SUMMARY OF THE 7th GHTF STEERING COMMITTEE MEETING

The seventh GHTF Steering Committee (SC) meeting was held in Paris on 28 and 29 June 2004, hosted by Afssaps, the French Health Products Agency. On that occasion, Mr. Marimbert, Director General of Affsaps, declared that Afssaps' offer to host the meeting reflected the commitment of France to the work of GHTF, aimed at bringing about convergence between regulatory systems and practices and the exchange of information and experiences between regulators and industry at the global level. In this way, Mr. Marimbert stated, GHTF contributes to providing patients with innovative, performing and safe devices, allowing the achievement of a high level of safety in health care.

1. Introduction

Mr. Cornelis Brekelmans (EU) chaired the SC meeting. He welcomed new SC participants: Dr. Daniel Schultz (US), Mr. Don Boyer (Canada), Dr. Hiroshi Yamamoto (Japan), Mr. Shigetaka Miura (Japan), Mr. Jos Kraus (EU), Mr. Jean-Claude Ghislain (EU), Mr. Alain Prat (EU) and Dr. Antonio Lacerda (EU). The Chair also paid tribute to those SC members that had left or who participated in this meeting for the last time: Dr. David Feigal, Dr. Taisuke Hojo , Mr. Kenichi Matsumoto (Japan), Dr. David Jefferys (EU) and Mr. Rainer Voelksen (EU).

The Chair asked participants to communicate their contact details to the Secretariat.

The SC took note that the handover meeting between the outgoing and the incoming Chair, as foreseen according to point 7.0 of the GHTF Roles and Responsibilities, was held in Brussels on 26 to 28 January 2004.

2. Update of Main Developments in Founding Members Regulatory Systems

Each Founding Member reported on the main developments in its regulatory system.

a) Europe

In Europe, the Directive on Medical Devices is currently under revision. It is widely recognized that the Directive provides an appropriate legal framework, and that its implementation needs to be reinforced.

The revision will mainly address the need for some clarification and improvement, identified in the light of experience, and a number of new developments, such as medical software and the results of work of a task-force on clinical evaluation as well as alignment with the directive on active implantable devices. Wherever possible, GHTF documents are taken into account, e.g. with regard to the possibility of e-labelling. Europe is currently also in the process of developing a regulatory framework for human tissue engineering.

b) United States

In the light of changes in the FDA's Center for Devices and Radiological Health (CDRH) management, the US delegation confirmed its continued support and commitment to the work of GHTF, in particular by continuing to support the permanent secretariat to the Chair. The US delegation also presented an overview of the organization of the FDA, in particular the

CDRH and the Office of Regulatory Affairs, and their respective involvement in GHTF activities. SC Members from the other regions agreed to provide a similar organizational overview at future meetings.

c) Canada

The Canadian delegation reported that most of the GHTF documents have been incorporated or implemented in Canadian legislation and regulation. Addressing the reuse of medical devices and reinforcing market surveillance activities are the most important regulatory issues in Canada at the moment.

d) Japan

The Japanese delegation reported on the revision of the Pharmaceuticals Affairs Law which is explicitly intended to promote convergence between the regulatory requirements and practices of Japan with GHTF guidance documents.

e) Australia

Australia reported on the first 18 months of experience with its new regulations for medical devices, largely based on GHTF guidance. New legislation on IVD's is currently under development, as well as rules whereby reprocessed products will be subject to the same requirements as new products. Special attention was also drawn to the Trans Tasman Agreement between Australia and New Zealand.

