



GLOBAL HARMONIZATION TASK FORCE

ANNUAL REPORT: 2001 - 2002

**A Presentation to the Plenary Session
of the 9th GHTF Conference**

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Singapore

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Australia

Opening Remarks

Ladies and Gentlemen

It is my great pleasure to present to you, the GHTF Annual Report: 2001 - 2002.

In presenting this Report, I am continuing the tradition begun by the GHTF Chair during the 7th Conference in the USA. The purpose of the GHTF Annual Report is to share with you, the GHTF Membership, the major activities undertaken and the progress we have made since our last Conference. Importantly, my report will also focus upon the challenges we face as an organisation.

In January 2001, Australia (represented by the Therapeutic Goods Administration, TGA) assumed the GHTF Chair on behalf of the Asia/Pacific Region.

From September through to December 2000 my predecessor, Beth Pieterse, from Health Canada, undertook the necessary steps to ensure a smooth transfer of all GHTF records and responsibility, from Ottawa, Canada to Canberra, Australia.

An official transition meeting took place in Canberra during the first week of March 2001, immediately following the inaugural meeting of the GHTF Steering Committee. In July this year, a similar transition will begin as the GHTF Chair undertakes its next rotation from Australia to Japan.

Personally, it has been a pleasure, privilege and a challenge for me to Chair this important global forum on Australia's behalf. This has truly been an exciting period for the GHTF and Australia's term as Chair has been one of intense activity.

The GHTF has made many significant achievements in harmonising the international regulatory requirements for medical devices since its inception in 1992. As an organisation, the GHTF continues to evolve.

It is my hope that the work done during Australia's term as Chair will provide a number of new outcomes and achievements for the GHTF that will allow for its continued growth and evolution into the future.

Hosting of the 9th GHTF Conference in Singapore

Most of you will be aware this 9th GHTF Conference was originally scheduled to be held in Barcelona, Spain during October 2001, but was subsequently postponed due to the September 11 terrorist attacks in the United States.

I will diverge momentarily to reflect on these horrific events which have changed our lives forever. We all shared in the tragedy of a day we truly hope the world will never bare witness to again. The greatest impact was of course felt by our friends from the USA.

In those early, uncertain days, our hearts and feelings certainly went to our American GHTF colleagues, their families and friends - hoping that all were safe and well. It is so good to see so many of our American friends here in Singapore and I wish to extend our best wishes and on-going support to you all.

Following September 11, the Steering Committee decided to re-convene its scheduled meeting in London. During the Meeting, Members unanimously agreed to re-schedule the 9th Conference and asked that I raise the possibility of hosting the event in Singapore with Dr Clarence Tan, the Chief Executive Officer of Singapore's Health Sciences Authority (HSA).

Singapore is a travel hub in the Asia/Pacific Region and the countries of the Region with developing regulatory systems have demonstrated an enthusiasm for adopting the GHTF model. Whilst Australia is the current Chair of GHTF we hold it on behalf of the Asia/Pacific Region. The 6th GHTF Conference was held in Sydney and the GHTF Steering Committee felt it more appropriate to hold the Conference in a venue accessible collectively to countries in the region.

From Day 1, we have received tremendous support from Dr Tan and the team he assembled comprising HSA staff and representatives from the Medical Technology Industry Group of the Singapore Confederation of Industries. With this support, it has been possible for us to co-host the re-scheduled 9th GHTF Conference here in Singapore, and we are truly delighted to be here.

You will also be aware that the GHTF is co-hosting the 2nd APEC Seminar on the Harmonisation of Medical Device Regulations immediately following our Conference. This event is a GHTF training initiative which has been made possible through APEC funding and the generous commitment of GHTF Members, particularly those from the 4 study groups, in volunteering their time and expertise to participate as 'trainers' during the Seminar.

I have been delighted to find that most of you are, in fact, staying on in Singapore to attend this training seminar. There are approximately 150 registrants for the Seminar.

I would particularly like to thank my Steering Committee colleague, Mr Bob Britain and Mr Jeffrey Gren from the US Department of Commerce, for the work they have put into this event. Also thanks to Mr Craig Davies from the Therapeutic Goods Administration and Dr Clarence Tan and Mr Yew Sin Wong from the Health Sciences Authority, Singapore, for their hard work in putting the total program together.

