Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

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4-8 December, 2017 I New Delhi

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Work Group 4 Post-Market Work Progress Report

Chair: Ms Jennifer MAK (Dept of Health, HKSAR)

Co-Chair: Ms Kitty MAO (GE Healthcare, Singapore)

Advisors: Dr Jorge GARCIA (TGA, Australia)
Ms Joanna KOH (Singapore)

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Updates (1)

- No. of WG members: **17** (excluding chair and co-chair)
  - **3** from **Regulatory Authorities** (Hong Kong, Korea and Saudi Arabia)
  - **14** from **Industry** (Chinese Taipei, Hong Kong, Korea, Malaysia and Singapore)

Updates (2)

- Activities
  - Review of WG4 work plan & identification of work tasks in 2017
  - Formation of 3 task teams each working on a 2017 work task
  - WG telecons held on 11 May and 26 Oct 2017
  - Presentation of WG4 work and SADS at APEC Harmonization Centre Medical Device Vigilance Workshop in Seoul in Sep 2017
  - Progress summary on WG4 matters for WG members (23 Dec 2016, 11 Jan, 20 Feb, 22 May, 24 Jul, 22 Sep & 31 Oct 2017)

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Work Plan 2015 – 2017 (1)

Priority	Work Item	Deliverables	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	Revised Guidance Document	**2016** (completed)
2	Review the Safety Alert Dissemination System (SADS)	Review Report	**2015** (completed)
3	Arrange Post-market Surveillance (PMS) Training	Training Sessions	**2015** (completed)
4	Develop guidelines on Adverse Events (AE) reporting details for specific type of devices	Guidelines	**2016** (completed)
5	Review and update the existing WG4 guidance documents on SADS	Revised Guidance Documents	**2016** (completed)

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Work Plan 2015 – 2017 (2)

Priority	Work Item	Deliverables	Timeline
6	Develop guidance document for Adverse Event Trending based on GHTF documents	Guidance Document	**2016/2017** (Withdrawal)
7	Develop guidelines on proper handling of medical devices after complaint and AEs	Guidelines	**2016/2017** (Withdrawal)
8	Conduct a post-market survey (including both reportable AEs and FSCAs)	Survey Report	**2017** (to be completed)
9	Identify post market systems (AE or safety alert) or guidance from various regulatory authorities and web sources	Hyperlinks for sharing to be provided at the AHWP website	**2016** (completed with on-going updates)

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WG4 Progress Update

since last AHWPTC Meeting in Mar 2017 (Hong Kong)

No.	Work Item	Status	Achievements	Timeline
1	Conduct a post-market surveillance system survey	**Completed**	Completion of survey report and results presented at the AHWPTC Workshop and reported at the AHWPTC Meeting	**2017**
2	Analyze global and local adverse event reporting practices	**Completed**	Results reported at the AHWPTC Meeting	**2017**
3	Update the post-market resource centre	**Completed with on-going updates**	The hyperlinks of the post-market resource centre updated and submitted to Secretariat for sharing at the AHWP website	**on-going from 2016**

Post-market Survey (1)

- **Scope**
  - Post-market surveillance system implemented in different jurisdictions
- **Objective**
  - Provide information on the latest development of post-market controls in different jurisdictions
  - Three fundamental elements will be covered in the survey:
    1. Adverse Event Reporting
    2. Product Recall
    3. Field Safety Corrective Actions (FSCA)

Post-market Survey (2)

Survey Method

- The survey was conducted during July – September 2017
- Questionnaire was prepared in both hard copy and online version and sent out to AHWP primary representatives (26 AHWP members) via AHWP Secretariat
- Representatives from other jurisdictions were also reached out for returns in different occasions during the period (Australia, Europe, Germany, Japan, Papua New Guinea, Peru and USA)

Post-market Survey (3)

Survey Results

- 20 survey returns received from **13 AHWP member economies** and **7 non-AHWP jurisdictions**
  - **AHWP member economies** – Abu Dhabi, Chile, Chinese Taipei, Hong Kong SAR, Indonesia, Kingdom of Saudi Arabia, Malaysia, Philippines, Republic of Korea, Singapore, Thailand ad Yemen
  - **Non-AHWP Jurisdictions** - Australia, Europe, Germany, Japan, Papua New Guinea, Peru and USA

Post-market Survey (4)

- **Survey Results** (Cont'd)
  - Highlights of the survey shared during the session **"Post-market Surveillance of Medical Devices - How far have we gone towards Harmonization?"** at the TC workshop
  - Details available in the AHWP Document **"AHWP Post-Market Surveillance (PMS) Survey Report 2017"**

Analysis on AE Reporting Practices (1)

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Analysis on AE Reporting Practices (2)

- Analysis Roadmap

Brainstorming & Formulate Work Item	Develop Questionnaire	Execute Survey	Process & Analyze Data	AE Analysis
Jan-Feb 2017	Mar-Apr 2017	May-Sep 2017	Oct-Nov 2017	Dec 2017
	• WG4 Develop Qs. • TC Chairs & Advisors give feedback • Finalize Qs • Build up e-survey	• AHWP Secretariat distributes Qs; • Korea MFDS broadcast in AHC	• WG4 collect, process, analyze data; • Circulate draft analysis for comments/feedback	

Analysis on AE Reporting Practices (3)

