Summary 11th GHTF Steering Committee Meeting

The 11th GHTF Steering Committee (SC) meeting was held on 29 and 30 November 2006 in Brussels. This meeting marked the end of the three year chairmanship of Europe.

1. Welcome and apologies

The meeting was chaired by Georgette Lalis (EU). The Chair welcomed all participants, which were for Europe Sabine Lecrenier, Laurent Selles, Mathias Neumann, Jos Kraus, Maurice Wagner (Vice-Chair), Brian R Matthews, Christine Tarrajat, Werner Schönbühler, Carl F Wallroth, from Japan, Tomiko Tawaragi, Shinichi Takae, Shigetaka Miura and Hiroshi Ishikawa from Australia Rita Maclachlan, Rohan Hammett, Anne Trimmer and Johan Brinch; from Canada Roland Rotter, Stephen Dibert; from the US Larry Kessler, Gail Costello, David P. Kelly, Melinda Plaisier (observer), Robert Britain, Michael Gropp, Janet E. Trunzo; the Study Group Chairs Ginette Michaud, Markus Zobrist and Greg LeBlanc (acting Chair SG 5); for the Secretariat Jean Olson and Susanne Höke.

2. Summary Records from the 10th Steering Committee Meeting

The summary records of the last meeting were adopted subject to a corrections from Japan on the regulatory development update in the last Open Session.

In relation to the *ad hoc* group on software it was agreed to change the approach to possible membership agreed at the last meeting and to allow also experts that are neither SC nor Study Group (SG) members to participate.

3. GHTF Strategic Directions

Michael Gropp presented a paper concluding the discussion on the Strategic Directions which was endorsed by the SC. The paper took account of a contribution received following the last SC in Lübeck and was further completed based on discussions in this SC.

The following conclusions and recommendations were endorsed by the SC:

(1) The six existing Strategic Goals in the GHTF Strategic Direction remain essentially valid and appropriate, and should be confirmed in substantially their current form.

(2) By its nature, the Strategic Direction is intended to guide the work of GHTF over the long term. It is expected that regional Chairs will develop shorter-term action plans, in agreement with the Steering Committee, to promote the achievement of those goals during their tenure.

(3) Taken together, the existing guidance documents developed by GHTF Study Groups form a comprehensive basis for a harmonized global regulatory model for medical devices. Further development and refinement is still needed in some areas.

(4) While continuing the development and/or refinement of guidance documents, GHTF should as a high priority focus its general efforts on:

a. Continuing implementation of GHTF guidance documents by Founding Members
b. Creating and maintaining a secure GHTF website and database containing national competent authority vigilance reports, and making that information available, under appropriate controls and in cooperation with the World Health Organization, to regulators
c. Continuing the work on the Summary Technical Document ("STED") and promoting greater mutual acceptance by regulators and conformity assessment bodies of these documents as the recognised form of evidence of a medical device's conformity with the harmonised Essential Principles
d. Promoting greater mutual acceptance of reports of audits of manufacturer quality management systems as evidence of conformity with the harmonised quality system requirements
e. Establishing a training strategy and effective means of providing timely and consistent high quality training on the GHTF global regulatory model to regulators and industry in Founding Members and Participating Members (a small group could develop a training "manual", centralise the documentation, update it, provide the communication material and educate a pool of trainers).

(5) The *ad hoc* group's review identified several areas of valuable future work. Guidance on these topics should be developed by either existing Study Groups or newly formed *ad hoc* working groups of experts according to work plans agreed by the Steering Committee.

(6) The Steering Committee should continue to reflect on ways to widen the GHTF process (new Members/participating Members/liaison Members or other forms).

(7) The Steering Committee should further facilitate guidance development by, as appropriate, establishing *ad hoc* working groups for specific topics and placing some Study Groups in "maintenance mode" (and amend the Seville Steering Committee documents accordingly).

In the context of the Strategic Directions the SC discussed a letter received by Mr Michael Cheng and Mr Cheng's role in relation to GHTF. SC members of all regions emphasized that Mr Cheng has no affiliation with them or the SC and is in no way representing GHTF. He will be advised accordingly.

