THE STEERING COMMITTEE

5.1.1 As the mandate of the Ad Hoc Procedures Group (AHPG) did not include reviewing and endorsing Study Group Work Plans, at the 3rd AHPG Meeting (September 2000) it was agreed that Work Plans would not be submitted by the Study Group Chairs until the concept of a Steering Committee (as proposed in the draft procedural documents) was endorsed by the GHTF membership. The procedural documents were endorsed at the Plenary Session of the 8th GHTF Conference (September 2000).

5.1.2 The Chair indicated the aim of this item was to obtain agreement on the processes and format for Study Group Work Plans to be referred to the Steering Committee for consideration, amendment and/or endorsement. This would allow the Study Group Chairs to submit their Work Plans for consideration at the next meeting, to which they will be invited.

5.1.3 The Steering Committee acknowledged the Study Groups are the 'engine room' of the GHTF and emphasised the current discussion concerning Study Group reporting is being undertaken in a constructive manner to determine the most appropriate 'way forward' for all concerned parties and the organisation at large.

5.1.4 During discussion of this item, the following points/suggestions were raised -

- Study Group work items may need re-evaluation as time progresses, as certain items may become redundant and therefore need to be removed from the Work Plans;
- The need to consider whether all elements of a global regulatory system are currently in place and/or being considered via the collective efforts of the Study Groups;
- In order to provide clear guidance, the Steering Committee needs to endorse the Study Group priorities;
- The Steering Committee would not wish to be overly prescriptive as it understands there are different *modus operandi* across the Study Groups which work well for some, but not all;
- Whether the balance of representation and expertise on each Study Group is appropriate and the best available;

- When is there a need to form new Study Groups?;
- The importance of focusing on; and completing each task which is commenced (since some Study Groups have had documents in draft format for a considerable period of time);
- Further to the preceding point, there may be a need to re-define smaller mandates for the Study Groups, as some work programs may have grown too large over time and become unwieldy;
- The duration of Study Group meetings should be a minimum of three days due to the high cost of international travel being borne by those organisations involved;
- Whether a rotational system for Study Group Chairs needs to be implemented, while ensuring the Study Groups maintain a sound corporate knowledge base via consistency in their membership;
- The on-going requests received by the Study Group Chairs to include additional organisations in the Study Group memberships; and
- The work plan 'template' developed by the former Secretariat may serve as a useful starting point for addressing the current matter.

5.1.5 The Steering Committee agreed to ask each Study Group Chair to complete a Work Plan using a standard format; and submit the Plans to the GHTF Secretary for inclusion in the agenda of the second Steering Committee meeting.

Action:

GHTF Secretary to-

1. update the Study Group Work Plan 'template' developed by the former Secretariat;
2. circulate the document to the Steering Committee for any further comments; and
3. distribute a final, amended version to each Study Group Chair for completion to enable further consideration of this matter at the second Steering Committee meeting.

ITEM 5.2: STUDY GROUP 1 PROPOSED DOCUMENT - *"MEDICAL DEVICES CLASSIFICATION"*

5.2.1 The Meeting's attention was drawn to a significantly revised version of the Study Group 1 (SG1) Proposed Document entitled, *"Medical Devices Classification"* which was included among the agenda papers at Item 5.2, Paper B.

5.2.2 The Steering Committee agreed to the request from SG1 Chair, Mr Maurice Freeman to have the revised version posted on the GHTF website for comment (over-writing the version which currently exists).

Action:

GHTF Secretary to post the revised version of the SG1 Proposed Document entitled, *"Medical Devices Classification"* on the GHTF website, over-writing the version which currently exists.

ITEM 6: GHTF STRATEGIC REVIEW

6.1 At the 3rd Meeting of the Ad Hoc Procedures Group, it was "agreed that one of the first priorities of the new GHTF Steering Committee would be to undertake a strategic review and then to develop a strategic plan for at least the next five (5) years".

6.2 The Chair introduced Mr Tom Hayes AO (former Secretary-General of the World Customs Organisation) to lead the discussion on this item. Mr Hayes advised the objective of the Strategic Planning exercise would be to –

- Establish where the GHTF wants to be positioned in 3 to 5 years time;
- Determine what Members' believe the organisation should accomplish;
- Ascertain the major challenges to meeting the organisation's goals and how these challenges might be overcome. (The Meeting noted these challenges will come from the regulators, industry and the global environment at large); and
- Consider the "key elements" required to move forward.

