Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# FINAL DOCUMENT

**Title:** AHWP Post-Market Surveillance (PMS) Survey Report 2017

**Authoring Group:** Work Group 4, Post-Market

**Date:** 8 August 2018

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*Chair, Work Group 4*

## Content

# 1. Objectives

1.1 Medical devices play an important role in health care setting by offering opportunities for improved diagnosis and management of disease, but at the same time, they also carry substantial risks. After a new medical device is introduced to the market, the process of post-market surveillance (PMS) provides ongoing assessment and monitoring on the safety and effectiveness of the device. Although different jurisdictions may adopt different approaches in medical device PMS, all medical device regulatory systems share the same goal in protecting public health while ensuring the continued access to the benefits of new technologies. A survey has been conducted to see how the PMS on medical devices differ in various jurisdictions.

1.2 The following fundamental post-market controls will be covered in this survey report:
(a) Adverse Event Reporting;
(b) Product Recall; and
(c) Field Safety Corrective Action (FSCA)

# 2. Definitions

**Note:** *The definitions of "Adverse Event (AE)", "Product Recall" and "Field Safety Corrective Action (FSCA)" were not provided in the survey questionnaire, as the survey aims at collecting the latest information regarding the availability of the said definitions in different jurisdictions. For the purpose of this survey report, definitions on the terms are provided for reference only.*

2.1 **Adverse Event (AE)** in general, means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including abnormal laboratory finding, in patients, users or other person. For detailed reporting criteria of ***adverse events, in relation to medical device,*** please refer to the AHWP Guidance Document "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (AHWP/WG4/F001:2015)".

2.2 **Product Recall** means the permanent removal from the market and/or destruction of devices, when the device has or may have a safety problem.

2.3 **Field Safety Corrective Action (FSCA)** is any remedial action, including preventive and

corrective, taken by a manufacturer for reducing the risk of death or serious deterioration in the state of health associated with the use of the medical device. The action includes product recalls, device modification, implant alert, device precaution and user warning.

## 3. Survey Method

3.1 The survey was conducted during 11 July 2017 to 30 September 2017. Both hard copy and online version of the Questionnaire on PMS (**Appendix 1**) were prepared. The questionnaire was sent out to the AHWP primary representatives through the AHWP Secretariat. Representatives from other jurisdictions were also reached out for returns in different occasions during the period.

AHWP jurisdictions

| | | | |
|---|---|---|---|
| Abu Dhabi | Indonesia | Myanmar | State of Kuwait |
| Brunei Darussalam | Jordon | Pakistan | Tanzania |
| Cambodia | Kazakhstan | People's Republic of China | Thailand |
| Chile | Kingdom of Saudi Arabia | Philippines | Vietnam |
| Chinese Taipei | Laos PDR | Republic of Korea | Yemen |
| Hong Kong SAR, China | Malaysia | Singapore | |
| India | Mongolia | South Africa | |

Non-AHWP jurisdictions

| | | | |
|---|---|---|---|
| Australia | Germany | Papua New Guinea | USA |
| Europe | Japan | Peru | |

3.2 There are a total of 20 survey returns received from 13 AHWP and 7 non-AHWP jurisdictions:

AHWP jurisdictions

| | | | |
|---|---|---|---|
| Abu Dhabi | Indonesia | Republic of Korea | Yemen |
| Chile | Kingdom of Saudi Arabia | Singapore | |
| Chinese Taipei | Malaysia | Thailand | |
| Hong Kong SAR, China | Philippines | Vietnam | |

Non-AHWP jurisdictions

| | | | |
|---|---|---|---|
| Australia | Germany | Papua New Guinea | USA |
| Europe | Japan | Peru | |

## 4. Survey Results

**Note:** *This survey report was fielded in July – September 2017, and the survey results may not reflect the latest development of the post-market measures adopted in individual jurisdictions.*

### 4.1 Medical Device Legislation

4.1.1 The majority (95%) has medical device legislation implemented in their jurisdictions (**Chart 1**).

4.1.2 Most regulatory authorities of the jurisdictions (75%) implement post-market control under their medical device legislation - 65% fully implemented and 10% partially implemented. 15% of them only implement voluntary post-market control (**Chart 2**).