4. Study Group's work - Progress reports and documents

4.1. Study Group 1(Regulatory Framework)

The Chair of Study Group 1, Ginette Michaud, reported on the work of SG 1. In relation to ongoing work, the Summary Technical Documentation (STED) document still raises a number questions and the SG intends to present a document for the first quarter of 2007. The IVD subgroup is very active, documents have been well advanced and are planned to be proposed to the SC for endorsement in 2007.

Proposed Document

The SC endorsed the document as SG1(PD)/N044 on Role of Standards as proposed document and to be posted on the GHTF website for comments. This document is an update of an already existing document and besides the use of standards in relation to IVD's in particular addresses questions in relation to the use of superseded standards. The SG is looking for comments, in particular on issues such as normative references and devices already in use and already marketed.

New Work Items

The SC discussed four proposed new work items.

- New Work Proposal IVD STED

This work item was endorsed by the SC as a first priority.

- New work proposal on the definition of manufacturer

This work item was endorsed by the SC as a second priority. The SC discussed the relation between this work item and the Glossary of GHTF terms that is being developed in parallel and currently contains two manufacturer definitions. SC members agreed that the Glossary lists harmonized definitions, but does not in itself harmonizes and that therefore the work of SG 1 on the definition of manufacturer could be taken up. It was emphasized that close cooperation on this issue with other SG's, in particular 3 and 4, is necessary.

- New Work Proposal Registration & Listing

The SC endorsed this document as third priority. It emphasized the need to involve SG's 3 and 4. This work is of particular importance for third countries and it should be considered whether cooperation with WHO is possible on this subject.

- New Work Proposal Combination Products

The proposal to work on combination products raises a number of challenges and will require cooperation with other organisations, such as ICH. Given that the SC felt that this subject might not yet be ripe and that there were questions as to which SG should best address this issue, it was agreed that each region will send a report on the current legal status and requirements as background for the next SC meeting. It is envisaged to set up an *ad hoc* group at the next SC meeting, preferably chaired by a SC member. A SC member was proposed as Chair. This designation will take place at the next SC meeting.

In this context the SC asked Mr Neumann and Mr Gropp to develop ideas for a framework for *ad hoc* groups and to elaborate on composition of Study Groups.

4.2. Study Group 2 (Vigilance)

Mr Ishikawa reported on behalf of the Chair, Jorge Garcia, on the work of SG 2. Jorge Garcia could not participate, but had provided a written report to the SC.

Final Document
The SC endorsed document SG2N54 R 8 Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices as final.

New Work Item
The SC also endorsed a new work item already presented at the last SC in Lübeck GHTF SG2 N96R1 - Public Disclosure of Information Exchanged Through The NCAR Program. This new work item will essentially help to address the access of WHO to non confidential vigilance data.

The SC underlined that cooperation with WHO is of highest importance. Larry Kessler reported on the work of the *ad hoc* group formed at the last SC on this issue and the contacts with WHO. The SC concluded that the best way forward is for SG 2 to work on the new work item and to slightly broaden its remit. Since the preferred way to share information would be to make such data available in a targeted manner (access to regulators only) through the GHTF website, SG 2 should address in particular a mechanism to make information available to a targeted audience.

No progress could be presented in relation to the pilot project in relation to electronic adverse event reporting by manufacturers to National Competent Authorities since Tony Sant, the project leader, had to leave SG 2. Europe proposed Ekkehard Stoesslein to take over Mr Sant's work and Mr Stoesslein will take up contact with Mr Garcia to this end.

In relation to Hong Kong's application to join the NCAR system as full participant the SC concluded that Hong Kong fulfils the necessary requirements set out in the SG 2 documents. It was, however, emphasized that Hong Kong must ensure that data is not shared with third parties, in particular not in the context of the AHWP Memorandum of Understanding on vigilance.

In relation to Cuba's application to join the NCAR system as full participant, the SC concluded that the request will be taken up depending upon resources and priorities and that of course all requirements, in particular in relation to training, have to be fulfilled. Cuba had requested training by Health Canada, which is currently faced with scarce resources. The Chair will reply to Ms. D. Martinez accordingly.