6.3 By way of introducing the topic, Mr Hayes gave a brief overview of the original concepts of strategic planning ie. to help do a better job, to focus energy, to develop a common vision, to produce a fundamental set of decisions and actions, to determine whether the organisation has a definite purpose and understanding of the surrounding environment and to consider whether the organisation is looking at the 'big picture'. Mr Hayes also reminded the Meeting of the GHTF's goals and objectives, as specified in the procedural document, *"GHTF Guiding Principles"*.

6.4 The Meeting agreed with Mr Hayes' suggested agenda -

1. Assess the environment,
   - For the medical devices industry;
   - For the regulators;
   - Determine the "real-world" pressure points; and
   - Consider the future outlook.
2. Consider stakeholder perceptions and expectations of the GHTF - industry and regulatory;
3. Create a Vision Statement which provides an image of what success will look like in approximately five years time; and
4. Agree upon those activities which need to be addressed in order to achieve that success.

6.5 Mr Hayes invited Members to provide an assessment of the industry and regulatory environments in which they operate (including identification of relevant 'pressure points').

6.6 The medical device industry assessment of its environment is summarised as follows -

1. The industry is a Global Industry with 'like' products and performance standards, less 'players' and the need to be cautious with regard to barriers to market entry;
2. Balancing competing pressures - consumer expectations, government requirements (including funding pressures) and maintaining investor confidence which is critical to sustained development;

3. Technological changes - a rapid rate of change, with the industry continuing to evolve with more biologically based products emerging compared to the more traditional biomedically engineered products;
4. Cost constraints - need holistic assessments of technology value, reforms to the supply chain and adaptation to new purchasing practices (eg. the internet); and
5. The need for on-going consumer awareness and 'regulatory assurances'.

6.7 The regulators' assessment of the regulatory environment is summarised as follows -

1. The need to ensure global public confidence in regulatory systems (consumers, health professionals, government and industry) vs application of the appropriate regulatory weight taking consideration of Mutual Recognition Agreements, trade pressures, global standards of best practice, cost pressures and institutional constraints;
2. Consideration of Risk vs Benefit trade-offs, taking account of factors such as new, emerging technology, high risk and public confidence, terminal illness and longer life long promises and ethical considerations, including new risks;
3. Balance between timely availability and a quality/safety focus – consideration of the product life cycle, market entry vs market sustainability, maintenance of industry's competitive edge;
4. Resource constraints – need to address access to shrinking expertise due to competition for available resources between research institutions, public agencies and industry, and the downward cost pressures on governments;
5. Increased political sensitivity of medical devices – regulators have the significant responsibility of balancing industry needs/concerns and ensuring public health and safety; and
6. Increasing criminal activities - counterfeit and fraudulent activities are increasing in the medical devices industry and subsequently impact upon the entire system, particularly the issue of timely availability, as regulatory scrutiny necessarily increases.

6.8 During the discussion that followed, the point was made and accepted that the GHTF processes do not create a binding obligation to adopt final guidance documents, but do represent a commitment to embark on a process to determine what aspects of the GHTF's work can be adopted into national regulatory systems and how this work may be effectively and consistently implemented.

6.9 Mr Hayes then invited Members to provide an assessment of the industry or regulatory perceptions and expectations of the GHTF.

6.10 The medical device industry representatives acknowledged the benefits of industry and government sitting at the same table, including identification of common issues and a reduction in regulatory burdens. Industry perceptions and expectations of the GHTF are summarised as follows -

1. GHTF's effectiveness – provides a major contribution to the climate of understanding, has identified ways to progress regulatory practices and is the "best of the available forums" to discuss such matters;
2. GHTF's limitations – needs to increase visibility of its work processes and achievements, encourage wider ‘take-up’ of GHTF outcomes and some progress with GHTF work has been too slow;

3. GHTF will influence a more common approach to regulation;
4. GHTF needs to provide a tangible benefit to countries in the process of developing regulatory systems; and
5. That through the GHTF, industry and government will continue working together to improve the acceptance of new technologies.

