Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Update on Work Group 4 Post Market

26th GHWP Annual Meeting

15 Feb 2023

Riyadh, The Kingdom of Saudi Arabia

WG 4 Post Market (1)

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Chair: Mr. Yorkie CHOW (Medical Device Division, Department of Health, Hong Kong SAR, China)

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

Advisors: Dr. Jorge GARCIA (Medical Devices Branch TGA, Australia)

Ms Joanna KOH (Mdnet Regulatory Consultants, Singapore)

WG 4 Post Market (2)

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Regulator

1.	Ms. Aisha AL-GHAITHI	Sultanate of Oman
2.	Mr. Ahmed ALQARNI	Kingdom of Saudi Arabia
3.	Mr. Alex CHOI	Hong Kong SAR, China
4.	Ms. Althea LAU	Hong Kong SAR, China
5.	Mr. Karl LEUNG	Hong Kong SAR, China
6.	Ms Nancy PRESSLY	United States of America

Medical Device Industry

1.	Ms. Chueh-pin CHEN	Chinese Taipei
2.	Ms. Judy CHEUNG	United States of America
3.	Ms. Jacqui CUI	People's Republic of China
4.	Ms. Laleetha DEVI	Malaysia
5.	Mr. Prashanth SRIRANGAM	India
6.	Ms. Terrenz LEUNG	Hong Kong SAR, China
7.	Ms. Carrie LI	Hong Kong SAR, China
8.	Ms. Carol LIU	Hong Kong SAR, China
9.	Ms. Lois YEUNG	Hong Kong SAR, China
10.	Mr. Tony YIP	Hong Kong SAR, China
11.	Dr. Henry HOU	Hong Kong SAR, China

Updates

Global Harmonization Working Party
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- Activities
  - Formulation and implementation of WG4 work plan
  - WG Tele-con meetings: 21 May 2020, 23 Nov 2021 & 19 Jan 2023
  - WG4 internal e-mail updates: 1 Mar 2021, 22 Nov 2021, 23 Nov 2021, 24 Oct 2022
  - Regular progress updates to TC

Work Plan from 2020

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Work Item	Description	Deliverables	Timeline
1	Updating the Post-market Resource Centre (PMRC)	• Updates hyperlinks and information posted in the PMRC • Updates: Once / Twice a year	**On-going**
2	Gap analysis on the implementation of AHWP guidance among AHWP members	• Gap analysis report	**Q4,2022**
3	Participation in the development works of ISO TC 210/WG6	• Provide comments on drafting the technical document ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers	**Q2, 2022**
4	Report on post-market support in relation to COVID 19	• Report on post-market support in relation to COVID 19	**Q3, 2022**
5	Study on post-market trend in medical devices with AI and cybersecurity	• Report on post-market trend in medical devices with AI and cybersecurity	**Q3, 2023**

Work Item 1: Updating PMRC

- Purpose
  - Develop a “one-stop” location on GHWP website for RAs and MD Industry with convenient access to post-market regulations and reporting information in various jurisdictions
- Progress
  - First launched: 26 Nov 2016
  - Updates to be done once or twice per year
  - Last Update: Jan 2023
  - Coming update: Jul 2023

Link: http://www.ahwp.info/node/809

Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (1)

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- Purpose
  - Determine if there is any shortcoming of the GHWP proposed framework and the progress of harmonization among GHWP members
  - Identify improvement areas in the work of GHWP on post-market surveillance
- Progress
  - Both hard copy and online version of the survey were prepared, and distributed to AHWP RA members via AHWP Secretariat on 24 Sep 2019
  - Efforts had been made to encourage response (e.g. reminders to RAs, further extension of submission). The survey was completed on 31 Dec 2022

Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (2)