4.3. Study Group 3(Quality Systems)

In the absence of the Chair of SG 3, Egan Cobbold, Mr Schönbühler presented the work of SG 3. In relation to ongoing work it was reported that work on document SG3(WD)N17 Quality management system – Medical devices - Guidance on the management of procured products, outsourced processes and their suppliers will still occupy the SG 3 for some time.

New Work Item

The SC endorsed the proposed new work item proposal SG3(NWI) N18 Quality Management System – Medical devices- Guidance on Corrective and Preventive Action (CAPA) Principles and activities.

Two other work items, which SG 3 intends to present at a later stage, were shortly discussed. These relate to the review of work previously performed by GHTF regarding Quality Plans and Quality Management System – Medical devices- Guidance on quality management system deficiencies. In particular the last item found support in the SC and SG 3 was encouraged to present this work item.

On membership, SG 3 underlined that there is a vacancy for an European regulator. A possible merger of SG's 3 and 4 was also discussed but without result.

The SC discussed the upcoming review of ISO standard 13485 on quality systems and the possibility to contact ISO and advise that no changes should be made at this point, but to rather allow a few years to gather experience. SC members agreed to consult their respective regions on this point and to develop a position until May to allow decision on the further approach at the next SC.

4.4. Study Group 4(Auditing)

Mr Zobrist, the Chair of SG 4 reported on the work in progress.

Proposed Document

The SC endorsed the document N 33 R 13 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports as proposed document.

New Work Item

The SC also endorsed a new work item in relation to audits of manufacturers with multiple production sites. Industry cautioned in this context that too extensive requirements here can pose real problems as suppliers lose interest, in particular when they are not medical device manufacturers and might be confronted with various audits from all customers. At a minimum, acceptance of one audit report for multiple customers should be considered. SG 4 should work with ISO committee CASCO on this work item.

4.5. Study Group 5 (Clinical Evidence)

Greg LeBlanc, the acting Chair of SG 5, presented the SG's work. SG 5 is short of European regulator and industry members. The Chair advised that European regulator members had just been appointed.

New Work Items

The SC endorsed two new work items, one on Clinical Evaluation for In-Vitro Diagnostic Devices and the other on Guidance on the Need for Clinical Investigation as Part of Clinical Evidence. In relation to the last work item there was some concern as to whether SG 5 is ready to address this issue or if it should first concentrate on the existing work items. To address these concerns it was agreed that SG 5 will start work on the issue and present to the SC in May a skeleton of the work to be developed. Based on that the SC will decide whether the SG is to continue work on this item.

The SC also agreed that Dr. Susanne Ludgate of the United Kingdom MHRA will take over the Chair of SG 5. Dr. Harris was thanked for his past commitment and achievements.

5. Future approach on software – status report

Larry Kessler reported on the *ad hoc* group on software. The Chair, Brian Fitzgerald, is creating this team. Work is closely related and is to be coordinated with the work on ISO 80001, which will specify general requirements for the application of risk management of IT-networks incorporating medical devices that achieve essential properties such as safety, effectiveness, data & system security and interoperability. A number of members of the *ad hoc* group are also members of the ISO group

working on ISO 80001 and it was therefore agreed to hold the first meeting of the ad hoc group on 11 January 2007 in San Diego, where an ISO meeting will take place as well.

6. Follow-up from initiatives at last Steering Committee meeting

6.1. Proposal for the document for GHTF Wordbook and Glossary

Mr Ishikawa reported on the progress on the GHTF wordbook and glossary, he prepared a first draft of the document. There is still some updating work to do which will require input from SG Chairs. It was suggested to clarify the scope and rationale of the document to underline that the document compiles existing definitions and does not in itself create new definitions. The SC also agreed to include the definitions from ISO 13845, SG 3 will provide that information to Mr Ishikawa. Once the document is cleared up it can go on the GHTF website as information document. Since it only compiles existing definitions there is no need for a comment period. The document should be continuously updated and SG's should ensure that the necessary information is provided to Mr Ishikawa.