6.11 The regulators' perceptions and expectations of the GHTF are summarised as follows -

1. The need to balance the timely availability and differing degrees of quality, performance and safety requirements for medical devices with varying risk profiles;
2. Within resource constraints, reinforce pre-market processes in an environment with an increasing focus upon post-market activities;
3. The GHTF represents a sound platform for the on-going exchange of information between government and industry; but requires further stream-lining of some processes eg. how to make the organisation more transparent?, how to reduce ambiguity with regard to developing nations?, should the GHTF be establishing regulatory models for developing countries?;
4. The need to ensure the Steering Committee's efforts are broadly applicable to all stakeholders;
5. The need to address issues relevant to both, the major world markets and the emerging markets of developing countries;
6. The need to determine a process to further involve developing countries in GHTF activities;
7. The need to effectively harness limited resources;
8. GHTF members should continue sharing experiences, information and resources to further assist with the timely availability of products to market; and
9. In recognising there are benefits from learning from each other, there is a need to ensure (through appropriate management) that future Study Group documents are suitable for achieving the organisation's objectives and thereby contribute to the further convergence of regulatory requirements.

6.12 Following discussion of the above matters, the Committee divided into three focus groups which convened in separate locations to develop a description of the "key deliverables" which would describe and define a successful GHTF in five years time. The major points developed by each Focus Group are outlined below.

6.13 Dr Feigal presented the **Group 1** outcomes. He highlighted the importance of non duplicative, inter-country regulatory processes and identified a range of "key deliverables" with regard to GHTF Documents, Harmonisation, Liaison and Training/Outreach/Consultation/Education. These included -

1. GHTF Documents
   - in general, provides a ‘big picture’ overview and individual documents indicate a measure of the regulatory processes which have been adopted and implemented;
   - the need for a maintenance process;
   - Development of 4 Study Group work plans (which include the manner by which to consider new issues and how consideration of the issues affecting 'old' devices, 'new' devices and combination products fit within each work plan); and

- Developing countries - determine a method to ensure GHTF documents are useful for these stakeholders and include an "approach for developing countries" in relevant documents.

2. Harmonisation
   - Relates to both, developed and new/developing regulatory systems. Hence there is the need to create an entity to address the issues of developing countries eg. a sub-steering group or 'developing country committee' to examine existing GHTF documents and consider the need for developing additional, more specific documents; and
   - Develop a mechanism to somehow include this entity in the Steering Committee's processes within the next three years.
3. Training/Outreach/Consultation/Education
   - Platform to implement training and consultation;
   - Strategy to determine what the Steering Committee is able to undertake and what may be undertaken by external organisations;
   - How to measure the success of training programs; and
   - Consideration of the GHTF Conference as a 'forum' and incorporate a full day into the program for 'developing country issues'.
4. Liaison
   - With public health organisations, standards setting organisations, training organisations and regional harmonisation groups (with the aim being to provide further opportunities for such groups to participate in GHTF activities); and
   - Develop a mechanism for deciding what type of liaisons are appropriate for the GHTF.

6.14 Mr Gropp presented the **Group 2** outcomes. He identified the following "key deliverables" -

1. The multilateral acceptance of extra-territorial conformity assessment elements/results (where decision making would remain with individual countries, but each would accept assessments from other countries after a confidence building period undertaken within an agreed timeframe);
2. A comprehensive model outlining the best pre- and postmarket regulatory practices for medical devices;
3. Practical technical guidelines for specific topics;
4. Management tools or procedures for the exchange of information eg. vigilance reports, quality systems reports, registration processes, etc;
5. Clear definition of the legal status of GHTF documents;
6. Documentation of the differences between existing regulatory requirements (and the reasons therefore);
7. A "rapid reaction force" which would take a common regulatory approach to addressing emerging issues/technologies eg. e-commerce, devices incorporating biological tissues, etc;
8. Seminars focusing on "horizon scanning" for new technologies, including -
   - predicting impacts;
   - consideration of a harmonised regulatory approach; and
   - examine whether existing regulatory systems can address the new issues;
9. Actual use and mutual acceptance by others of Study Group documents; and
10. Faster processes and work outputs from the Study Groups.

6.15 Group 2 considered the infrastructure necessary to support the above deliverables would include the circulation and warehousing of Study Group documents; the enhanced promotion of GHTF work products; and clarification of the relationships with third parties.