3. Report on the Work of Study Groups

The SC proceeded to a detailed examination of the work programmes of the Study Groups.

a) Study Group 1

The SC took note that the following documents were posted on the GHTF website and that the comments received will be analyzed by SG 1:

- SG1/N011R17, Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- SG1/N015R22, Principles of Medical Devices Classification
- SG1/N029R13, Information Document Concerning the Definition of the Term "Medical Device"
- SG1/N041R6, Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)
- SG1/N044R4, Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)

The SC took note that work on the STED document, an important document for manufacturers, is in progress. It also underlined the importance to be attached to the work on conformity assessment and the fact that this work is closely related to the work on medical device classification and can not be considered separately. The SG 1 Chair reported that steady progress is made with the document on conformity assessment and that a document could be ready within one year for advancement as a Proposed Document. Much of the future

work of SG 1 will concentrate on modifying the existing documents in order to introduce specific requirements for *in vitro* diagnostics devices.

The SC agreed to advance the revised final document on "Labelling for Medical Devices", SG1/N043R6, to the Proposed Document stage and to post the document in the GHTF website for comments.

The SC also took note of a new work item proposal on "Content and Format of Registration and Listing Information for Medical Devices". The SC underlined the priority given to the current ongoing work of SG 1 and agreed to postpone a decision on this new work item until the next SC meeting in May 2005.

b) Study Group 2

The SC agreed to advance the document on "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program", NCAR SG2 N38R14, to Proposed Document stage and to post it on the GHTF website for comments. The SC expressed its support for changes introduced to the document, allowing for a wide participation of non Founding members in the exchange programme. Canada confirmed its continuing provision of the secretariat to the NCAR exchange programme.

The SC supported the consolidation of the documents N21, N31, N33 and N36 into one document N54 and in this context the revision of N21.

The SC also accepted a proposed new work item of SG 2 on NCAR Exchange, SG2 N71R2. This work item includes possible adaptations to the form set out in document N9. However, the SC noted its concern that SG 2 should very carefully assess any changes to this widely used form. The SC asked SG 2 to carry out work on this new work item as quickly as possible.

c) Study Group 3

SG 3 reported on the work carried out with regard to the document on Risk Management as an integral part of the Quality Management System, SG3/N15R6. The SC took note that the document is intended to be presented to the SC at its next meeting. The auditing of risk management will be discussed in a joint SG 3 and SG 4 drafting committee meeting. The SC welcomed the ongoing coordination of the two SGs on this work.

d) Study Group 4

SG 4 reported on the work on "Guidelines for Regulatory Auditing of Quality Systems of Medical Devices" and on its cooperation with SG 3 with regard to the integration of auditing in regard to risk management. The SC confirmed the high importance given to the work on the "Part 2: Regulatory Auditing Strategy", N 30 R6, but also emphasized the high importance it attaches to the work on "Part 3: Regulatory Audit Reports". The SC requested that SG 4 give priority to work on the audit reports.

The SC took note of the successful training seminar organized by SG 4 in Japan.

Concluding this point of the agenda, the SC congratulated the Study Groups on the excellent work and progress made and invited them to present in the light of this discussion an updated version of their work programmes. The SC also highlighted the need to keep the number of participants in SG meetings manageable and particularly underlined the need to ensure that participants are able to contribute to the activities of the SG and can ensure a continuous presence and participation in line with the criteria set out in 10.2 of the GHTF Roles and Responsibilities. SG Chairs and the SC also highlighted the need for good co-operation between the SG's and suggested more joint meetings of the SG's.

4. New Study Group 5 on clinical evidence

The SC examined the report prepared by the ad hoc working group on clinical evidence chaired by Mr. Michael Gropp, suggesting the creation of a new Study Group. It congratulated the members of the *ad hoc* working group for their excellent work and agreed to set up a Study Group 5, addressing clinical evidence. Close coordination with SG 1 should avoid overlaps.
The SC considers that the work of SG 5 should concentrate on:

- Harmonized definitions of terms;
- Review of existing GHTF documents on classification, conformity assessment procedures and risk management, and applicable ISO/ICH documents, for relevant principles/considerations and to ensure that terminology is consistent and interfaces are clear;
- Harmonized guidance on how to conduct and document the clinical evaluation;
- Harmonized content and format for clinical investigation reports (summary presentation of clinical evidence should be done in coordination with GHTF SG1, e.g., STED).