6.2. GHTF Training – Training Institute

The SC agreed that a coordinated effort is needed to develop a training programme. To this end the SC set up an *ad hoc* group led by Larry Kessler, who will be joined by Horst Frankenberger, Peter Linders, Janet Trunzo, Roland Rotter, Mr Ishikawa and Rita MacLachlan. In particular this group will collect training material and develop a process to update such material. It was also agreed that dedicated material such as a training handbook would be needed. One starting point is the CD with the materials of the Lübeck conference (however, broader use of that material will require waivers).

7. Status of Global Medical Device Nomenclature (GMDN)

The Chair had requested members to report on the use of GMDN in their respective regions and proposed to SC members the idea to jointly fund and maintain GMDN to ensure its public availability and coherence.

In Australia a new system for registration of medical devices was introduced in 2002, including all medical devices. The system records manufacturers and suppliers. The level of information will depend on the risk class of the device. The Therapeutic Goods Act refers to "system nomenclature code". The regulations prescribe the use of GMDN making reference to the ISO 15225 - 2000 (E). Depending on class preferred terms (class III) and template terms (class I) are used.

Australia recognizes that there are and will be gaps in GMDN that need to be addressed and that a lot of education is required. It is the responsibility of the manufacturer to define the device and assign the GMDN code. From 2007 onwards manufacturers will have to obtain licenses from the GMDN maintenance agency, until October 2007 TGA pays an overall license fee to assist in the change over and also assists in obtaining missing codes at no cost to the applicant. These costs are recovered through the overall registration fee. For IVD's a lot of work is still required. TGA intends to provide one full time staff to GMDN agency to assist in that work.

Japan uses the JMDN, which is a translation of an early version of GMDN. It is used for regulatory purposes to define all classes of devices and was established in 2005. There are currently no ongoing

contacts with the maintenance agency and the new terms developed by it. Coherence on the international level and the creation of new terms are therefore an issue. However, there is currently no plan to join an international effort.

Canada is currently not requiring GMDN for registration, but captures GMDN codes if they are provided. While Canada intends to introduce GMDN for regulatory purposes on the long run, it is awaiting the US to advance on the issue.

The US has put tremendous efforts into the system. It is a very useful tool for post-market surveillance. FDA has two people constantly working with the GMDN maintenance agency. Before the US can introduce GMDN codes for regulatory purposes a complete mapping with UMDS is still necessary. Guidance is intended to be developed until end 2007 and then intends to move to use of GMDN.

The US is investigating the possibility to have the national library of medicine take over GMDN. Then there might be no need to have licenses and the nomenclature would be publicly available. This would also include the creation of new terms.

Europe is planning to use GMDN in Eudamed for regulatory purposes. Europe is intending to follow the current GMDN license system, but Member States have major concerns to oblige manufacturers to buy a license. Europe would therefore welcome any possibility to consider whether alternatives of financing on an international level are possible. This could result in a joint funding of the GMDN Agency. Europe is planning to translate GMDN into all official Community languages and would store the translations in the GMDN website and have the same licensing policy apply to them than to the English version.

The Chair advised that GMDN was asked to work out a business plan, which would be used to decide upon the next steps. It was concluded that SC members will study the information provided by the GMDN agency to see if there are possibilities for a joint approach

8. Preparation of Open Session

WHO

In recapping the discussions on WHO Mr Kessler reported on the *ad hoc* group that had worked on the WHO request to access to the non-confidential part of vigilance data. Following discussion of a number of questions raised by the *ad hoc* group, the SC agreed to charge SG 2 with a new work item (see 4.2.). Possible other areas of cooperation with WHO could be the training.

IEC

This is the first time IEC participates in the Open Session. The SC strongly supports cooperation with IEC. In this context it is underlined that the HTTF recommendations should be revisited for guidance on cooperation. Either Liaison Membership or a Memorandum of Understanding with TC 62 could be first steps.

ISO

The SC agrees to submit the collected comments on the ISO Guide to Using International Standards in Technical Regulation to ISO. The US submitted additional comments.

The SC also discussed a Japanese proposal to contact ISO and request incorporation of key elements of "Risk Management" into ISO 13485. SG 3 is not in favor of this proposal. Japan was asked to prepare a paper to clarify the Japanese view for the next SC. SG 4 will also investigate the issue.