6.16 Mr Vale presented the **Group 3** outcomes. He described where the GHTF would like to be positioned in five years time, in the following terms -

1. To be seen as a body of expert opinion and advice, with a pro-active advocacy role in relation to existing regulatory requirements and emerging issues;
2. To be a good communicator and respected for its delivery of services and advice, in an effective and economical manner;
3. Employs Study Groups that embody expert opinion and which operate with clear guidelines and mandates that are subject to regular review;
4. To have a common technical dossier for the evaluation of medical devices;
5. To have an international vigilance system;
6. To further articulate some of the principles that support effective regulation eg. training, the 'regulatory building blocks'; and
7. Deliver common technical requirements for new technologies & emerging issues.

6.17 Mr Hayes said that the detailed and constructive reports of the three focus groups taken together represented a comprehensive description or vision of where Members would like the GHTF to be in five years time. After some discussion, it was agreed that the task now was to draw from the work of the focus groups the Strategic Themes of GHTF endeavour requiring priority attention.

6.18 The Steering Committee then identified and agreed upon seven such themes (which were subsequently condensed to six). It was further agreed that refinement of the key issues and the preparation of specific proposals under each theme would be best progressed by smaller Working Groups comprising Steering Committee members only. Each Working Group would be co-convened by one government and one industry representative.

6.19 The six Working Groups would convene via e-mail and should be able to utilise a common, private page to be established within the GHTF website. The Meeting agreed that e-mail communications about the deliberations of each Working Group and access to the 'private page' should be restricted to Working Group members, but acknowledged Members may seek advice/input from other representatives within their respective organisations. The Steering Committee agreed that each Working Group would provide their reports to the GHTF Secretary by Tuesday 1 May 2001, for inclusion in the agenda papers for the Committee's second meeting.

Action:

GHTF Secretary to arrange for the establishment of a private, password-protected page within the GHTF website for use by the Steering Committee Working Groups carrying out work on the six GHTF Strategic Themes.

Action:

Working Group co-convenors to provide reports on the key issues and specific proposals under each Strategic Theme to the GHTF Secretary by Tuesday 1 May 2001, for inclusion in the agenda papers for the Steering Committee's second meeting.

6.20 The six, GHTF Strategic Themes and membership of each Working Group are set out below. During its discussion of each Theme, the Committee flagged specific points that would need to be considered by each Working Group. These points are shown under each Theme.

1. New, emerging technologies/issues/topics

   - mechanisms to identify issues and principles, then recommend actions, exchange information

   Working Group - Dr David Jefferys and Mr Jim Benson (co-convenors), Dr David Feigal, Mr Kenichi Matsumoto, Mr Masato Yoshida, Dr Soichiro Isobe and Mr Kevin Murray

2. Implementing Guidance Documents/Acceptance of GHTF Outputs

   - evaluating impact, process of adoption in national regulatory systems (NCA's);
   - implementation plan (National Competent Authority);
   - enhancing Study Group process, including "implementability" (SG);
   - training dissemination/founder members/third countries; and
   - monitoring

   Working Group - Mr Cornelis Brekelmans and Mr Brian Vale (co-convenors), Dr Lillian Gill, Dr Soichiro Isobe, Mr Michael Baker and Ms Beth Pieterson

3. Common Method of Exchanging Regulatory Information and Mutual Acceptance of Data Requirements/ Non Duplicative

   - eg. nomenclature, registration, listing, recalls, approvals?;
   - Vigilance (SG2 ongoing);
   - recognition of reviews between regulatory agencies;
   - hierarchy of acceptance, including risk;
   - regulatory requirements across device life cycle;
   - acceptability of assessment results; and
   - role of standards

   Working Group - Dr David Feigal and Dr Egid Hilz (co-convenors), Dr Daisaku Sato, Mr Dennis Baker, Mr Robert Britain, Mr Kevin Murray and Mr Hans-George Will

4. Evolving Regulatory Systems

   - need recommendations;
   - resolve ambiguity on involvement;
   - training, liaison;
   - relationship to Study Group documents;
   - Regional Groups; and
   - Advocacy? – policy on outreach

   Working Group - Ms Beth Pieterson and Mr Michael Gropp (co-convenors), Mr Robert Britain, Mr Rainer Voelksen and Dr Daisaku Sato.