**Chart 1 Medical Device Legislation Implementation**

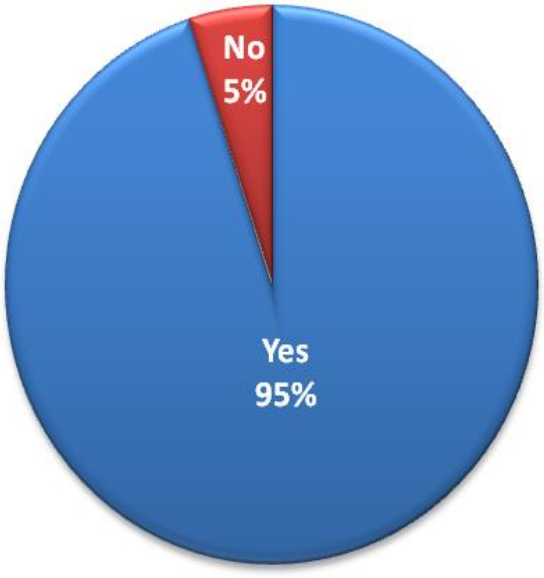
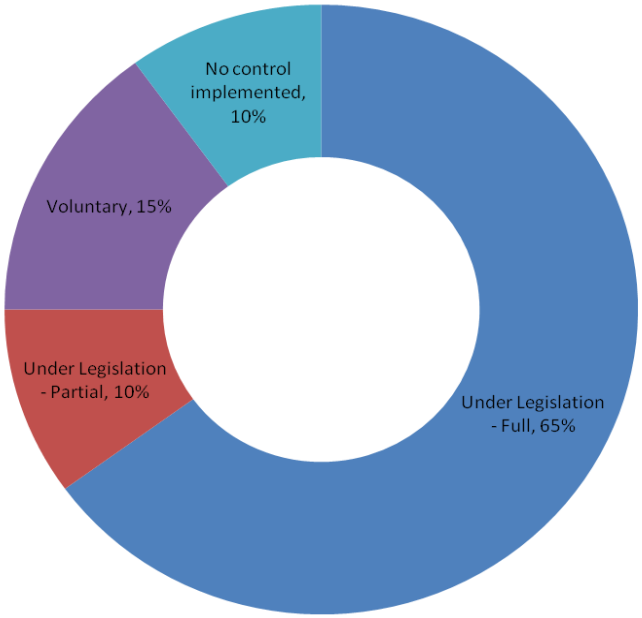
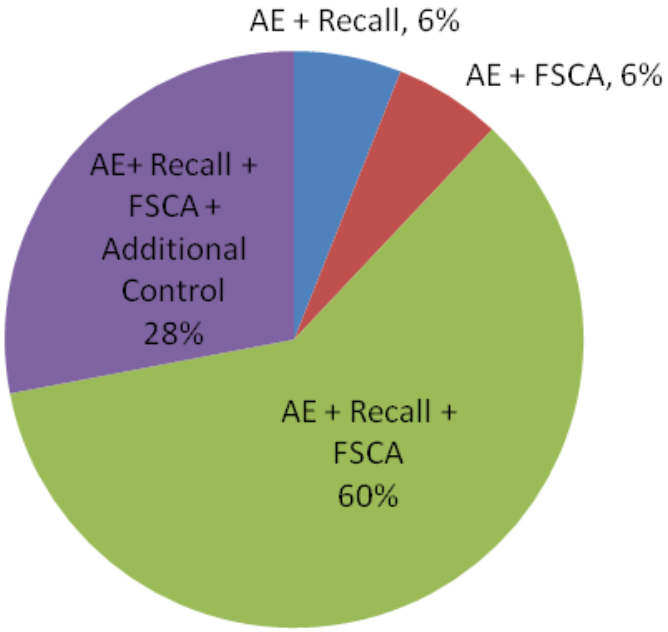



**Chart 2 Post-market Controls Implementation**



4.1.3 The post-market controls implemented in most of the jurisdictions (60%) include the adverse events (AE) reporting, product recall and FSCA (**Chart 3**). Some regulatory authorities of the jurisdictions (28%) strengthen their post-market systems by imposing additional controls, e.g. testing of product samples, compliance audit of manufacturers and periodic post-market reviews.

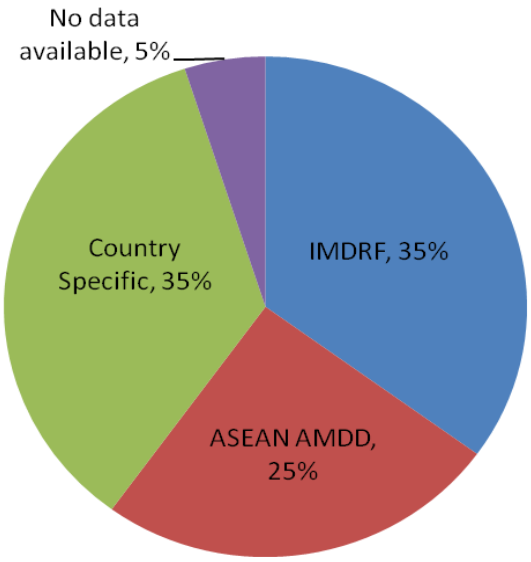
**Chart 3 Elements of post-market control**



## 4.2 Adverse Event Reporting

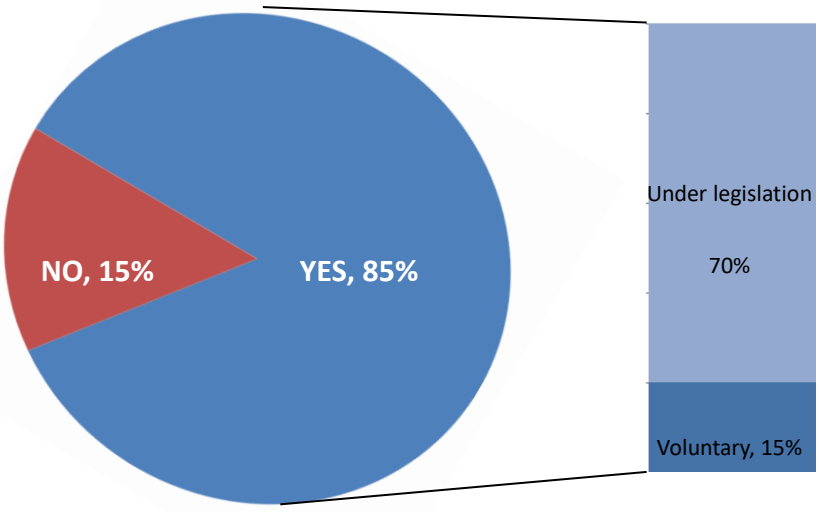
4.2.1 The regulatory authorities in all jurisdictions have defined "Reportable Adverse Event" (**Chart 4**), with 35% of them adopting the International Medical Device Regulatory Forum (IMDRF)'s recommendation, 25% adopting the definition suggested by ASEAN Agreement on Medical Device Directive, while 35% of them have their own definitions.