ISO/IEC Rapporteur

The GHTF Steering Committee wishes to establish a well-defined communication process for liaison with ISO/IEC. The proposed process is as follows:

- For high level considerations at any time, direct communications should occur between the Chair of the GHTF Steering Committee and ISO/IEC. The Chair will refer matters to the Study Group Chairs as needed.

- To enable the identification/co-ordination of issues that require consideration by the GHTF Steering Committee, GHTF will designate a Steering Committee member who will act as "Rapporteur" for standards issues.

The "Rapporteur" will :

1) Contact the Chairs of ISO/IEC prior to each GHTF Steering Committee meeting and seek an information update on emerging issues and developments in standards processes.

2) Communicate with ISO/IEC after each GHTF Steering Committee meeting to inform them of the outcome of Steering Committee deliberations on these matters.

The "Rapporteur" will be appointed by the Chair of GHTF after discussion with the Steering Committee for a period of 1 year. The SC agreed to appoint Mr Carl F Wallroth to take over the first term (pilot period) of this function.

The Chairs of the GHTF Study Groups will retain the authority to communicate directly with ISO/IEC regarding issues of relevance to their Study Group. This will not be the responsibility of the "Rapporteur".

AHWP

AHWP is now Liaison Body to GHTF. There was no representative in this meeting. Points that could be taken up with AHWP in future meetings could be:

- the geographical scope of AHWP
- any plans in relation to vigilance systems and exchange of vigilance data within the AHWP
- the use of GMDN in the AHWP member countries.

9. Coordination with The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

The SC held a first exchange of views on possible cooperation with ICH. The SC recognized the challenges of such cooperation, starting with a different representation in both organisations. Canada is only observer to ICH and Australia not at all represented. Systems in relation to implementation differ considerably. The area in which cooperation could be envisaged would be on postmarket surveillance and vigilance and potentially in relation to combination products. Given that this was merely a first brainstorming, the discussion will be continued in the next SC meeting. The point was made that if an initiative is taken on combination products, ICH should involve medical device experts.

10. Unique Device Identification

The US inform the SC that there are ongoing reflections to include medical devices in the bar code rule that has originally been established US in 2002. Bar codes can be very useful in the case of recalls, adverse events etc. Following intense stakeholder consultation and a large stakeholder meeting in October the comment period elapsed. The overall recommendation is likely to be to go ahead with obligatory bar codes for medical devices. Different levels of information will be required depending on class of device, but generally information on manufacturer, product description (GMDN) and date and place of manufacturer would be included.

The US invites SC members to communicate any concerns in this regard to the US. There is a document on the FDA website with a number of questions that the US would in particular welcome comments on, as acceptance on the international level is one of the concerns.

11. Summary Technical Document (STED) and Third Party Review

The US informed that STEDs reviewed by a third party are now acceptable in the US as well and thanked Bob Britain for raising this issue. The reason that this was not previously the case was that the FDA wanted itself to gain experience with STED first.

12. Upcoming meetings

12.1. GHTF Action Plan by FDA

The incoming North American Chair has prepared an action plan for its tenure, which was briefly discussed by the SC. SC members are invited to comment in the next 6 weeks on the ideas developed in this document.

The Action Plan proposes to concentrate in the next three years on three goals. Goal 1 is to better ensure guidance implementation. It is proposed to concentrate on single audits used in multiple jurisdictions and the operation of the National Competent Authority Report system in a first step. Goal 2 is the improvement of organizational logistics, which includes better working structures, such as clear rules for *ad hoc* groups as well as a complete revamp of the GHTF website. Goal 3 is expansion, which proposes to reach out to other organizations similar to how this has been done with AHWP and in particular envisages the development of a training plan. Finally, the Action Plan proposes a

restrospective assessment and communication strategy, which would include a study to review the success of GHTF.

12.2. Upcoming meetings

The next SC meeting will be held on May 6, 7, 8 and 9 2007 in Newport Beach close to Los Angeles. Two regional meetings in Central and South America are planned during the North American Chair as well.

13. Closing Remarks by Chair

The Chair expressed her personal thanks to all SC members for the support, and to all SG Chairs for many excellent documents adopted under the EU Chair. The Chair also expressed gratitude for the Member States that hosted SC meeting under the European Chair and thanked Maurice Wagner as Vice-Chair and the European industry for its support, in particular in relation to the Conference.