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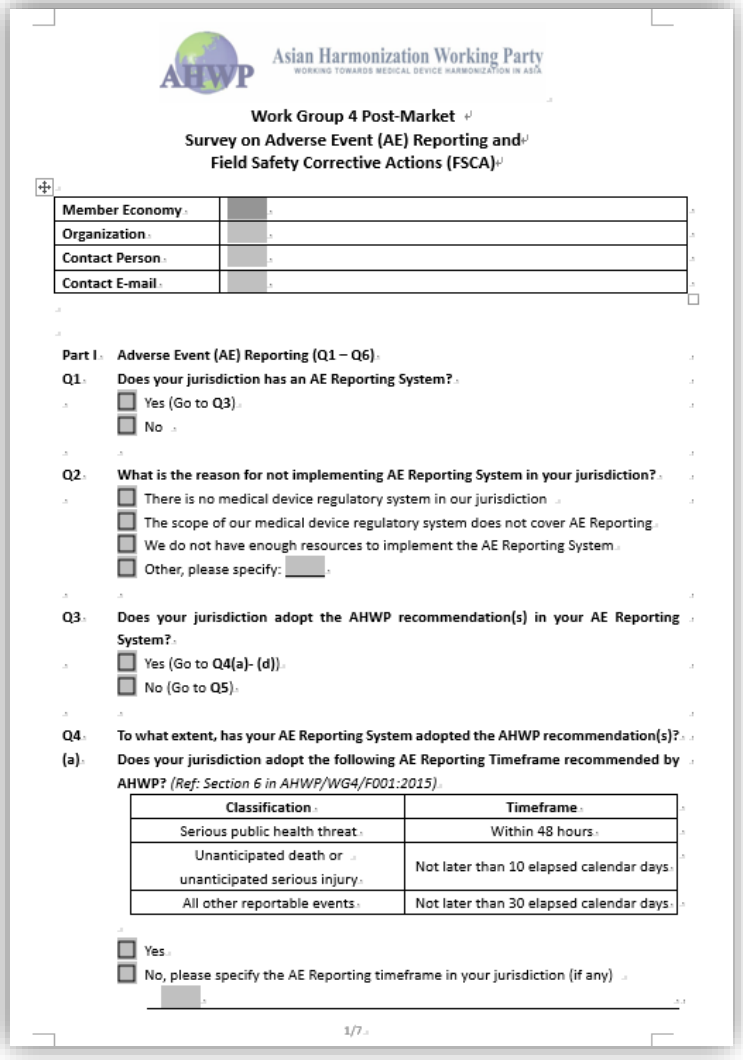
- Progress
  - As of 31 Dec 2022, only SIX (18.75%) returns were received from 32 GHWP members:



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Work Group 4 Post-Market
Survey on Adverse Event (AE) Reporting and Field Safety Corrective Actions (FSCA)

Member Economy	
Organization	
Contact Person	
Contact E-mail	

Part I Adverse Event (AE) Reporting (Q1 – Q6)

Q1 Does your jurisdiction has an AE Reporting System?

☐ Yes (Go to Q3)
☐ No

Q2 What is the reason for not implementing AE Reporting System in your jurisdiction?

☐ There is no medical device regulatory system in our jurisdiction
☐ The scope of our medical device regulatory system does not cover AE Reporting
☐ We do not have enough resources to implement the AE Reporting System
☐ Other, please specify: ____

Q3 Does your jurisdiction adopt the AHWP recommendation(s) in your AE Reporting System?

☐ Yes (Go to Q4(a)- (d))
☐ No (Go to Q5)

Q4 To what extent, has your AE Reporting System adopted the AHWP recommendation(s)?

(a) Does your jurisdiction adopt the following AE Reporting Timeframe recommended by AHWP? *(Ref: Section 6 in AHWP/WG4/F001:2015)*

Classification	Timeframe
Serious public health threat	Within 48 hours
Unanticipated death or unanticipated serious injury	Not later than 10 elapsed calendar days
All other reportable events	Not later than 30 elapsed calendar days

☐ Yes
☐ No, please specify the AE Reporting timeframe in your jurisdiction (if any)

1/7

Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (3)

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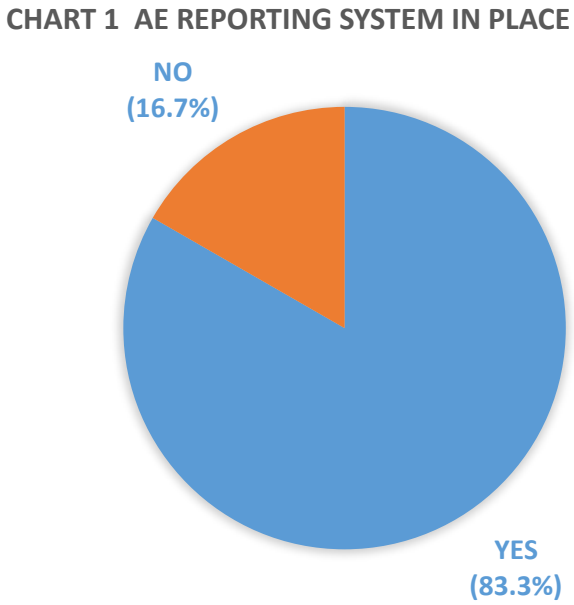
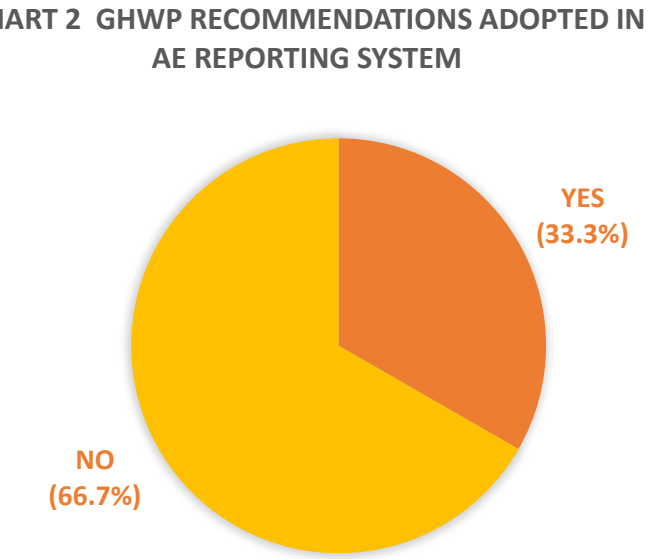
- **Survey Results Summary –** Adverse Event (AE) Reporting
  - **Five** respondents (83.3%) have AE reporting system in place .
  - Only **two** respondents (33.3%) adopt the GHWP recommendations in their AE reporting system.