**Chart 4 Definition of Reportable Adverse Event**



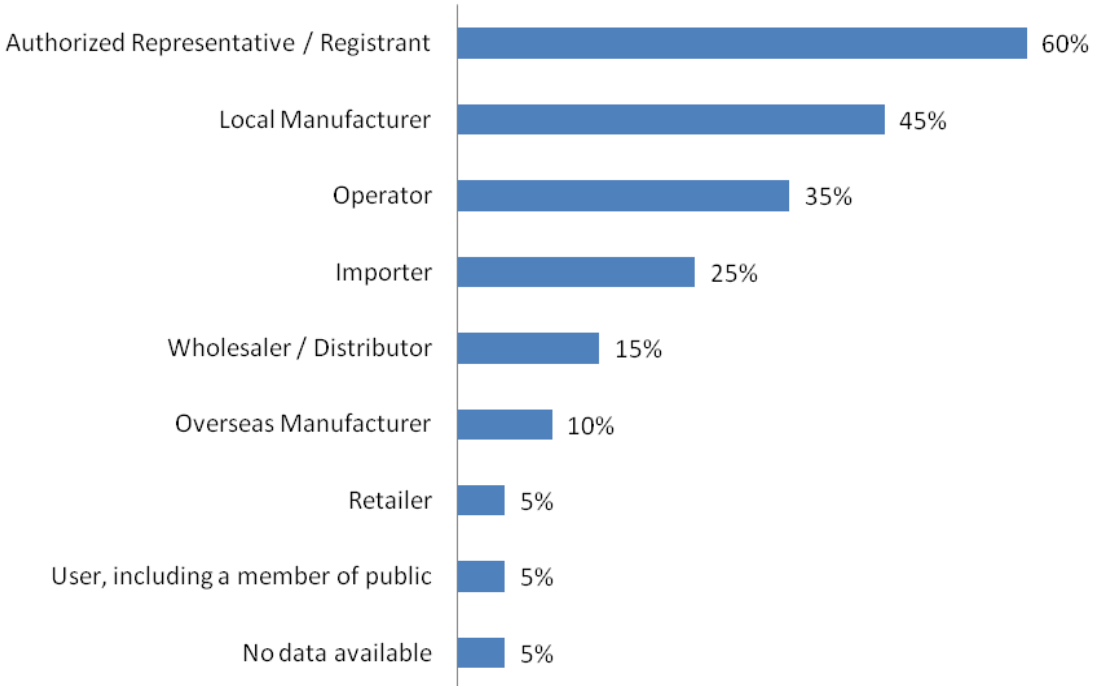

4.2.2 The majority (85%) requires mandatory reporting of the AE under either the medical device legislation or a voluntary system (**Chart 5**).

**Chart 5 Mandatory Reporting of Adverse Event**



4.2.3 Authorized representative (60%) and local manufacturer (45%) of the medical device are required to report the AEs in most jurisdictions (**Chart 6**).

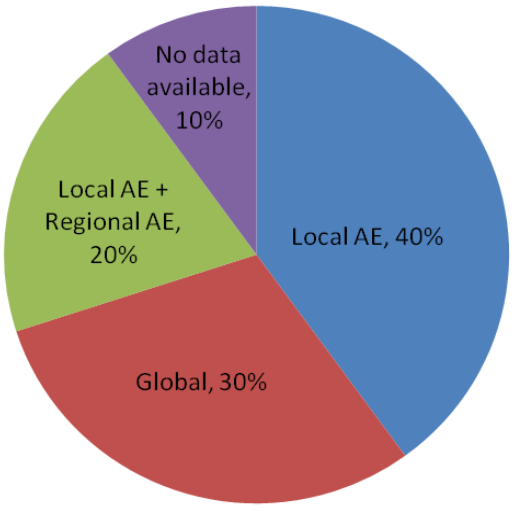
**Chart 6 Party responsible for the Mandatory Reporting of Adverse Event**




*Note: Operator refers to Healthcare Institutions or Healthcare Professionals*

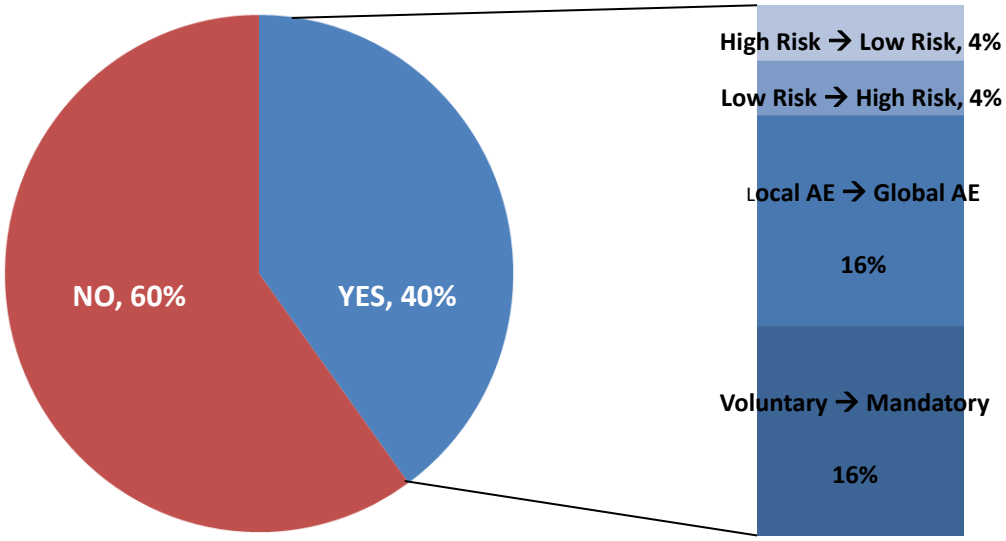
4.2.4 Regarding the reporting scope, 40% of the regulatory authorities require local adverse events to be reported only. 25% of the regulatory authorities require both local and regional adverse events to be reported and 30% of them require global adverse events to be reported (**Chart 7**).

