AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

ANNEX 6

DEVELOPMENTAL DIRECTION FOR THE AHWP COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

(For Discussion and Approval)

REPROT OF THE

12th AHWP Meeting

New Pride International
Convention & Exhibition Center
Chengdu West, PR China
26-27 October 2007

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Presented to AHWP Meeting on 26 Oct 2007

Aim

The aim of this paper is to seek AHWP member economies' approval for the direction of development for the AHWP Common Submission Dossier Template (CSDT)

Definition

(1) In this paper, the following definitions apply;

(i) AHWP Common Submission Dossier Template (CSDT) refers to the document titled "AHWP Common Submission Dossier Template version 1" dated 14 Sep 2006. The document is available from www.asiahwp.org/

(ii) GHTF STED document: refers to the document titled "Summary Technical Documentation (STED) [GHTF SG1/N011R17] for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices".

Introduction

(3) In order to meet its objective of developing a harmonised format for pre-market submission that is suited for use in AHWP Member Economies, WG01 of the Technical Committee (TC) has developed the CSDT.

(4) CSDT is a guidance document intended to be used by all medical device manufacturers (big & small) when submitting device information to the regulatory authorities of AHWP Member Economies.

(5) The proposed guidance document serves to provide guidance for submission of device information to the regulatory authorities; structured in the format of one common template acceptable by all AHWP member economies regulators. It is hoped that the eventual adoption of this guidance document in AHWP Member Economies will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities.

(6) CSDT can be construed to consist of two parts;

(i) components similar to GHTF's SG1 STED for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices; and

(ii) additional components containing useful information (eg an executive summary).

(7) CSDT applies to all products that fall within the definition of a medical device, as defined by GHTF Study Group 1 in document "SG1-N29R16:2005".

Challenges for Adoption of CSDT in Asian Economies

(8) One of the common challenges faced by regulators and industry alike revolves around the following issues;

(i) lack of understanding on the depth of technical details asked for in CSDT;

(ii) lack of understanding on the type of technical details asked for in CSDT;

(iii) lack of knowledge and experience in adopting an externally drafted document into current regulatory systems; and

(iv) lack of experience using the CSDT.

(9) Collectively, the aforementioned issues revolving around the lack of understanding, knowledge and experience with CSDT present challenges in its adoption in AHWP Member Economies .

Plausible Strategy for Determining Direction of CSDT and Its Eventual Adoption

(10) Besides the challenges presented by the issues mentioned in paragraph 8, AHWP has to make a collective decision on the plausible strategy to adopt as this will influence the direction of CSDT. The following strategies are proposed to the regional grouping for consideration;

Plausible Strategy	Measures / Tools Used	Advantage(s)	Disadvantage(s)
1) Revise the current CSDT and adapt for use in committed AHWP Member Economies	- Revise current CSDT to include examples of dossiers prepared in CSDT for various classes of devices - Solicit commitment from manufacturers and regulators to pilot adoption of CSDT in their current regulations - Continued engagement with GHTF SG1	- Builds upon foundation and understanding of CSDT in various Member Economies (e.g. ASEAN) - Implementation timeline dictated and within control of AHWP - Showcase example of regional harmonization	Non-harmonized pre-market submission format globally
2) Await publication of the revised STED document (in its draft form) before adopting a decision on the direction of CSDT	- Continued engagement with GHTF SG1	- Harmonized pre-market submission format globally	Delay in implementation of a harmonized common submission dossier template in Asia
3) Take a collective decision to adopt STED	- Continued engagement with GHTF SG1 - Discontinue the CSDT project	- Harmonized pre-market submission format globally	- Delay in implementation of a harmonized common submission dossier template in Asia - Implementation timeline in Asia is influenced by external factors beyond AHWP control

Conclusion

(11) With the increased visibility of AHWP on the global scene of medical device harmonization, and the expansion of its membership, this period in time presents the grouping with a window of opportunity to harmonize medical device regulations in one of the fundamental aspects of pre-market submission.

(12) To showcase to the world Asia's efforts in harmonization, commitment from regulators and industry alike is needed for this initiative to be successful.

This paper is submitted for Chairman and AHWP Member Economies approval, please.