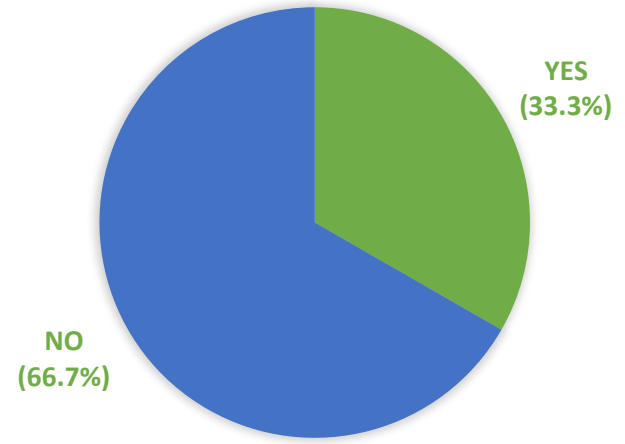


Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (4)

- **Survey Results Summary –** Adverse Event (AE) Reporting

  - **Two** respondents (33.3%) think the existing GHWP recommended AE reporting framework could be improved in terms of the AE definition, classification and reporting form.

CHART 3 IMPROVEMENTS TO THE GHWP RECOMMENDED AE REPORTING FRAMEWORK



Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (5)

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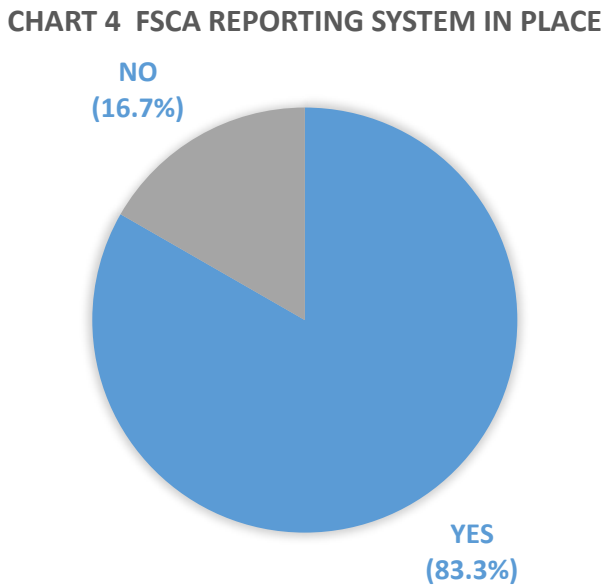
- **Survey Results Summary –** Field Safety Corrective Actions (FSCA)
  - Five respondents (83.3%) have FSCA reporting system in place (Chart 4).
  - ALL respondents have not adopted GHWP recommendations in the FSCA reporting system.
  - ALL respondents indicate that they have similar FSCA definition and types of FSCA as GHWP
  - One (16.7%) suggested GHWP could improve the existing recommended FSCA reporting system by providing more guidance on the FSCA reporting timeframe, classification and trending.



Work Item 2: Gap Analysis on Implementation of AHWP Post-market Guidance (6)

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- **Conclusion and Observations**

  - In light of the 32 GHWP Member Economies, the number of returns (six only) was comparatively small. Hence, the survey results may not be reflecting the whole picture for GHWP members at large.
  - Even though the data may not be very significant, they did shed some light on the areas where the Working Group should focus on the way forward, such as reviewing and aligning the GHWP Recommendation on PMS.

Work Item 3: Participation in the Development Work of the ISO TC 210/WG6

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- **Purpose**
  - Liaise with ISO TC210/WG6 regarding the development of the technical reference document: ISO TR20416 Medical devices – Post-market surveillance for manufacturers
- **Progress**
  - The document ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers was published in Jul 2020. No further actions for WG4.
  - WG4 will continue to liaise with ISO TC210/WG6 on post-market areas to promote global regulatory harmonisation and convergence.

Work Item 4: Report on post-market support in relation to COVID-19

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- **Purpose and Rationale**
  - Explore the post-market support in relation to COVID-19 in different jurisdictions during the COVID-19 pandemic
- **Progress**
  - Work progress was affected by the COVID-19 pandemic.
  - Study write-up is being compiled.

Work Item 5: Study on post-market trend in medical devices with AI and cybersecurity

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- **Purpose and Rationale**
  - Explore the post-market trend in medical devices with AI and cybersecurity in different jurisdictions
- **Progress**
  - The matter is in many jurisdictions outside the purview of the medical device regulatory authority, making the collection and understanding of relevant statutory information very difficult.
  - WG4 is still trying to collect more information and complete a report by the work item end date of Q3, 2023

End of Update on WG4