5. Communications

- internal to GHTF - co-ordinators;
- stakeholder;
- other interested parties eg. ISO/IEC/CEN/CENELEC, WHO, PAHO, Regional Harmonisation Groups;
- educators eg. RAPS;
- GHTF Website; and
- secure GHTF Chat Room.

Working Group – Ms Rita Maclachlan and Mr Kevin Murray (co-convenors), Mr Dennis Baker and Mr Barry Evers-Buckland.

6. Organisation/Infrastructure

- to support 'deliverables';
- Secretariat;
- Study Group work planning, membership and expertise;
- document control;
- monitoring, evaluation (tracking system)
- funding

Working Group – Dr Soichiro Isobe and Mr Robert Britain (co-convenors), Mr Jim Benson, Mr Michael Baker and Ms Beth Pieterson.

ITEM 7: GHTF TRAINING

7.1 At the 3rd Ad Hoc Procedures Group (AHPG) Meeting (September 2000), it was agreed that the GHTF review the training provided by Study Group and AHPG members with the goal of examining how best to provide training to interested parties about the GHTF and its documents.

7.2 The AHPG re-acknowledged the need for general training and information dissemination about the goals and activities of the organisation as a whole. It was also agreed this subject would be re-visited at the first Meeting of the Steering Committee.

7.3 The Steering Committee discussed whether consideration of a GHTF Training Program should be deferred until the completion of the Strategic Review; or whether a Training Program should be developed in parallel to meet the needs of countries developing medical device regulatory systems.

7.4 The Meeting agreed that further consideration of a policy relating to a GHTF Training Program and any formal requests for training should be deferred until the 2nd Steering Committee Meeting, in light of the Strategic Review undertaken at Item 6. It was noted that consideration will be given to training-related issues by some of the Steering Committee Working Groups.

7.5 As an interim measure, the Meeting agreed that Steering Committee Members and Study Group Chairs need to carefully consider any requests to undertake 'training' (including presentations at seminars/conferences). Specifically, those requests which relate to the GHTF and its activities should be referred to the Chair for consideration. Any requests relating to specific national issues should continue to be addressed by the relevant regulatory agency.

7.6 In reaching agreement on the above interim measure, the Meeting emphasised there is no intention to 'control' the content of presentations; but rather to help ensure that -

1. matters related to the GHTF and its activities are handled in a coordinated manner via the Chair/Secretariat; and
2. the Steering Committee is kept informed by being advised of such proceedings.

Action:

The concept of a GHTF Training Program be re-considered at the 2nd Meeting of the GHTF Steering Committee, in conjunction with the GHTF Strategic Review.

7.7 The Chair advised the Meeting of a funding proposal being developed by the Therapeutic Goods Administration for consideration by AUSAID. The proposal has been developed in an attempt to receive training funds under the auspices of the GHTF. Any funds received would primarily be utilised in the south-east Asian region.

Action:

Ms Maclachlan to update the Steering Committee on progress of the AUSAID funding proposal at the next meeting.

7.8 Previously, the GHTF Ad Hoc Procedures Group also considered a proposal by the Study Group 2 Chair (Dr Larry Kessler) relating to a training organisation for the vigilance exchange program. In view of the above consideration, the Steering Committee agreed it would further discuss Dr Kessler's proposal with him at its next meeting once a work plan for Study Group 2 has been submitted for consideration (Item 5.1 refers).

VISIT BY SENATOR THE HON GRANT TAMBLING

Prior to consideration of the next agenda item, the Steering Committee was visited by Senator the Hon Grant Tambling, Australia's Parliamentary Secretary to the Minister for Health and Aged Care. Due to Parliamentary commitments, Senator Tambling was able to attend the Meeting during Friday morning, 2 March 2001.

The Chair introduced Senator Tambling to the Committee, advising his ministerial responsibilities include the regulation of medical devices, medicines and food in Australia. Ms Maclachlan then provided a brief overview of the meeting to date (including the major outcomes) and then asked each Member to introduce themselves to the Senator.

Senator Tambling advised of his keen interest in medical device legislative developments being undertaken in conjunction with relevant stakeholders. He stated Australia is proud of its regulatory system for therapeutic goods and is largely free of any major political tensions. The Senator noted Australia's new regulatory system for medical devices is based on GHTF principles and the requirements of the European system.