Following consideration by the SC of substantial progress of the work in the first phase, in a second phase, the Study Group will work on:

- Harmonized principles to determine when a clinical investigation, as opposed to other forms of clinical evidence, is necessary.

Other possible work areas identified in the report were regarded as important, but of lower priority.

As regards the composition of SG 5, the SC highlighted the need for a balanced representation from all Founding Members and particularly underlined the need for those with experience in clinical trial methodology. The SC decided to invite Dr. Graeme Harris from TGA as Chair of the newly constituted SG and invited nominations of members to be submitted by the end of July to Dr. Harris and to the SC Secretariat.

5. Nomination of Study Group Chairs

The SC congratulated the current SG Chairs on their excellent job and the large number of important documents created over the past years. However, bearing in mind that the GHTF Roles and Responsibilities introduce an underlying principle of rotation for Study Group Chairs and that the Chair of SG 2 had announced his wish to step down eventually, the SC should examine the appointment of SG Chairs.

Taking account of the need to ensure continuity and a regional equilibrium of SG Chairs, the need for experience and consensus building abilities, and the possibility of appointing vice-chairs in future, the SC adopted the following conclusions:

For SG 1, the SC invites Dr. Ginette Michaud from the FDA to take over the Chair from Mr. Maurice Freeman as from May 2005. This appointment does not interfere with the organization of the work of SG 1, and in particular with its IVD subgroup.

For SG 2, the SC asks Mr. Kim Dix to stay on another year and decided to re-examine the situation in May 2005, in particular since many of the SG 2 documents are in an advanced stage of finalization. Mr. Dix agreed to hold the Chair until May 2005 and the SC invited SG 2 to formally propose a new Chair in the light of progress of its work.

For SG 3, the SC invites Mr. Alain Prat of Afssaps to take over the Chair from Mrs. Kimberly Trautman as from May 2005.

For SG 4, the SC appoints as Chair the current interim Chair, Prof. Horst Frankenberger, who agreed to hold the Chair until his retirement in two years.

For SG 5, the SC invites Dr. Graeme Harris from TGA to take the Chair.

6. GHTF Procedural Matters

The GHTF procedural rules are codified in three documents: the GHTF Roles and Responsibilities, the GHTF Guiding Principles and the GHTF Operating Procedures. All three documents were adopted by GHTF participants in Ottawa in September 2000. In line with the Roles and Responsibilities and Operating Procedures, which foresee their review every three years, the SC began an in-depth debate on these documents, underlining that any such review must also be consistent with the Strategic Directions of GHTF, adopted in 2002.

The Chair emphasized that one of the main objectives of the review is to facilitate the work of the Study Groups. In the subsequent debate many suggestions of strategic and procedural nature were made. In conclusion, the Chair invited SG Chairs to provide their input to Mrs. Kimberly Trautman, Chair of SG 3, to allow her to consolidate those comments in one document to be submitted to the Chair by the end of September. Other SC members were invited to provide their input, equally by the end of September, directly to the Secretariat.

The SC invited the Chair, jointly with the vice chair, the secretariat and the permanent secretariat, to present a consolidated version of the comments and its own proposals by October. The Chair will organize a special (electronic) meeting of the SC in November 2004 to review comments.

Proposals should cover the changes necessary in light of experience, the institutional framework of GHTF, rights and obligations relating to the different forms of membership and the role of the Conference, including the possibility of regional conferences.

7. New Work Items

a) Design for Patient Safety

The SC examined a paper on design for patient safety introduced by the European delegation. Design for patient safety is an important new holistic concept, which seeks to further improve patient safety and contribute to improving the quality of care for patients. It has been identified by all Founding Members as increasingly important. SC members reported on various initiatives undertaken at national level and on activities of international organizations and standardization bodies in relation to design for patient safety.

