WG1 – Pre-Market Submission and CSDT

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Co-Chair: KWEK, Alfred

Secretary: YAN, Carol

No. of Active WG members: 35

Content

- Status of previous WG items (completed)
- Work Plan in Progress (ongoing & new)
- Progress Updates

Status of Previous WG Items (Completed)

No.	Previous Work Item	Status
1	**Mapping of CSDT to STED**	Completed mid 2012 Information published on AHWP website *AHWP/WG1/R001:2012*
3	**Review of amended GHTF definition of medical device**	Completed end 2012
4	**Introduce software overview** **Training on Medical Software**	Completed mid 2012 Catered for training on software in Manila meeting (Jun 2012)

Work Plan in Progress (Ongoing & New for 2014 onwards)

No.	Work Item	Deliverables	Action Plan & Timeline
1	**Gap analysis in pre-market aspect for ASEAN medical device control harmonization**	Identification of areas in need of guidelines (e.g. Grouping, borderline product classification) Appointment of a dedicated sub-group team to carry out process	Ongoing Ongoing
2	**Medical software guidelines for pre-market registration**	Summary of current classification practices in regulatory agencies, globally Draft guidelines for software classification (MD or non-MD) for harmonization circulated for comments Publish guidelines on classification	Q1 (Mar) 2014 Q2 (Jun) 2014 Q3 (Sept) 2014
		Summary of current pre-market submission guidelines in regulatory agencies, globally + identification of standards Gap analysis and proposal of pre-market registration guidelines on best practices	Q4 (Dec) 2014 Q1 (Mar) 2015

Work Plan in Progress (Ongoing & New for 2014 onwards)

No.	Work Item	Deliverables	Action Plan and Timeline
3	**Combination products (Medical Device) guidelines**	Information gathering on combination product classification & review practices in ASEAN and IMDRF member economies	Q1 (Feb) 2014
		White paper on summary of combination products guidelines in AHWP and IMDRF jurisdictions	Q1 (Mar) 2014
		Gap analysis & circulation of draft AHWP guidelines for comments	Q2 (Jun) 2014
		Publication of guidance	Q4 (Dec) 2014
4	**Medical Device Grouping guidelines (new)**	Data search on jurisdictions that currently have grouping guidelines & tabulate and present results	Q2 (Jun) 2014
		Identify best practices & perform gap analysis of guidelines. Road map proposal to bridge the gaps – Position paper	Q3 (Sept) 2014
		Propose a guideline document	Q2 (Jun) 2015

Work Item: Combination products (Medical Device)

Approach

- Research
  - Not a survey!
  - Questionairre + published info + telephone interviews
- White Paper
  - Current practices
  - Common challenges
  - Recommended solutions
- Guidance draft

	Formal Definition in Regulation	Formal Status Determination Mechanism	Separate Co-ordination body	Evaluation Process	Evaluation Agency	Fees	Manufacturing Controls	Labelling	Postmarket Reporting	Clinical Trials	Clinical Data Requirements	Planned Changes
USA	Y		Y									
EC	N	Y	N	C	P	C	C	C,X	P	P	P	R
AUS	N	Y	N	C	P	S	C,S	P,X	P	P	P	
JPN	N	N	N	P	P	P	P	C,X	P	P	P	
CAN												
CHN	Y	Y	Y	P	P	N	C	C	U	P	P	R
SIN												
INA												
KOR												
HKG												
TPE	Y*	Y*	N	P	P	P	C	C,X	P	P	C	G
THA												
MAS	N	Y	Y	D	P	D	P	U	P	C	P	R,G
KSA	Y	Y	Y	P	P	P	P	P	P	P	P	R

Key:
Y: Yes, N: No
P: Regulations or practice applicable to PMOA applied
C: Regulations for all components applied
L: Review coordinated by Lead agency
D: Regulations under development
S: Special Fees for combination products
X Cross labelling requirements for co-dependent products
R: Changes to Regulation
G: Changes to Guidance
U: Undefined – no regulation or guidance established
*Guidance in preparation

Key Issues

- **Need for coordinating (adjudicating) agent**
- **Application of manufacturing and clinical trials controls – ISO, ICH or both**
- **Above all ensure necessary expertise is brought to bear**
  - *ensure public safety*
  - *ensure reviews are appropriate and based on required expertise*
- **Postmarket requirements almost always follow PMOA.**
  - *This presents a possible risk of overlooking safety issues.*
- **Technical dossier format**
  - *CTD or STED/CSTD.*
  - *Note IMDRF plans to align STED with CTD*

Work Item: Environmental Scan Update on Software

Software

Completed

- Environmental scan done & presented at AHWP Manila meeting (attached)
- Environmental scan updated due to recent global developments in medical device regulation, especially **standalone software**

Pertinent to keep this on-going due to rapid technology development & updates by other agencies and the IMDRF

- Software white paper on scan
  - Classification of software (MD or not MD) **done**

In Progress

- Software white paper on environmental scan and identification of best practices for adoption
  - Classification of software (MD or not MD) **done**
  - Titration of controls
  - Submission requirements (CSDT and change control)

Future work (long-term)