In Memory of Mr Gordon Higson

2001 was marked by another sad event, which I had planned to mention to you in Barcelona. It was with great regret that I heard of the death of Mr Gordon Higson, who passed away on the 9th of August 2001.

This news saddened many of us in the GHTF community as Mr Higson was one of the original and principal founders of the GHTF. In addition, he was also the Director of the UK Department of Health's Scientific and Technical Branch, which was the predecessor of the current Medical Devices Agency.

Mr Higson was the first Chairman of the ISO Technical Committee, TC210, with which the GHTF now has a formal Memorandum of Understanding. Mr Higson also went on to be a success with Medical Technology Consultants and held numerous other positions that touched many people involved in the medical devices field.

Mr Higson's final piece of work was his latest book entitled, "*Medical Device Safety - The Regulation of Medical Devices for Public Health and Safety*". Mr Higson passed away while the book was in production, but it certainly represents a fitting memorial to him and should be of interest and value to those involved in the regulation of medical devices.

The book is available through The Institute of Physics Publishing, an organisation with offices around the world, including London and Bristol in the United Kingdom, and Philadelphia in the USA.

Mr Higson wrote the Preface of his book during February 2001 and I would like to share with you, part of what he has to say –

QUOTE:

"After spending some 30 years promoting international harmonization by participation in international standards committees, it is being involved in the initiation of the GHTF which gives me greatest satisfaction".

"The degree of commitment shown by the members has been remarkable and has led to the appearance, in an astonishingly short time, of a framework for an economical and effective world-wide system of regulation for medical devices. I am optimistic that the next decade will see such a system brought into widespread use. Gordon R Higson, February 2001".

On behalf of all representatives of the GHTF, I wish to pay tribute to Mr Higson's pioneering efforts towards the international approach to harmonising medical device regulatory requirements. I also warmly extend our belated sympathies to Mr Higson's family and close friends.

Other 'personnel' matters

The past 16 months has also seen the retirement of a number of key, long standing GHTF Members. These Members have either retired from the work force after long and distinguished careers, or moved onto other jobs not necessarily associated with the regulation of medical devices.

I wish to formally acknowledge the following people and place on the public record the GHTF's appreciation of their significant contributions to the organisation and international harmonisation -

- Robert Allen - former Chair of GHTF Study Group 4, from the UK Medical Devices Agency;
- Michael Baker - Director-General of EUCOMED;
- Dr Egid Hilz - a European industry representative from COCIR who has been a Member of three GHTF Study Groups and the Steering Committee;
- Dr Elizabeth Jacobson - a former GHTF Chair, from the US Food and Drug Administration;
- Dr Larry Kessler - former Chair of GHTF Study Group 2, also from the US FDA; and
- Beth Pieterse - another former GHTF Chair and my predecessor, from Health Canada's Medical Devices Bureau.

And following this Conference Jim Benson, representing the US Industry Group ADVAMED, will also retire.

GHTF Business Activities/Achievements

The remainder of my report will focus on the main business activities of the GHTF during the past 16 months. I would like to make specific reference to the following initiatives -

- Establishment of the GHTF Steering Committee;
- the GHTF Strategic Review;
- the Global Medical Devices Nomenclature (GMDN) and the GMDN Maintenance Agency Policy Group;
- Implementation of the National Competent Authority Report (NCAR) Exchange Program; and
- Consideration given to the establishment of a permanent secretariat for the GHTF.

GHTF Steering Committee

At the Ottawa GHTF Conference in September 2000, the GHTF established a Steering Committee, responsible for management oversight and policy setting for the organisation. The Steering Committee is now the GHTF's governing body and replaces the previous informal body, established under the US FDA's Chairmanship, which was known as the Ad Hoc Procedures Group.

Under the GHTF procedural rules, the Steering Committee comprises a maximum of 24 Members, consisting of 4 government regulators and 4 medical device industry representatives from the three major geographic regions, being North America, Asia-Pacific and Europe.

Under its chairmanship, Australia hosted the inaugural meeting of the Steering Committee in Sydney, Australia from 28 February - 2 March 2001. The second and third meetings have since been held in Brussels (during June 2001) and London (during October 2001). Of course, the Committee's fourth meeting has just been held as part of this Conference.

