Progress Report of WG1a IVD medical devices - Subgroup

16th AHWP Meeting,

Indonesia , Bali - 8th -12th Nov,2011

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Agenda

- Introduction
- 2010- 2011 Work Plan
- Collaboration with GHTF
- Achievements and progresses
- Recommendations
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AHWP WG1a IVD Subgroup

Chair:	Eng. Essam Mohammed Al MOHANDIS Saudi Food & Drug Authority Kingdom of Saudi Arabia	Regulator
Co-Chair:	Mr. Jeffrey Jiin Feng CHERN Industrial Technology Research Institute Chinese Taipei	NON-Regulator
Member:	Mr. Lun AU YEUNG Medical Device Control Office, Department of Health Hong Kong SAR, China	Regulator
Member:	Dr .Phana CHHIENG Ministry of Health Cambodia	Regulator
Member:	Mrs .SAR Kuy HEANG Ministry of Health Cambodia	Regulator
Member:	Ms. Jeong Jin JO Korea Food & Drug Administration Korea	Regulator

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Member:	Ms. Pauline LAW Perkin Elmer Singapore	NON-Regulator
Member:	Ms. Maria Cecilia MATIENZO Department of Health Philippines	Regulator
Member:	Ms. Suhoung THITISATTHAYAKORN Medical Devices Control Division Food and Drug Administration Thailand	Regulator
Member:	Mr .Benjamin CHAN MediConcepts Ltd Hong Kong SAR, China	NON-Regulator
Member:	Mr .Alan CHANG Director of President Office Taiwan Medical and Biotech Industry Association Chinese Taipei	NON-Regulator

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Member:	Mr .Shekhar GANU Ortho-Clinical Diagnostics India	NON-Regulator
Member:	Mr. Bryan SO Hong Kong Productivity Council Hong Kong SAR	NON-Regulator
Member:	Mr. Ming-Che WANG Center for Drug Evaluation Chinese Taipei	NON-Regulator
Member:	Dr .Rama Sethuraman Health Science Authority Singapore	Regulator
Member:	Ms. Susan Chan Sanofi-Aventis Singapore	NON-Regulator

2010-2011 Work Plan

Work Item	Deadline
●Gap analysis of IVD medical devices regulations in member economies. ●Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF.	Mar 28, 2010 (Extended to Jul 31, 2010) **Achieved**
Liaise to GHTF in developing related documents on **clinical evidence** for IVD medical devices ,(Proposed Draft).	Jul 31, 2010 **Underway** (SG05 July 4th before SC,2011)
Liaise to GHTF in developing related documents on the **Essential Principles and labeling** of IVD medical devices,(DD).	Dec 31, 2012 **Underway**
Holding workshop on GHTF documents on IVD medical devices regulations .	The 2010 AHWP Annual Meeting (Nov 2010) **Achieved**
Feasibility study on the adoption of the **IVD STED, definition and concepts on clinical evidence** of IVD medical devices proposed by GHTF .	Sep, 2011 **Underway**

Collaboration with GHTF

- The subgroup has been cooperating with GHTF to review the following documents:
  - SG1-N45:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification.
  - SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices .
  - SG1(PD)/N063 "Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices" .

  Accepted as a final document by the Steering Committee - March 11, 2011 teleconference and posted on the GHTF website.

Collaboration with GHTF

- The subgroup has been cooperating with GHTF to draft the following documents:
  - "Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation" *(May,2011 Brussels meeting-PD).
  - "Clinical Evidence for IVD medical devices–Key Definitions and Concepts" (underway).