Europe took over the Chair from Japan in January 2004. During the European Chair five Steering Committee meetings were organized in Paris, Seville, London, Lübeck and finally in Brussels. These meetings and the work carried out in the Study Groups allowed GHTF to make considerable progress during the last three years.

The Chair emphasized that certainly one of the highlights under the European Chair was the GHTF Conference in Lübeck in June 2006. This conference was attended by more than 400 participants and was extremely well perceived. It brought the important subject of design for patient safety high on the agenda. And, importantly, it left GHTF with a time capsule of presentations and other training materials on CD reflecting the current state of play of GHTF.

Under the European Chair many crucial documents were endorsed as final and made available on the GHTF website. The finalisation of critical documents on medical devices classification, principles of conformity assessment and the essential principles essentially completed the GHTF regulatory model. Important achievements were made in the GHTF National Competent Authorities Report exchange program. This is a very tangible area of practical cooperation that attracts much interest, such of WHO. Work in relation to quality systems and their audit advanced greatly. Under the European Chair, Study Group 5 dealing with the important subject of clinical evaluation was successfully set up.

In fact work of GHTF has advanced to such an extent that the questions about the future direction of GHTF has become imminent. In many fields GHTF effectively completed its tasks, at the same time there are new challenges. The European Chair therefore started the reflections on the Strategic Directions for GHTF in the years to come.

Certainly one of the most important achievements under the European Chair was the review of the GHTF procedural documents. These documents are now adapted to GHTF's work in the future. Setting out clear criteria for cooperation with non-Members was one of the priorities. One of the key missions of the European Chair was to either start or revitalize cooperation with non-Members such as AHWP, ISO, IEC and WHO and thus making GHTF truly global. A lot has been achieved. AHWP is now a Liaison Body to GHTF. So-called 'Open Sessions' of the Steering Committee were introduced and offer a forum for cooperation with non-members.

While a lot has been achieved the incoming Chair will have important tasks ahead. Finalising the discussion on the Strategic Directions, finding solutions to the issue of training and shaping the started cooperation with organizations such as ISO, IEC, WHO and the AHWP are only to mention a few. The Chair wished the incoming Chair lots of success.

Open Session (30 November 2006 afternoon)

The SC welcomed the guests for the Open Session, Mr Björn Fahlgren from WHO, Mr Tim Hancox from ISO and Dr. Robert Schaefer, Chairman IEC SC 62D: Electromedical equipment and Dr. Norbert Bischof, Secretary IEC TC 62.

14. 10th GHTF Conference Review

Mr Wallroth reported on the evaluation carried out of the GHTF conference held in Lübeck in summer 2006 over 400 visitors from 33 nations a big success and well received. The evaluation carried out gives useful information for the incoming Chair. Mr Wallroth also presented the CD with the conference proceedings that participants will receive before Christmas.

Presentation for Global Conference

The US gave a short overview of the upcoming GHTF conference to be held in connection with the Advamed Global Medical Device conference.

Given that the program is still in an early stage comments or suggestions are still welcome over the next 3 or 4 weeks. The US are particularly also looking at support in the preparation of workshops.

15. Update of Main Developments in Founding Members Regulatory Systems

Canada

Canada reported that the planned regulation of reuse of single use medical devices could not go ahead as there is not sufficient regulatory authority under the Food and Drug Act. Canada will now try to address this issue in another context. Canada also informed that it authorized the sales of silicon breast implants, but is facing extremely burdensome documentation requests from Parliament in this regard. In terms of its internal administration, Health Canada is working under very severe budgetary restrictions.

Canada has concluded Memoranda of Understanding with the Australian TGA and with US FDA.

Australia

In response to the budgetary situation outlined by Canada Australia underlines the advantages of TGA being a 100% cost recovered organisation.

Transition to the new regulatory framework for medical devices, based on the GHTF model, will be finalized in 2007. However, many companies have not yet switched to the new system and TGA is following a proactive approach to ease the phasing in for all companies.