- Project Objective
  - **Assess** Post-Market reporting **framework** across jurisdictions globally, **provide analysis and considerations** on common practices. This provides an **information platform** for member economies to **identify best practices for their system.**

On-Line Survey Form

Please fill in accordingly:
* Member Economy

* Organization

* Contact Person

* Contact E-mail

* Q1. Are medical device regulatory controls currently legislated in your jurisdiction?
- ☐ Yes
- ☐ No (Please select i or ii or iii)
- ☐ i. Currently there is no medical device regulatory controls
- ☐ ii. But plans underway for legal regulations (estimated effect date of the medical device legislation: Please specify the number of years in the box provided below)
- ☐ iii. But there is a voluntary regulatory system and plans underway for legal regulations (estimated effect date of the medical device legislation: Please specify the number of years in the box

Please specify:

Analysis on AE Reporting Practices (4)

- Background
  - Total survey response: 20
  - Fully implemented AE reporting: 13
    - >10 years of mandatory AE reporting: 7
    - <10 years of mandatory AE reporting: 6
  - Analysis based on 13 countries' data, countries represented by letters, which do not correspond to country names

Analysis on AE Reporting Practices (5)

- If a country requests global AE data, the same country also performs AE trending ?

	Performs AE Trending	Does **NOT** Perform AE Trending
Request **Global** AE data	A*, B*, C*, E*, I	-
Request **Regional** AE data	-	F, J, K
Request **Local** AE data	G*, H*, M, L*	D

Legend:

Majority manufacturer

Majority importer

Based on 13 Responses

* Agencies that have implemented AE reporting for >10 years

Analysis on AE Reporting Practices (6)

- **What** is AE Trending?
  - Trend analysis, obtained by calculating and observing **rates of events over time**, can **identify significant changes that suggest new problems** (or, if improving, that safety measures are working). Trends can also be detected using statistical control methodologies. These assist a particular organization in discerning whether its own trends when **compared with benchmarks**, are attributable to what is known as "special cause" variation, rather than stemming from normal process fluctuations.

Sources:
WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005

Analysis on AE Reporting Practices (4)

- **Why** do AE Trending?
  - Presents a **new piece of information** about a device or its **performance in a clinical setting**
  - May indicate **underlying change in the performance** of the device or in its use by clinicians, patients or other customers.

Sources:

GHTF SG2 - Manufacturer's Trend Reporting of Adverse Events - January 2003

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Analysis on AE Reporting Practices (5)

- **How** to do AE Trending?

$$\text{Observed Incidence (\%)} = \frac{\text{Number of events } (n)}{\text{Used product volume in the market (by clinicians / patients) } (d)}$$

calculated for each *t*

- **Baseline** – risk analysis, dependability & reliability testing, historical data, medical and scientific publications
- **Threshold** – upper value of the normal range of variation that specifies the trending (depends on product category)

Source: GHTF SG2 - Manufacturer's Trend Reporting of Adverse Events - January 2003

Analysis on AE Reporting Practices (6)

- Number of Officers ***vs*** Number of AE Reports and AE Trending

Number of AE reports received annually

Number of officers	<100		100-800			3,000-5,000			~50,000
< 10	I	M	L*	J	D	C*	K		
10-25							G*		
25-50									B*
50-100								E*	
>100									

Only 10 Valid Responses
**Agencies that have implemented AE reporting for >10 years*

Legend:
- no AE trending
- AE trending
- Global reporting

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Analysis on AE Reporting Practices (7)

- ***Best Practice*** *(for consideration)*: Local Reporting → Trending

Local Report

Ref. agency trend info.

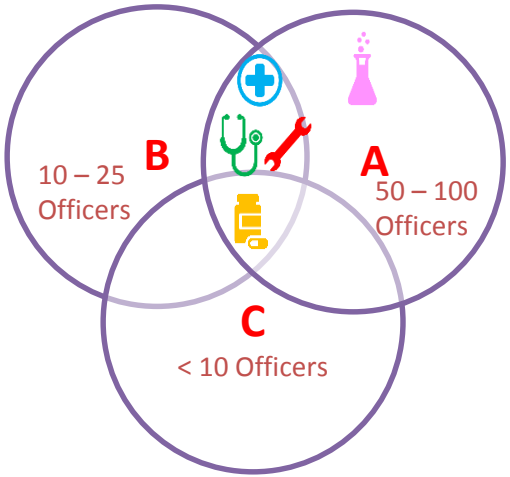
Local Analysis

1. Target audiences
2. Product Details
3. Purpose of communication
4. Summary of problem
5. Recommendation to users & patience
6. FDA Activities

Analysis on AE Reporting Practices (8)

- Education/professional backgrounds of the officers involving in AE

Global Reporting + Trending



Local Reporting + Trending

Legend:

- Pharmacist
- Medical Practitioner
- Nurse
- Engineer
- Scientist

Scope: 6 Valid Responses; Agencies that have implemented AE reporting for >10 years

Analysis on AE Reporting Practices (9) - Conclusion

- Reference for planning for regulatory framework (i.e manpower & capability)
- Smart regulation
  - ✓ Balancing resources with critical needs
  - ✓ Leveraging on work done by reference agencies
- Risk-based regulation, allows patient access to safe and quality products while NOT introducing unnecessary regulatory burden to stakeholders.

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Thank You