As a conclusion of its debate the SC agreed to record the activities in each region with a view to further discussions on the subject in its next meeting and invited members to communicate their activities to the Chair by the end of October 2004. It supported further exploration of the idea of organizing a Workshop with healthcare providers and the patient safety movement. This workshop could be a forum in which to present and discuss the past contributions of the medical devices industry to this topic and to consider whether there is a need to develop a best practice guide. Such a Workshop could either be held on the occasion of the Global Conference in Lübeck or in cooperation with WHO.

b) Medical Software

The different regions presented the activities currently ongoing and the existing guidance available on medical software and took note of the work undertaken at international level and in the GHTF SG. They agreed to exchange information on this matter to allow SC members to draw on the experiences of others when addressing this issue in their own regulatory system.

c) New Technologies

The SC confirmed the importance it attaches to regulatory challenges, in particular to those resulting of emerging public health risks and emerging technologies, as identified in goal 1 of the GHTF Strategic Directions. Members agreed to provide information to the Chair on ongoing activities in their respective regions, allowing this discussion to be continued at the next SC meeting.

8. Follow-up to High Level Workshop on international standards for medical technologies of ISO-IEC-ITU

The Chair reported on his intervention on the occasion of the High Level Workshop on international standards for medical technologies of ISO-IEC-ITU[*] in February 2004. He also proposed that the SC welcome Mr. Alan Bryden, Secretary General of ISO, representing on this occasion ISO, IEC and ITU. The Chair, emphasizing the important role GHTF members attach to international standards in support of meeting GHTF essential safety and performance of medical devices and quality systems, congratulated Mr. Bryden on the success of the workshop.

[*] http://www.iso.org/iso/en/domains/WSC-MedTech/index.html

The following discussion allowed participants to highlight the issues and concerns in a highly constructive spirit. Bearing in mind the institutional differences between GHTF and ISO, the following conclusions were drawn from the meeting:

- To ensure a coherent and transparent program of the three standardization bodies (WSC), preferably taking due account of the hierarchy of standards suggested by the GHTF document on the Role of Standards in the Assessment of Medical Devices, ISO will provide the Chair before mid-September with a proposal for a framework and format for the presentation of the programmes of WSC members in the area of health technologies for comment;
- Consultations on horizontal issues, in particular a Guideline on the links between ISO standards and the GHTF essential safety principles (based on the principles of ISO Guide 63:1999, now obsolete), but also on optimization of work between WSC members, and between them and national standardization bodies, and standardization developing organizations to avoid duplication of work will be enhanced. In this context, ISO proposed to make available a list of current collaborations with other globally relevant standardization organizations.
- Particular attention was given to the issue of normative references to standards, as for example in a new standard on software to ISO 13485 (quality systems) and ISO 14971 (risk management), and to the question under which conditions such references to horizontal standards could be appropriate, without limiting the choices of manufacturers and reducing the potential for regulatory authorities to endorse such standards as supporting regulatory requirements;
- The WSC program could be examined in a meeting, which would also include WHO, in the first half of next year;
- On Global Medical Devices Nomenclature (GMDN), the SC considered that the legal status of the maintenance agency and the copyright issues require clarification.

9. Report on World Health Organization

The SC welcomed the correspondence between the Chair and the Director-General of WHO. The SC also instructed the Chair to pursue contact with a view to identifying possible areas of cooperation and to set up a meeting between the Chair, the Vice-Chair, the Secretariat and WHO. The Chair invited SC members to provide him with issues they would like to be taken into consideration.

10. Timetable for future GHTF Meetings

The SC confirmed the venue of its next meeting in Sevilla, Spain - the exact date is to be confirmed before the end of July - and agreed to meet on 7 and 8 November 2005 in the UK. It also confirmed the plan to set up an e-meeting in the second half of November 2004 on the review of the Ottawa documents.

The SC invited the SGs to organize their meetings to allow timely presentation of documents to the SC.

11. Closing

The Chair congratulated Mr. Marimbert, Mr. Ghislain, Mr. Prat and their whole team on the excellent organization of the SC meeting and for their hospitality.

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