**Chart 7 Geographical scope of Adverse Event Reporting**



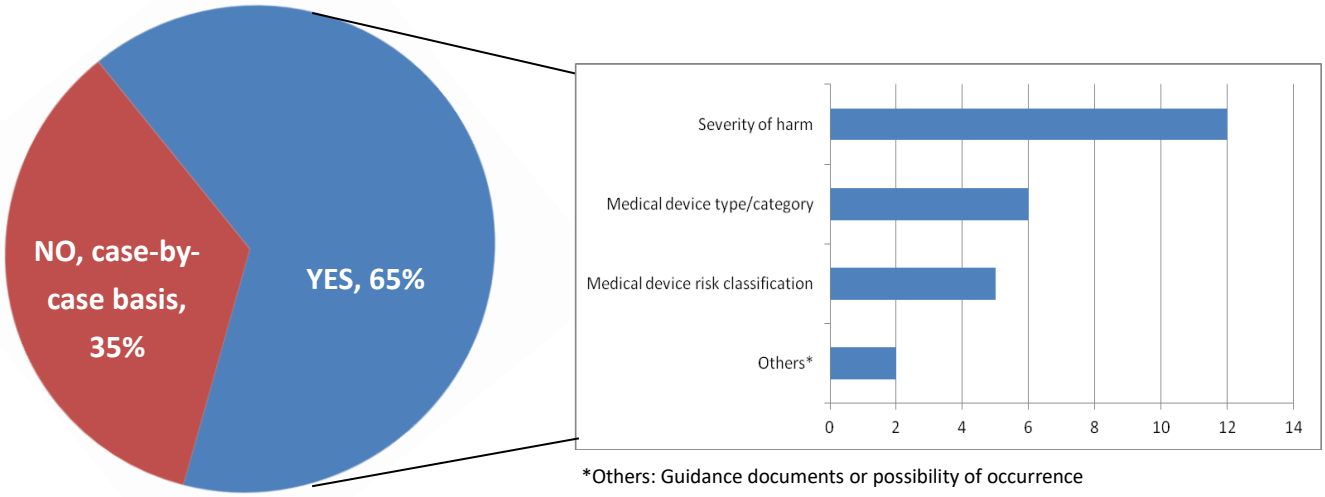
4.2.5 The adverse events reporting controls were not implemented by phases in most jurisdictions (60%) (**Chart 8**).

**Chart 8 Phase Implementation for Adverse Event Reporting Controls**




4.2.6 Over half of regulatory authorities in the jurisdictions (65%) categorize the adverse events according to medical device risk classification, medical device type / category and severity of harm (**Chart 9**).

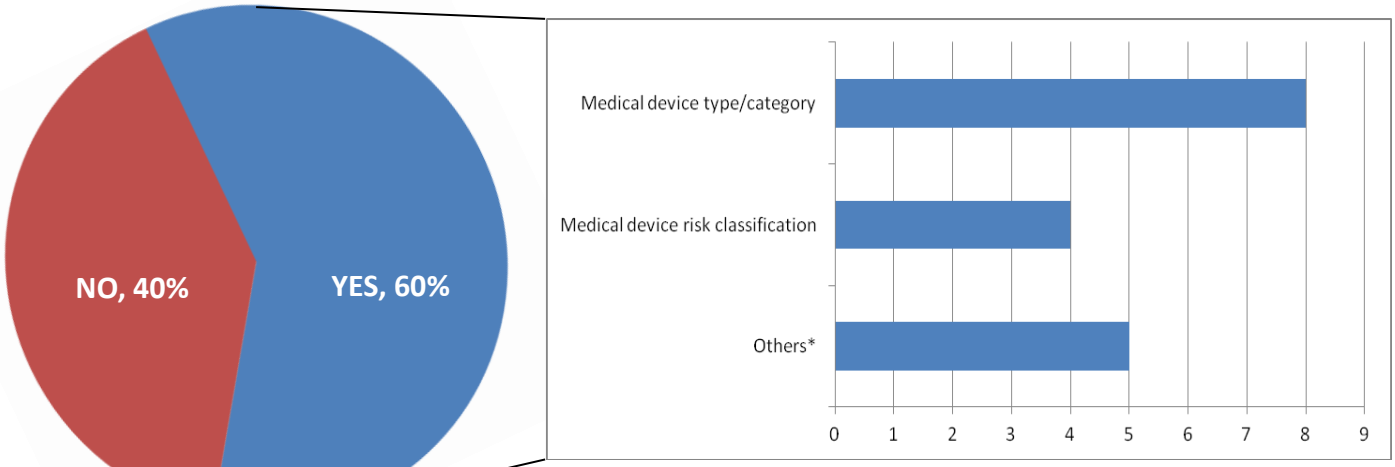
**Chart 9 Categorization of Adverse Events**




*Others: Guidance documents or possibility of occurrence

4.2.7 60% of regulatory authorities in the jurisdictions conduct adverse events trending according to medical device risk classification and medical device type / category (**Chart 10**).

