Outlines of AHWPTC WG Documents towards Endorsement

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ASIAN HARMONIZATION WORKING PARTY

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White Paper on Medical Device Software Regulation – Software Qualification and Classification

WG 1 – Pre-market: General MD

Chair: Ms. Ming Hao TAN Co-chair: Mr. Alfred KWEK

- **Scope of paper:** Types of software used in healthcare and their regulatory controls in various identified countries/ jurisdictions (Australia, China, European Union, Canada, Japan, USA)
- **Objective of paper:** Identify harmonized regulatory elements in qualification of software as a medical device (SaMD), to aid in development of AHWP technical guideline to harmonize controls across member economies.
- **Summary:**
  (i) Harmonized elements were identified across regulatory agencies in qualifying SaMD
  (ii) Majority of such guidelines specify classification assignment based on intended purpose and degree of risk the user(s) is/are exposed to
  (iii) Qualification guidelines are not (yet) completely uniform across countries/jurisdictions
  (iv) AHWP aims to align as far as possible to global harmonization or convergence of SaMD guidelines

Summary of Findings

- **Overall guiding principle in SaMD qualification:**

  Software that does not fall under the definition of a medical device is not subject to regulation as such.
- **Further guidelines in SaMD qualification (across RAs referenced):**

Software Type *	Qualification
Hospital Information Systems (HIS) or Workflow Management Systems	**Non-medical device**
Electronic Health Records	**Non-medical device**
General well-being software	**Non-medical device**
Communication Systems for patient monitoring	**Qualification varies**
Communication Systems for controlling medical devices	**Medical Device**
Decision Support software	**Medical Device**

** Note: Refer to white paper (www.ahwp.info) for further definition & elaboration of each software type*

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Comparison between Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices

WG 2 – Pre-market: IVDD

Chair: Ms. Emily WU

- **Scope of paper:**
  - This document applies to all products that fall within the definition of *In Vitro Diagnostic (IVD) Medical Device*.

- **Objective of paper:**
  - The availability of summary technical documentation in an agreed format should help eliminate differences in documentation requirements between jurisdictions, thus decreasing the cost of establishing and documenting regulatory compliance and allowing patients earlier access to new technologies and treatments.
  - This document is intended to provide information on the differences between the recommended content of the ASEAN CSDT for IVD medical devices and the GHTF STED for IVD medical devices to support building AHWP guidance for common submission file for IVD medical devices.

- **Summary:**
  - The document contains the comparison table between the two documents. The core content of each document is the required content of the technical documentation to be submitted to a regulatory authority. In this respect, the ASEAN CSDT for IVD medical devices contains detail which may enhance the GHTF STED for IVD medical devices; the combination of the two documents form the basis of the AHWP recommendation for a common submission file for IVD medical devices.
  - The CSDT incorporates the requirements for labeling and instructions for use, as well as for clinical evidence. The GHTF includes these requirements as headings only, with the detailed requirements included in separate guidance documents.

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Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative

WG 4 – Post-Market

Chair: Ms. Jennifer MAK Co-chair: Ms. Kitty MAO

- **Scope of paper:** Adverse Event Reporting Timelines

- **Objective of paper:** To provide guidance and information to Regulatory Authorities and the Medical Device Industry on the adverse event reporting timelines

- **Summary:** The guidance suggests adverse events that resulted in
  (i) Serious public health concern shall be reported within 48 hours; and
  (ii) Death or serious injury shall be reported immediately, but not later than 10 elapsed calendar days following the awareness of the event.
  (iii) All other reportable events shall be reported as soon as possible, but not later than 30 elapsed calendar days following the awareness of the event.

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Guidance on Medical Device Quality Management System – Requirements for Distributors

WG 7 – Quality Management System: Operation & Implementation

Chair: Mr. Ali M AL-DALAAN Co-chair: Mr. Ee Bin LIEW

Scope of the document

- All AHWP member economies, for organizations that distribute or import medical devices

Objective of the document

- To provide medical device distributor as well as importer of AHWP member economies with the guidance on the implementation of quality management systems to ensure their conformity with ISO 13485: 2003 expectations.

Summary

- The distributor must ensure the products meet the requirements specified by regulatory authority and the manufacturers when they distribute, deliver or service medical devices.
- The safety and performance of finished medical devices may be affected by various conditions such as warehouse conditions, transportation, installation, servicing, duration of storage, and user training. Post-market surveillance activities such as collection of customer feedback, implementation of field safety corrective actions for the associated medical devices may be conducted by the manufacturer through cooperation with its distributors.
- To ensure the medical device continue to comply with the specifications and quality assurance requirements specified by the manufacturer, AHWP TC WG3 developed this guidance for organizations that distributes or import medical devices.
- Another purpose of this guidance document is to assist regulatory authorities and/or conformity assessment bodies in the planning and the performance for regulatory auditing of the distributors under their jurisdiction.
- This document provides guidance on the applicability and implementation of ISO 13485: 2003 clauses for medical device distributors.

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Role of Standards in the Assessment of Medical Devices

WG 8 – Standards **&** ***WG 2 – Pre-market: IVDD***

Chair: Mr. Lupi TRILAKSONO
Co-chair: Mr. Tony LOW

Chair: Mr. Emily Wu

- **Scope of paper:**
  - This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*.
- **Objective of paper:**
  - To:
    - encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the *Essential Principles of Safety and Performance of Medical Devices*;
    - encourage manufacturers to conform with appropriate standards;
    - persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the Essential Principles;
    - support the concept that in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.
- **Summary:**
  - The present guidance services as recommendation to Regulatory authorities, Conformity Assessment Bodies and Industry on the principle of appropriate use of standards in the assessment of medical devices from the development of recognition of standards, the use of these standards during and after the transition period, revision of standards, and thereby the changes of the status, status of devices designed using recognised standard before the end of transition period and alternatives to recognised standards.

THANK YOU