On reuse of single use devices, TGA had introduced regulation. The states and territories have ceased remanufacturing of critical devices. Compliance with the new regime was extended until July 2007 for semi-critical and non-critical devices.

Human and cellular therapy goods fall under a new category "biologicals".

The legislation of IVD's is still under preparation and will come under the joint agency with New Zealand. It will adopt the essential principles, the classification and the conformity assessment methods developed by GHTF. ANZTPA, the joint agency with New Zealand, is expected to open doors in late 2007. Australia will introduce a system of external accredited assessment bodies.

Hot topics in Australia include drug eluting stents, hip and knee prosthesis – for which up-classification is under discussion.

From the Australian point of view, considerations for device reclassification, extent and depth of clinical evidence, device tracking and structure and content of registries are issues that are particularly prawn for GHTF work.

Japan

To fulfill its mission to provide safe & effective medical devices to patients in a speedy manner, Japan is concentrating on establishing technical standards for 3rd-party certification/approval, on utilizing existing data, e.g. accepting foreign clinical data, on promoting communication between applicants and reviewers by utilizing the preconsultation system and on developing guidance documents for innovative medical devices with new technology.

US

Priority in the US is the strengthening of the postmarket program. This includes improved data systems, enhancing risk benefit communication, better collaboration on enforcement strategies including also medial societies. The US will in this regard also look into using screening techniques.

In relation to funding, medical device user fees account for about 50 % of the review budget and this is intended to stay like that. Pilot Multipurpose Assessment Program in the context of the Memoranda of Understanding with Australia and Canada will be actively addressing companies to take part.

The US also reported on the success of the project "Harmonization by Doing", which is a cooperation between Japan and US involving academia and currently focusing on cardiovascular devices.

EU

The EU is still in the process of reviewing the medical device directives. The proposal was made a year ago, it is a rather technical revision, and is still in progress and under deliberation in Council and

Parliament. One of the main issues is the reuse of single use devices. The European Parliament is very much in favour of establishing rules, Member States rather do not want any discussion. Another important issue for Europe are combination products that contain human cells. The European Parliament would like all combination products to be treated as pharmaceuticals. Adoption of the proposal is expected the earliest by June 2007.

In the context of the revision of the New Approach Europe is also working on a robust system on certification, better control of notified bodies and market surveillance. One step in this direction will be a study on implementation of the vigilance systems in the Member States.

In 2007, the Commission will also deal with the MRA's with Australia, the US and Canada, and discuss the addition of medical devices to the EU-Japan MRA.

16. Cooperation with international bodies (state of play)

16.1. IEC

A short presentation of IEC and its work in relation to medical devices was given. It was emphasized that the work of GHTF can facilitate considerably the development of IEC standards and that the work of IEC can, *vice versa,* help to promote and support the work of GHTF. IEC standards can be based on harmonized GHTF documents rather than local regulations. IEC encourages regulatory bodies to further participate in the Medical Device Standards development of IEC.

IEC also emphasized the existing cooperation with ISO. To ensure that their International Standards fit together seamlessly, ISO and IEC have a common set of rules for their work and are structured similarly. The working procedures for both organizations are virtually identical and joint projects and standards often combine expertise from both organizations.

Medical device work in IEC is essentially concentrated in TC 62. The aim of contacts with GHTF is to establish information channels on what and how it is to be done in relation to standardization. It was agreed to formalize cooperation in the form of a Memorandum of Understanding, respectively Liaison Membership if more appropriate. A draft MoU will be prepared ahead of the next SC meeting.

16.2. ISO

The SC and ISO confirmed the ongoing collaboration between GHTF and ISO. The SC informed ISO that comments on the Guide on the use of International Standards will be submitted. In particular Mr Hancox drew the attention of the SC to the WTO influence in standards development. Standards will increasingly need to meet trade requirements.

16.3. WHO

The SC and WHO discussed the follow-up given to the request to make vigilance data available to WHO. WHO was informed about the new work item given to SG 2, which will lay the ground for cooperation on this issue. Both sides emphasized that it is important to reach concrete results fairly quickly on this issue. Replying to a question of the Chair, the WHO representative stated that the reuse of single use devices was a major health problem , worldwide.

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