As a new governing body for the GHTF, I am sure my fellow Members would agree that the Committee has worked together very constructively in pursuit of the GHTF's international harmonisation goals.

GHTF Strategic Review

A major initiative of the GHTF during the past 16 months has been to undertake a strategic review of the organisation, leading to the subsequent development of a five year, GHTF Strategic Plan.

During the Strategic Review, the Steering Committee identified six key, strategic themes. The themes have been further refined and a number of goals and actions have been formulated as the core of our Plan.

The Committee has progressed a Strategic Directions document to a 'near-final' draft and this will be the subject of the next presentation by the GHTF Vice-Chair, Mr Brian Vale.

Global Medical Devices Nomenclature (GMDN) and the GMDN Maintenance Agency Policy Group

The GHTF recognises the significant achievement that has been made by the CEN-sponsored development of the Global Medical Devices Nomenclature (GMDN) system.

The nomenclature system will be of particular assistance to those countries with developing regulatory systems for medical devices. The GHTF also welcomes the creation of the GMDN Maintenance Agency Policy Group to continue work on the nomenclature. The Policy Group is chaired by Mr Maurice Freeman (who is also our Study Group 1 Chair) and the GHTF is specifically represented on the Group by Mr Don Boyer from Health Canada.

I am aware that some regulatory authorities are actively considering implementing the nomenclature and the GHTF encourages other participating regulatory authorities to undertake an evaluation of the GMDN within their own jurisdictions as soon as possible.

We urge that these evaluations be undertaken in partnership with the medical devices industry and in a manner that does not create a burden on the industry.

The Steering Committee believes the GMDN will be a major contribution to international harmonisation among regulatory agencies, particularly in vigilance and the worldwide registration of products.

Implementation of the National Competent Authority Report (NCAR) Exchange Program

The Steering Committee regulators have agreed the pilot 'vigilance exchange' scheme had been highly beneficial from a public health and safety perspective and has given 'in-principle' support to proceed towards full implementation of the scheme.

The Committee has already considered a proposal developed by Study Group 2 and raised a number of issues for further consideration, including -

- the various sources of incident reports;
- confidentiality of incident reports;
- how to ensure the most appropriate information is released at the most appropriate time; and
- criteria for accepting new participants into the scheme and training for these new participants.

These issues need to be further addressed before full implementation of the system can proceed. Study Group 2 is now working on a revised proposal for further consideration by the Steering Committee and we eagerly await further progress on this important post market initiative.

Consideration given to the establishment of a permanent secretariat for the GHTF

The question of whether or not to establish a permanent secretariat for the GHTF has been a long standing, unresolved issue.

The Steering Committee has spent a large amount of time considering the issue, but is yet to reach a final consensus on the most preferred, permanent model.

As you may be aware, the Secretariat currently rotates with each rotation of the Chair. To date, this system has worked well, but it is becoming increasingly difficult to continually move the Secretariat every 18 months, maintain efficiency of operations and maintain a 'corporate knowledge' base.

At its meeting which concluded on Monday, the Steering Committee gave further consideration to five possible options for the GHTF Secretariat, including retention of the current model.

I am pleased to report, the Committee has agreed to establish a small Working Group to further investigate the feasibility of establishing a single permanent location for the GHTF Secretariat.

There are different options to consider and the Committee has already identified a number of key issues to consider, including the hosting or location, governance and funding for a permanent secretariat. The Working Group will report back to a future Steering Committee meeting.

Other GHTF Activities

In addition to these major initiatives, since the 8th Conference in Ottawa, significant progress has been made with a number of other GHTF activities. These include -

- approval of more Study Group harmonised guidance documents as "proposed" and "final documents";
- the enhancement of our working relationships with the regional harmonisation groups from Asia and Central/South America;

- consideration of GHTF training initiatives, and Steering Committee and Study Group Members have continued to contribute to various training events around the world;
- monitoring the adoption of final GHTF guidance documents by each of the Founding Members;
- review and approval of the current Study Group Work Plans in conjunction with the Chairs of each Group;
- addressing a proposed merger between Study Groups 3 and 4; and
- consideration of a proposal for the GHTF to establish closer collaboration with the World Health Organisation (WHO).