Senator Tambling gave the commitment that the Australian Government is 'locked into' the GHTF processes and is very keen to have worldwide regulatory differences identified in order to minimise duplication of effort and resources. Although Australia is a smaller worldwide market, the Senator advised the meeting of the significant expertise which exists in the country's academic and research institutions. Senator Tambling warmly welcomed all Members to Australia and encouraged the Steering Committee to continue with its current work program.

The Chair thanked Senator Tambling for giving his time to attend the Meeting and reiterated his advice concerning the Australian Government's support to the TGA regarding its participation in the GHTF and for ensuring the continuation of sound regulatory practices.

ITEM 8: PLANNING FOR THE 9TH GHTF CONFERENCE

8.1 The Meeting noted the 9th GHTF Conference has been scheduled for 11-16 October 2001 in Barcelona, Spain (to coincide with the 9th Global Medical Devices Conference) and discussion lead to the development of a draft conference program.

8.2 The Chair acknowledged the assistance received to date from representatives of EUCOMED and thanked Mr Gropp for his offer of further assistance. The Meeting noted that in September 2000, EUCOMED prepared a "First Announcement" for the conference which was included among the agenda papers.

8.3 During the Meeting, Members made a number of points and suggestions including -

- The need to agree to a general framework under which the arrangements may progress eg. development of the draft agenda, conference registration details and costs, invitations to possible speakers (including a keynote speaker), timing of events, etc;
- The level of liaison between the TGA and EUCOMED needs to be increased;
- The revised registration fee of 165 Pound Sterling was considered to be more reasonable than that originally proposed;
- The host hotel in Barcelona (the Rey Juan Carlos Hotel) is particularly expensive and there is a need to identify a range of cheaper hotels and make some 'block' bookings. For example, the Meeting was advised that some South American representatives (sponsored by PAHO) who attended the 8th Conference in Ottawa indicated the price of $99 CDN per night for accommodation was too expensive;
- There is a need for EUCOMED to advise of any current arrangements or undertakings that have been made with the Rey Juan Carlos Hotel;
- The Conference program should include a 'Special Topic' on Tissue Engineered Devices; and any other suggestions should be referred to the Chair; and
- Several comments were made regarding possible special guest and keynote speakers for the Conference.

8.4 The Meeting considered several options for a conference program. It was agreed that the most preferred version from the Meeting be further refined by the Chair, Secretary, Ms Pieterson and Ms Kula; then circulated to Members for further comment prior to posting on the GHTF website.

Action:
GHTF Chair/Secretary to further refine the draft program for the 9th GHTF Conference, circulate to the Steering Committee for information or any further comment, finalise and post on the GHTF website.

ITEM 9: ESTABLISHMENT OF A PERMANENT SECRETARIAT

9.1 The 3rd Meeting of the Ad Hoc Procedures Group (September 2000) discussed the establishment of a permanent GHTF Secretariat, but agreed the TGA would re-visit this issue upon assumption of the GHTF Chair in January 2001.

9.2 In line with Item 6, the Steering Committee noted this issue will be addressed by one of its Working Groups under the terms of the GHTF Strategic Review. The Steering Committee therefore agreed to defer further consideration of this matter until its next meeting where discussion may continue in conjunction with the outcomes of the Strategic Review.

Action:

GHTF Secretary to include this item in the agenda for the 2nd Steering Committee meeting.

ITEM 10: INFORMATION ITEMS

10.1 No items were presented for 'information only'.

ITEM 11: OTHER BUSINESS/LATE PAPERS

ITEM 11.1: REQUEST FOR GHTF REPRESENTATION ON THE CHAIRMAN'S ADVISORY GROUP OF IEC TECHNICAL COMMITTEE NO.62

11.1.1 The Steering Committee considered a letter from Mr Rodolfo Godinez (Chairman of IEC Technical Committee No.62 - *Electrical Equipment in Medical Devices*) inviting the GHTF to nominate a member to the Chairman's Advisory Group of TC No.62.

11.1.2 In the interests of equity, the Steering Committee agreed that such requests cannot be considered in isolation; and must be considered in terms of the total number of standards setting bodies that could seek GHTF representation on their committees, in conjunction with the level of resources GHTF Members are prepared (and able) to contribute to such participation. The Meeting was advised to heed caution in that acceptance of one invitation may lead to numerous other requests; and this may present difficulties for the GHTF until its 'liaison strategy' is developed as part of the Strategic Review.