**Chart 10 Adverse Event Trending**



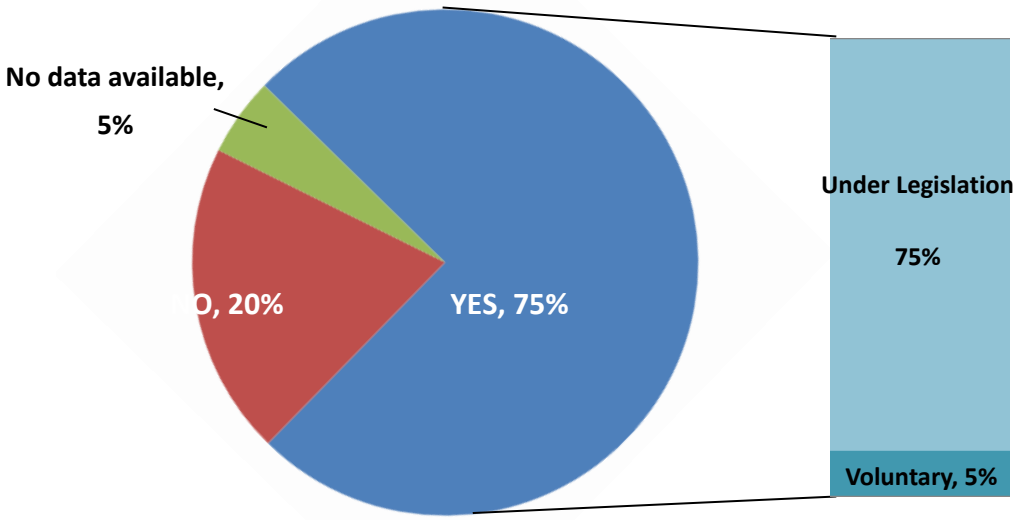

*Others – possibility of occurrence, severity of harm, case-by-case basis or other parameters, e.g. GMDN

## 4.3 Product Recall

4.3.1 The majority (75%) has its own definition of product recall (**Chart 11**), and mandatory reporting of product recall is required in 75% of the jurisdictions either under a statutory or a voluntary regulatory system (**Chart 12**).

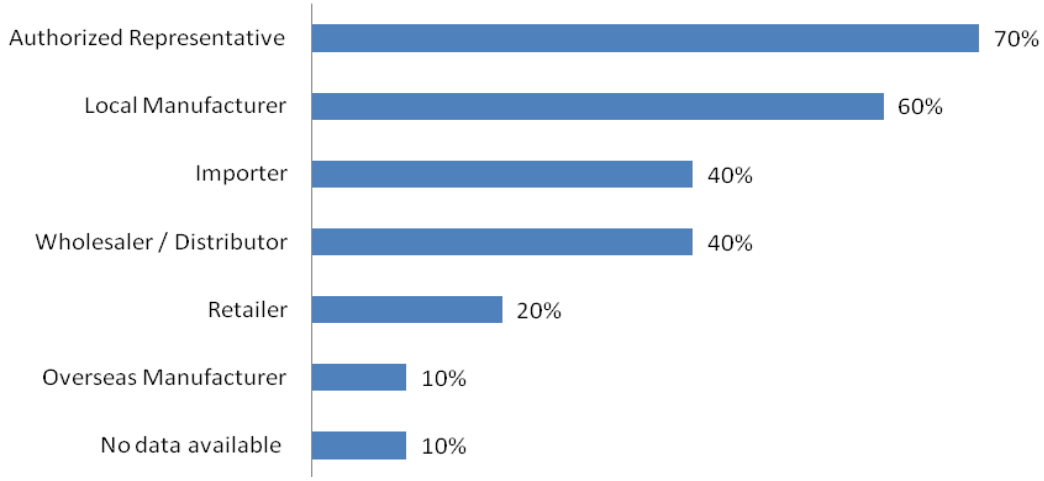
**Chart 11 Own definition of "Product Recall"**