4th Meeting of the GHTF Steering Committee

In addition to these GHTF business activities, I would now like to provide you with a brief update on the other major outcomes from the Steering Committee's fourth meeting which concluded here on Monday afternoon.

I have already addressed the GHTF Strategic Review and Permanent Secretariat. The Steering Committee also -

1. noted that final licences for use of the Global Medical Devices Nomenclature will be available in the near future;
2. approved as FINAL, the Study Group 4 Document - "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation";
3. approved the Study Group 2 Work Plan, including the new work item on postmarket surveillance studies;
4. approved as FINAL, the Study Group 2 Document, "National Competent Authority Report Exchange Criteria" (although this document will be subject to review as part of the finalisation of another SG2 document, N38);
5. noted recent reports presented by representatives of the regional groups from Asia and Latin America. You will hear more about their progress later this afternoon from Dr Clarence Tan and Mr Antonio Hernandez, but I would like you to know that the Steering Committee Members were highly impressed by the significant amount of progress which has been made by the Latin American countries with the adoption of GHTF guidance documents; and
6. agreed to give further consideration to GHTF involvement with EUCOMED's Global Standards Strategy Discussion Document.

The draft Minutes from our meeting will be prepared during the next few weeks and once accepted by the Steering Committee Members, the Minutes will be made available on the GHTF website.

GHTF Study Groups

As reflected by some of the GHTF's recent activities, the four Study Groups have continued to make significant progress with their substantial work programs which revolve around the development of harmonised guidance documents.

The Study Groups are fondly known as the 'engine room' of the GHTF and we are indebted to the tireless contributions of the Members of each Group. It is these efforts which assist the GHTF achieve its goals relating to international harmonization.

I thank all Study Group Members (and indeed their employers) for their on-going commitment to the GHTF. I would also extend a special vote of thanks to the four Study Group Chairs. These are the people who ensure progress continues on the important work items - Maurice Freeman (SG1), Kim Dix (SG2), Kimberly Trautman (SG3) and Horst Frankenberger (SG4).

Unfortunately, Kimberly and Horst were unable to travel to Singapore. Horst suffered a sudden and unexpected illness, and we wish him a speedy recovery. I would thank Dr Victor Dorman-Smith and Dr Markus Zobrist for agreeing to deputise as the SG3 and SG4 Chairs during the Conference at very short notice.

Looking to the Future

The past year has been one of accomplishments and has also seen the GHTF consolidate its previous achievements of **developing** a globally harmonised regulatory system for medical devices and implementing formal procedures for the on-going governance of the organisation.

I now turn to the theme of our Conference -

"The Global Medical Device Regulatory Model: From Development to Implementation".

Having developed the major pillars of the Global Model, the major challenge I now see is for the broad GHTF membership to start actively **implementing** the GHTF principles and final guidance documents into their national regulatory systems. This has commenced in some jurisdictions, but a significant amount of work is yet to be done before we are in a position to truly say the Global Regulatory Model has been **implemented**.

I am also very keen to see the interest already demonstrated by the Regional Harmonisation Groups continue. There has been significant progress made, with clear commitment being shown to the adoption of GHTF principles by countries with regulatory systems under development.

We all need to continue working together at both, the national and international levels in order to achieve our aims of further developing and implementing the Global Model in ways which harmonize our regulatory systems.

I would like to repeat one sentence of the earlier quote from Gordon Higson. In his book, Gordon has said -

"I am optimistic that the next decade will see such a system brought into widespread use".

Ladies and gentlemen, I commend this vision to you and look forward to much of this work continuing under Japan's leadership when the Ministry for Health, Labor and Welfare assumes the GHTF Chair later this year.

Closing Remarks

Ladies and gentlemen, in concluding, I hope you have found this Annual Report to be both, interesting and informative.

I wish to thank all Members of the GHTF Study Groups and the Regional Harmonisation Groups for their dedicated efforts in working cooperatively towards achieving the goals of the GHTF.

I also wish to sincerely thank the Members of the GHTF Steering Committee. A successful GHTF depends on team work and I am most grateful for the support I have received from my colleagues during Australia's term as GHTF Chair.

Thank you.

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