Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

Update from AHWP TC Officer Bearer

Joanna Koh, Ali M. Al-Dalaan, Daphne Yeh

November 4th, 2009
Hong Kong

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Update from TC

- **New TC Chair**

Joanna Koh, Director, Medical Device Branch
Health Products Regulation Group, HSA

- **New TC Work Group 1 Chair**

Marianne Yap, Senior Researcher, Medical Device Branch
Heath Products Regulation Group, HSA

- **Periodical Telcon among TC WG Leaders**

Linkage among TC officer Bearer (3), WG leaders (15), TC Secretary (3), AHWP Secretary (3), Total 25 members.

- **Linkage with GHTF SG members**

Encourage each AHWP WG establish linkage with GHTF SG
e.g. SG1 invited 2 more AHWP participants, set up SG/WG joint t-con

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Update from AHWP TC WG01

Marianne Yap
Daphne Yeh

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Update from WG01

Hand out Material:

AHWP Initiated Project

- **CSDT Guidance Document for comments**

GHTF Final Guidance Documents are subject to review and revision every three years.

- **SG1 Document: Classification of Medical Device for comments**
- **SG1 Document: Conformity Assessment for comments**

Update from WG01

Update from GHTF SG1 meeting Feb, 2009 in Sydney

- Invited by TGA and Australia industry
- **15 representative attended**. Daphne Yeh as AHWP representative attended.
- **Key Topics:**
  - Definition of Manufacturer
  - Registration of manufacturers and Listing of Medical Device (N065, review of proposed document
- **Follow Up Action: Survey on Definition of Manufacturer**

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Update from WG01

Proposed WG01 Survey: Definition of Manufacturer
Background: Gap Analysis on current APAC country regulation and GHTF SG1 document

a. Definitions of manufacturer. (Medical device regulation)

b. Requirement of Country of origin (Trade regulation)

c. Required information on registration of manufacturer and listing of medical device (is it required for manufacturer, actual manufacturer, or both?)

d. Required information on CFG or FSC (is it required for manufacturer, actual manufacturer, or both?)

e. Requirements of quality management (Is it required on manufacturer, actual manufacturer, or both?)

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Update from WG01

Update from GHTF SG1 meeting Oct. 13-16, 2009 at Brussel

- Ms. Sabine Lecrenier, EU Commission and Head of Unit for Medical Devices and Cosmetics, welcomed the SG1 and informed that SG1 work is very important for Europe in the context of the MDD recast.

- **13 representative attended**. Daphne Yeh represent AHWP attended

- **Key Topics:**
  - Labeling of Medical Device (revision of N043:2005)
  - Registration of manufacturers and Listing of Medical Device (N065, review of proposed document

- **Follow up action: Getting inputs on labeling document**

- **Next Meetings:**
  - Jan. 26-29 2010, Sao Paolo, invited by Abimed
  - May 18-21, 2010, Tokyo, invited by MHLW
  - Oct. Date TBD, Cologne, Germany, invited by European industry.

Update from WG01

SG1 Working Document:
Label and Instructions for Use for Medical Devices

a. Where national legislation, such as customs statutes and trade agreements, includes a requirement to indicate the 'country of origin' of the medical device, it should be noted that this will not necessarily align with the country location of the manufacturer (as defined in GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*) indicated in the labelling (see Section 5.2.1a).

Update from WG01

SG1 Working Document:
Label and Instructions for Use for Medical Devices

b. For imported devices, the name and postal address of either the authorised representative or importer established within the importing country/jurisdiction. This information may be added to the labelling by the authorised representative or importer itself rather than be provided by the manufacturer, in which case, the additional label must not obscure any of the manufacturer's labels.

REQUEST FOR PUBLIC COMMENT – Should this information be provided on a label or is it sufficient for the Regulatory Authority to hold this information on a database?

And there are more seeking for comment…

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Other Matters Discussions

Proposal of a nomination process to select APWP Representative to attend GHTF SG Meeting

Criteria of Candidates:

1. Nominated by AHWP member economies (both Regulator and Non-Regulator)
2. Commitment to attend the SG1 meeting, study SG1 document and contribute to AHWP WG discussions.

Nomination and Resolutions

1.Candidate list collected by WG leaders
2.Evaluate and approve by AHWP TC Chair

Current Case

Nomination of (1) Regulator and (1) Non-Regulator to attend the GHTF SG1 Meeting from Jan 2010

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THANK YOU!