**Chart 12 Mandatory Reporting of Product Recall**



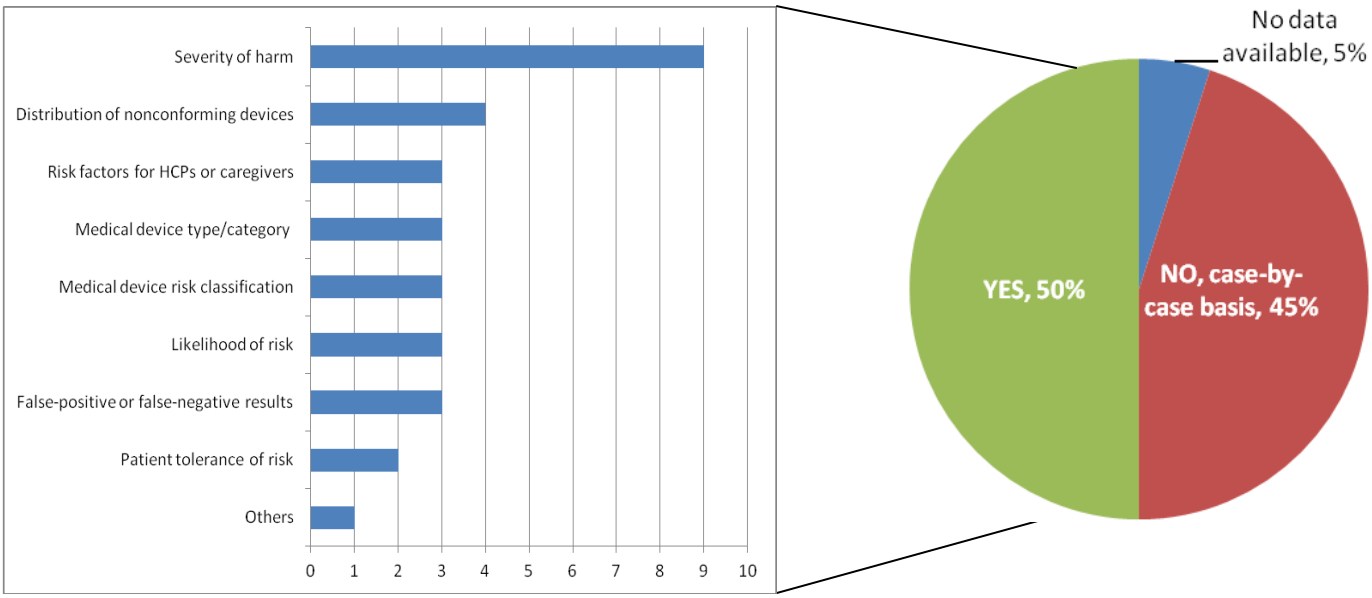

4.3.2 Authorized representative (70%) and local manufacturer (60%) are responsible for conducting the product recall in most jurisdictions; while importer (40%) and wholesaler/distributor (40%) are required to be involved in the product recall in some jurisdictions (**Chart 13)**.

**Chart 13 Party who is responsible for Conducting Product Recall**



4.3.3 Half of regulatory authorities in the jurisdictions categorize the product recall cases according to medical device risk classification, medical device type / category, severity of harm, distribution of nonconforming devices, likelihood of risk, false positive / negative results, etc (**Chart 14**).

**Chart 14 Categorization of Product Recall**




*Others: Guidance Documents; HCPs = Healthcare Professionals

## 4.4 Field Safety Corrective Action (FSCA)

4.4.1 Most of regulatory authorities in the jurisdictions (65%) have their own definitions of FSCA (**Chart 15**), and 70% of them require mandatory reporting of product recall either under a statutory or a voluntary regulatory system

(**Chart 16**).

**Chart 15 Own definition of Field Safety Corrective Action (FSCA)**

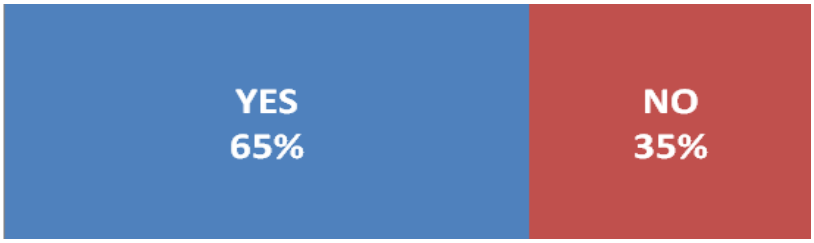
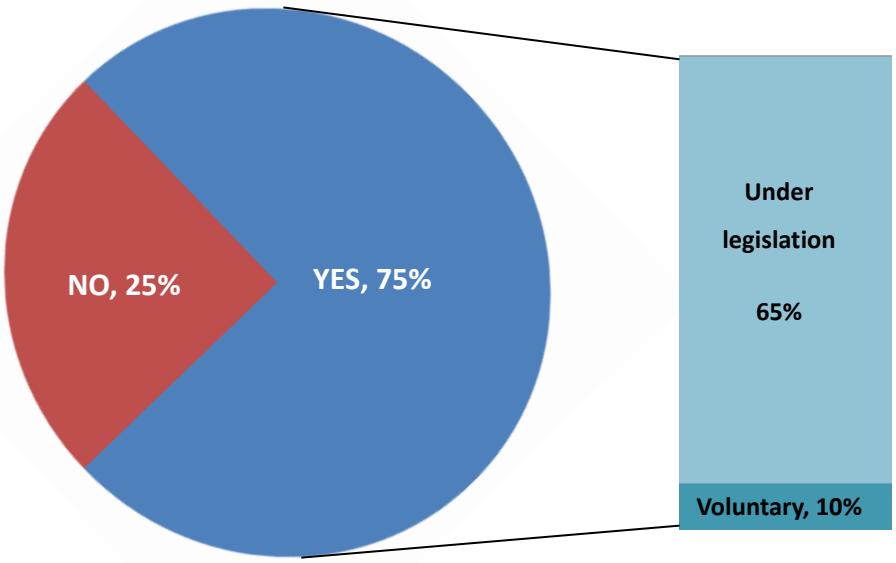
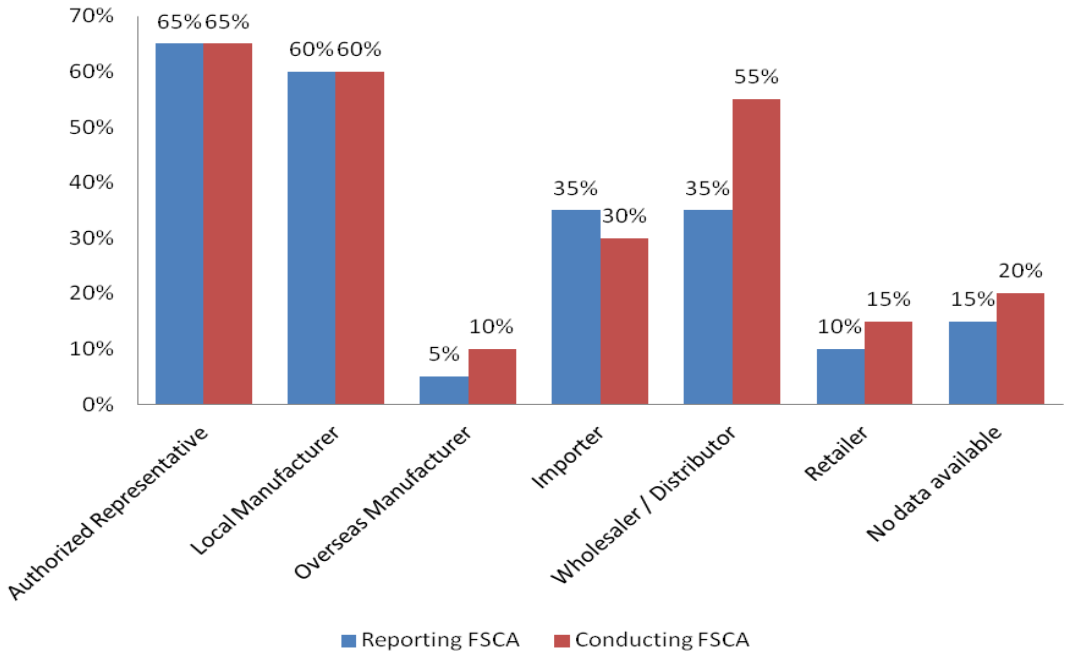