- AHWP WG1 Guidance document on software classification and review

Update on
4 Dec 2013

Scope

- Examples of medical-related software
- Regulation of software in US FDA, Health Canada, EU and Japan **[update on 4 Dec 13]**
- Existing standards for medical device software **[update on 4 Dec 13]**
- IMDRF Standalone Medical Device Software Working Group **[update on 4 Dec 13]**

US FDA Recommendations

Update on 4 Dec 2013

Guidance for Industry and FDA Staff – Mobile Medical Applications

- Draft of guidance issued on 21 July 2011
- Final guidance issued on 25 Sep 25, 2013 **[Update]**

Objective:

- Clarify the subset of mobile apps to which the FDA intends to apply its authority

Content of Guidelines:

- Definition for “Mobile Platform”, “Mobile Application”, “Mobile Medical Application”
- Defines broad criteria for mobile apps to be regulated as “Mobile Medical Application” – if meets statutory definition of a device
- Provides examples of mobile apps that (a) are not controlled as MMAs, (b) fall under the device definition but enforcement discretion is exercised
- Regulatory requirements for MMAs (Class I, Class II, Class III devices respectively)

EU Recommendations

Update on 4 Dec 2013

- European Commission looking to publish an updated version of MEDDEV 2.1/6
- Update should include:
  - improved definition of standalone medical software
  - additional examples of software that is an IVD device
- 2014 - foreseen to start with an elaborate revision of the MEDDEV 2.1/6, possibly taking into account concepts to be introduced in the new European MD regulation

Update on
4 Dec 2013

Updates on China

- Published submission requirements for medical device registration for the following defined software categories:
  - Standalone software
    - the software itself is a medical device or accessories, such as processing-type software and data-type software;
  - Software as component (Embedded Software)
    - the software is the constituent part of the medical devices, components or accessories, such as embedded software and controlling software;
  - Specialized software
    - other software for specific purposes, such as custom-made software.

Retrieved from CMDE, SFDA website on Apr 2012

Updates on Japan

Update on
4 Dec 2013

- Standalone computer-aided diagnosis software currently classified as medical devices under the revised Pharmaceutical Affairs Law (PAL), following cabinet decision on July 10th 2012

- Update on Nov 2012, Japanese industry associations (JIRA/JAHIS/JEITA) formed a joint work group aiming to make recommendations on the range of the regulations on software

IMDRF Standalone Medical Device Software Working Group

Update on 4 Dec 2013

- Project started by IMDRF on medical software
- Draft guidance currently out for *Standalone Medical Device Software: Key Definitions (7 June 2013)*
- Definitions provided:
  - Standalone medical device software
  - Medical purpose (for software – GHTF MD definition)
  - Software changes
  - Standalone Medical Device Software manufacturer
  - Intended use / intended purpose

Update on 4 Dec 2013

Available Standards

- IEC 60601-1-4:1996, *Medical electrical equipment, Part 1: General requirements for safety, 4. Collateral Standard: Programmable electrical medical systems. International Electrotechnical Commission, 1996.*
- IEC 62304:2006, *Medical device Software – Software life cycle processes. International Electrotechnical Commission, 2006.*

Draft of IEC 62304 Amendment 1 open for comments till end of 2013

- IEC 82304-1 Ed 1 - *Health software - Part 1: General requirements for product safety*
- IEC 61508:1998, *Functional safety of electrical/electronic/programmable electronic safety-related systems. International Electrotechnical Commission, 1998.*
- IEC 62366:2007 - *Medical devices - Application of usability engineering to medical devices.*
- ISO 14971:2007, *Medical Devices – Application of risk management to medical devices*
- ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*
- ISO/IEC 25000:2005, *Software Engineering – Software product Quality Requirements and Evaluation (SQuaRE) – Guide to SQuaRE*
- ISO/IEC 25051:2006, *Software engineering – Software product Quality Requirements and Evaluation (SQuaRE) – Requirements for quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing*

IEC 82304-1

Update on
4 Dec 2013

- Under development as future health software product safety standard
- Scope (health software products) is intentionally chosen to be wider than "just" medical software, in consideration that the term varies with time and jurisdiction

Work Item: Medical Device Grouping (Pre-market submission)

GROUPING GUIDELINES AIM & OBJECTIVE

Aim

Publish a position paper that identify strengths/weaknesses of grouping guidelines in different jurisdictions

Objective

Put forth a guideline for grouping of medical devices, for the purpose of pre-market MD registration in ASEAN member states that allow groups of devices to be submitted in a single pre-market dossier which will effectively contribute to cost-saving on pre-market registration for medical device companies, facilitate faster access for new MD to the market and streamline review processes for the regulator

Guideline document for grouping of medical devices can also cover the following:

- Advantages (risk / cost-benefit)
- Defined examples/situations
- Unidentified or further expected (but unresolvable) risk

GROUPING GUIDELINES STAGE I (Current)

Data search:

- **Benchmark** in order to Identify the Jurisdictions that currently have grouping guidelines which are officially published (Canada, FDA, Australia, UAE, Singapore, Saudi Arabia, Malaysia etc…)
- **Review existing industry/consultants** feedback or proposal
- **Seek consultation from experts** for unpublished / nonexistent data
- **Identify best practices for grouping** of MDs and set them as a target for the gap analysis
- **Tabulate and present**

Thank You