***Final draft guidance will be presented to SG05 for their comments and review by July 4th ,2011 before submitted to Steering Committee for endorsement .**

IVD Medical Devices Regulatory Elements and Related GHTF Guidance's

Regulatory Element	Status
Definition and Classification	SG1-N45:2008 (Final Document)
Conformity Assessment	SG1-N46:2008 (Final Document)
Declaration of conformity and Technical Documentation - STED	SG1-N63:2011 (Final Document)
Clinical Evaluation and Investigation	"Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation" (PD ,Final Draft)
	"Clinical Evidence for IVD medical devices–Key definitions and concepts" (Underway Draft)

Achievements & Progresses

Achievement

Work Item	Deadline	Status
●Gap analysis of classification and conformity assessment of IVD medical devices in member economies	Mar 28, 2010 (Extended to Jul 31, 2010)	Inputs from 5 member economies have been consolidated. Refer to Attachment 1 for summary . Half way Completed
●Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF	Nov,2011	

Achievement (2)

Work Item	Deadline	Status
Holding workshop on IVD medical devices regulations: ●Classification . ●Conformity assessment . ●Performance evaluation .	The 15th AHWP Annual meeting (Nov' 2010)	Dr. Petra Carls of SG1 IVD Subgroup was invited as trainer Completed

Achievement (3)

Work Item	Deadline	Status
Liaise to GHTF in developing the following documents: ●"Clinical Evidence for IVD medical devices–Clinical utility & performance evaluation" (PD-Final Draft) . ●"Clinical Evidence for IVD medical devices–Key Definitions and Concepts" (underway Draft)	Jul 31, 2010 (to the end of 2011)	Half way there

Progress (1)

Work Item	Deadline	Status
Liaise to GHTF in developing documents on the following : ●Essential principles for demonstrating the safety and performance of IVD medical devices. ●Labeling (including graphical symbols) of IVD medical devices	Dec 31, 2010 (Postponed, End 2012)	Underway: ▪ Conducting exercises on the EP for IVD medical devices, refer to Attachment 2 for details . ▪Continuously collect comments .

Progress (2)

Work Item	Deadline	Status
•Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF .	Sep, 2011	Underway

Recommendations

Recommendation (1

Conduct conformity assessment according to GHTF's proposal:

Conformity Assessment Element	Proposed Practice
Quality Management System	Establish QMS based on risk management .
Post-Market Surveillance System	Integrate as part of the QMS .
Declaration of Conformity	*Utilize the Essential Principles and Recognized Standards .*
Registration of Manufacturers and Their Devices	Follow specific practice in each country .
Technical Documentation	*Adopt IVD STED .*

Reference: SG1/N046：2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

Recommendation (2)

Use EP and recognized standards in the safety and performance evaluation of medical devices

STEP 1: Device classification	▪Determine the class of the device based on risks .
STEP 2: Conformity assessment	▪Determine the premarket and the post-market requirements of the device according to its class .
STEP 3: Safety and performance evaluation	▪Determine which essential principles (EP) should be used. ▪Locate appropriate recognized standards and/or other standards.
STEP 4: Technical Documentation	▪Prepare technical documentation based on the result of safety and performance evaluation

Refer to Attachment 3 as an example of the use of recognized standards in safety and performance evaluation.

Recommendation (3)

Preparation of Technical Documentation According to IVD STED

GHTF SG1-N63:2011

Summary Technical Documentation

For Demonstrating Conformity to Essential Principles of Safety and Performance of IVD Medical Devices

Refer to Attachment 4 for the use and contents of IVD STED.

Future Works …

- **Collaborating with GHTF to:**
  - **revise EP and labeling requirements for IVD medical devices.**
  - **establish methods of clinical evaluation and justification of clinical evidence for IVD medical devices .**

For the sake of new GHTF re-structure , all the work should be concludes by end of Dec, 2012 .

Future Works …. Cont.

- **Support guiding AHWP member economies to :**
  - **use EP and recognized standards to conduct safety and performance evaluation for IVD medical devices .**
  - **use STED to consolidate technical documentation .**
  - **draft guidance and templates if necessary .**
- **Other new working item plans**
  - Open for new ideas .

Commitment

Multidisciplinary integration

Involvement of member economies


Thank You