**Chart 16 Mandatory Reporting of FSCA**



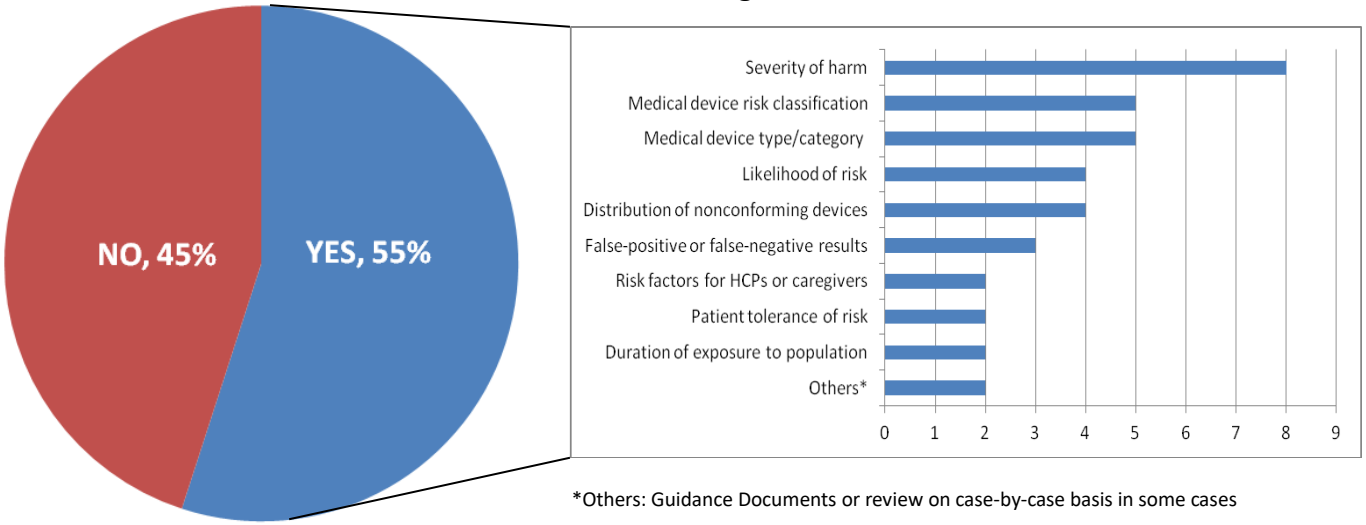

4.4.2 Authorized representative and local manufacturer are responsible for reporting and conducting FSCAs in most jurisdictions (**Chart 17**).

**Chart 17 Party responsible for Reporting and Conducting FSCAs**




4.4.3 More than half of regulatory authorities in the jurisdictions (55%) categorize the FSCA cases according to medical device risk classification, medical device type / category, severity of harm, distribution of nonconforming devices, likelihood of risk, false positive / negative results, etc (**Chart 18**)

**Chart 18 Categorization of FSCA**




*Others: Guidance Documents or review on case-by-case basis in some cases

### 4.5 Post-market Team Composition

4.5.1 Most of the regulatory authorities in the jurisdictions have less than 10 officers in their post-market team (**Chart 19**), with 1:1 ratio of officers (or efforts) in handling adverse events and product recalls / FSCAs (**Chart 20)**. Most of the officers in the post-market team are pharmacists, engineers and scientists (**Chart 21**).