AHWP Asian Harmonization Working Party
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Presentation to AHWP Meeting
Proposed Work Item for WG01

ADOPTING THE PRINCIPLES AND ELEMENTS OF CONFORMITY ASSESSMENT FOR MEDICAL DEVICES

REPROT OF THE
12th AHWP Meeting
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Alfred KWEK
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Objectives

(1) Proposed work item for WG01 (for AHWP Meeting approval)

(2) Commitment to share experience regulating medical devices

- Guidances (Nuts and Bolts)
- Experience sharing on implementation and interpretation of guidance (assembling a well-oiled machinery, using the nuts and bolts)

(3) Reach consensus on adopting the principles and elements of conformity assessment as a fundamental (starting point)

- The principles and elements of conformity assessment are similar to those recommended by GHTF for medical devices (including in-vitro diagnostic test kits), in GHTF/SG1/N40:2006 and SG1(PD)/ N046R3

Scope

Includes all products that fall within the definition of a medical device (including in-vitro diagnostic test kits). The GHTF definition of a medical device, as it appears in GHTF SG1-N29R16:2005.

Excludes discussion on;

- the form and route of conformity assessment for testing, inspection and certification;
- who undertakes and performs the task of conformity assessment (i.e. 3rd party review by conformity assessment bodies or review by regulatory authority); and
- the amount of information and data to be submitted for conformity assessment, as the risk class of a medical device increases

Elements of Conformity Assessment

Elements regulatory authorities may include in a conformity assessment system are;

(A) Conformity assessment of the quality management system:
1) a quality management system;
2) a system for post-market surveillance;

(B) Conformity assessment of device safety and performance:
3) summary technical documentation;
4) a declaration of conformity;

(C) Registration:
5) the registration of manufacturers and their medical devices by the regulatory authority.

Why the Need to Achieve Consensus on Conformity Assessment

Element	Description	Benefits to Member Economies
1	A quality management system	Emphasises that quality must be built into the device during the design and the production stage, as well as maintaining it throughout the entire product life cycle.
2	A system for post-market surveillance	To ensure the continued safety and performance of a device after it is placed on the local market. The obligation is on the manufacturers and its local authorised representative to have an effective post market surveillance system in place.
3	Summary Technical Documentation	Provides summarised technical data, in the format of the harmonised CSDT, for regulatory submission.
4	A Declaration of Conformity	Provides a legal basis and assurance when the manufacturer, or its local authorised representative, makes a declaration for a device product tested to an international standard, as well as meeting the local regulatory requirements.
5	Registration of manufacturers and their medical devices	In essence, to allow regulatory authorities to know “who” is selling “what” in their local markets. This is especially important for effective enforcement of local medical device regulations and the exchange of post market vigilance - information amongst AHWP medical device regulators.

Moving Forward

Moving forward, the proposal will require AHWP to:

- reach consensus on adopting the principles of conformity assessment as a fundamental (starting point);
- adopt the proposed elements of conformity assessment for medical devices;
- Commitment to share experience regulating medical devices (assembly of nuts and bolts into a machinery)

AHWP Asian Harmonization Working Party
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Presentation to AHWP Meeting
Proposed Work Item for WG01
IMPLEMENTATION PHASES AND TIMELINES

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Proposed work item for WG 01: AHWP Workgroup 1 Proposed Implementation Phases & Timeline (for AHWP Meeting approval)

CSDT

Draft Action Items	25/10/07 – 31/1/08	31/1/08 – 31/5/08	31/5/08 – 31/5/09	31/5/09
	Phase 1 • CSDT		**Phase 2** • Implementation	**Phase 3** • Review
Option One	• *2nd public consultation of CSDT draft version 2 (posted on AHWP website)* • Propose to AHWP Meeting to adopt the (AHWP – X) initiative for implementation	• Circulation (by email) of revised CSDT draft version 2 to TC members, based on feedback from 2nd public consultation • Circulation (by email) to all AHWP members economies for comments	• Implementation of CSDT in interested member economies, based on (AHWP – X) initiative.	• Review and revise
Option Two	• Await publication of GHTF STED document	• Member economies review STED for implementation feasibility • Implement GHTF STED document or CSDT?	• Implementation of GHTF STED or CSDT?	• Review and revise at next Meeting, whether to implement GHTF STED or CSDT?
	*25/10/07**	*31/1/08**	*31/5/08**	*31/5/09**

* Tentative dates

Conformity Assessment

Draft Action Items	25/10/07 – 31/10/09	31/10/09
	Conformity Assessment Implementation Guidance	Review
	Sharing of implementation experience (Based on Conformity Assessment Principle) – Guidance Document on Implementation • *Send formal request to AHWP Chair* • *Assessment by AHWP TC*	• Review and revise • Report to AHWP Meeting
	25/10/07	31/10/09

Note: Timeline not to scale