11.1.3 Mr Britain advised that USA industry representatives are already heavily involved in a number of IEC Committees, including TC62, SC62A, B, C and D. The Meeting considered that additional information (such as the meeting date, venue and the exact type of GHTF involvement Mr Godinez is seeking) is required before any formal GHTF commitment could be given.

11.1.4 Following the provision of such information and further consideration by the Steering Committee, it was suggested that as an initial measure, a Steering Committee member (either Mr Britain or Dr Hilz) may be able to attend the TC62 Chairman's Advisory Group meeting as an 'observer', on behalf of the GHTF.

Action:

1. The GHTF Chair to seek further details from the IEC TC62 Secretariat concerning the meeting date, venue and the exact type of GHTF involvement being sought, noting that GHTF involvement will have to be consistent with its liaison strategy which is currently under development.

2. GHTF Chair to provide a report on this matter at the next Steering Committee Meeting.

ITEM 11.2: GHTF WEBSITE

11.2.1 The Chair advised this item was presented to provide Members' with an opportunity to raise any issues or suggestions they have with regard to the on-going management of the GHTF website. No issues were raised for discussion.

11.2.2 Mr Brekelmans congratulated the former GHTF Secretariat, Ms Kula on the professional presentation of the website.

ITEM 11.3: APPROVAL OF TWO STUDY GROUP 4 DOCUMENTS AS "FINAL DOCUMENTS"

11.3.1 On 21 February 2001, the Study Group 4 (SG4) Chair, Mr Robert Allen provided the following SG4 documents to the Secretariat and requested the Steering Committee to consider them for approval as "final documents" –

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)"; and

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.6: Observed Audits of Conformity Assessment Bodies".

11.3.2 Mr Allen advised these two documents have been through the public review process, the comments received were discussed at the last SG4 Meeting (September 2000) and the documents have been amended as necessary.

11.3.3 The documents were tabled for consideration during the meeting. Given the importance of endorsing documents as "Final Documents", the Steering Committee agreed insufficient time had been allowed to give due consideration to the SG4 documents.

11.3.4 The Steering Committee noted the procedural document, *"GHTF Operating Procedures"* specifies a period of 8 weeks for the review of documents which are proposed for advancement to "Final Documents". The Steering Committee agreed to review the documents out-of-session and refer any comments to the GHTF Chair by Friday 27 April 2001.

Action:

Members to review the two SG4 documents, *"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplements Nos.4 and 6"*; out-of-session and refer any comments to the GHTF Chair by Friday 27 April 2001.

ITEM 11.4: TIMETABLE FOR FUTURE GHTF MEETINGS

11.4.1 As the Meeting was concluding, some Members made reference to a previous suggestion from the Study Group 2 Chair (Dr Larry Kessler) to convene meetings of the Steering Committee and four Study Groups in Australia, sometime during February/March 2002.

11.4.2 In the interests of forward planning, it was agreed to include this matter in the agenda for discussion at the next meeting.

Action:

GHTF Secretary to include this item in the agenda for the 2nd Steering Committee meeting.

ITEM 12: NEXT MEETING

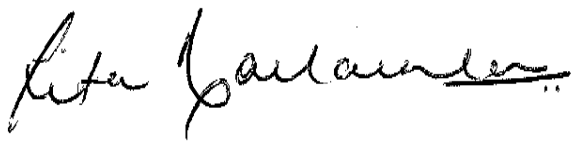
12.1 The Steering Committee agreed its second meeting would be held in Brussels from Tuesday 12 - Wednesday 13 June 2001 (with the venue to be confirmed following discussion between the Chair, Mr Brekelmans and Mr Gropp/EUCOMED representatives).

Action:

GHTF Secretary to confirm the venue for the second Steering Committee meeting.

12.2 The Chair closed the meeting at 12.15pm, thanked all participants for their attendance and contributions to the meeting's achievements; and looked forward to welcoming members to the Steering Committee's second meeting in Brussels.

Meeting record prepared by Mr Craig Davies, GHTF Secretary (Australia).



Rita Maclachlan
GHTF Chair; and
Director
Conformity Assessment Branch
Therapeutic Goods Administration

Craig A Davies
GHTF Secretary
Conformity Assessment Branch
Therapeutic Goods Administration

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