**Chart 19 Number of Officers in the Post-Market Team**

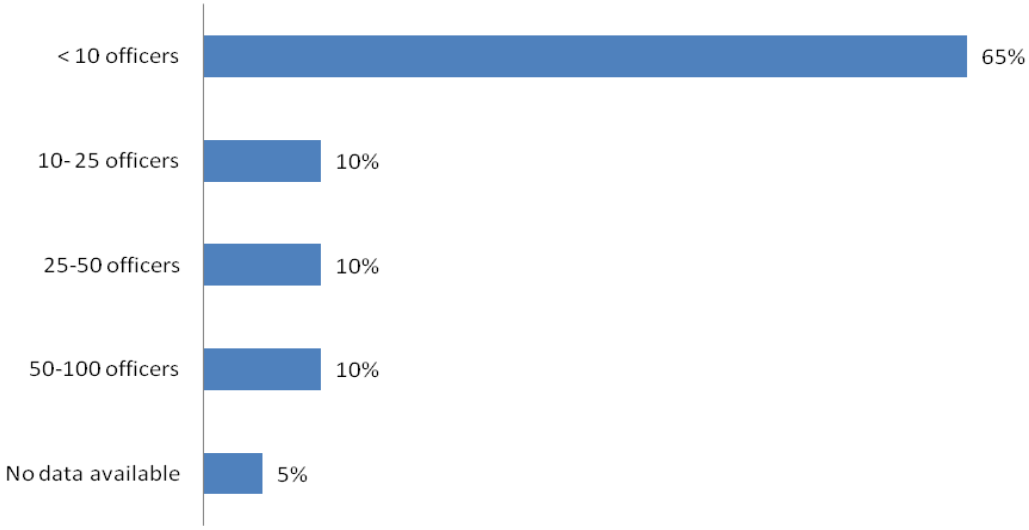



**Chart 20 Ratio of officers in handling AEs and Product Recalls/FSCAs**

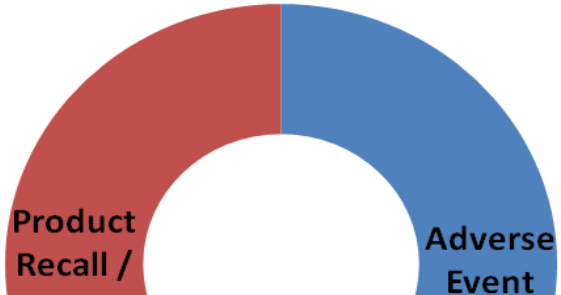
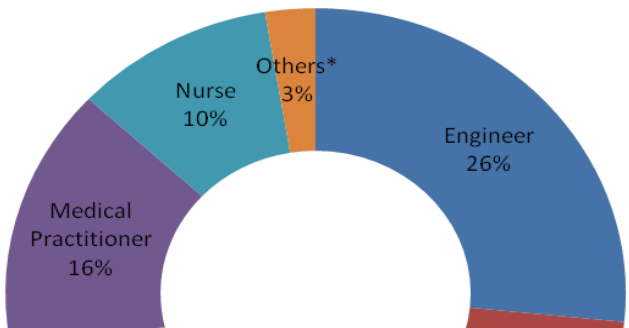



**Chart 21 Background of Officers in the Post-Market Team**



## 5. Observations

5.1 Similar PMS control frameworks covering the fundamental elements of AE reporting, product recall and FSCA are implemented in most jurisdictions. Depending on the resources available and public health concerns, the regulatory authority of individual jurisdiction may strengthen the PMS system by implementing additional controls, e.g. testing of product samples, compliance audit of manufacturers and periodic post-market reviews.

5.2 Survey data shows that "Reportable AE" is defined similarly in quite a number of jurisdictions (60%), either adopting IMDRF or AESAN recommendations. For jurisdictions with their own definitions, there is insufficient information to check how far their definitions deviate from the IMDRF or AHWP recommendations. It is also noted that regulatory authorities tend to adopt different approaches in managing AE, probably due to -

(a) The infrastructure of the local medical device industry;
(b) The local public health concerns; and
(c) The resources available.

5.3 The definition of FSCA suggested by the IMDRF or AHWP covers product recall. In order to cater the local situation, many regulatory authorities have their own definitions of FSCA and product recall rather than adopting IMDRF or AHWP recommendations. Yet there is insufficient information to check how far their own

definitions deviate from the IMDRF or AHWP recommendations. It is also noted that most of the regulatory authorities adopt two different systems in managing the FSCAs and product recalls.

5.4 Despite the lack of harmonized standards in managing FSCAs and product recalls, the survey data shows that a similar approach in managing FSCA and product recall is shared among half of the jurisdictions, which mainly based on the severity of harm.

## 6. Way Forward

From the above observations, harmonization for PMS of medical devices is found achieved to a certain extent for jurisdictions in this survey. To facilitate further progress, the following measured may be considered:

6.1 More experience sharing and exchange of views on PMS work amongst the regulatory authorities from different jurisdictions can be arranged to explore the possibility in aligning the actual implementation practice, while better communications with the industry would also help.

6.2 More guidelines on PMS related issues (e.g. managing the FSCA and product recall) can be developed as reference.

6.3 To have a better visualization on the harmonization progress of the PMS for medical devices, a gap analysis can be conducted in comparing how far the IMDRF and AHWP's recommendations including the definitions and systems of FSCAs and product recalls are being adopted in different jurisdictions. Further analysis can be carried out to see if the differences can be narrowed down without comprising the public health in different jurisdictions.

## 7. References

7.1 Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (AHWP/WG4/F001:2015)

7.2 Definition and Classification of Field Corrective Actions including Field Safety

Corrective Actions, Recalls and Non Safety related Field Corrective Actions (AHWP/WG2/F002:2012)

7.3 Medical Device Regulation (EU) 2017/745, Article 2 (57) Definition of adverse event


## Work Group 4 Post-Market
## Survey on Post-Market Surveillance (PMS)

| | |
|---|---|
| **Member Economy** | |
| **Organization** | |
| **Contact Person** | |
| **Contact E-mail** | |

**Q1** **Are medical device regulatory controls currently legislated in your jurisdiction?**

- ☐ Yes
- ☐ No
  - ☐ Currently there is no medical device regulatory controls
  - ☐ But plans underway for legal regulations (estimated effect date of the medical device legislation: _____(year)
  - ☐ But there is a voluntary regulatory system and plans underway for legal regulations (estimated effect date of the medical device legislation: _____(year)

**Q2** **Are post-market controls on medical devices currently implemented in your jurisdiction?**

- ☐ Yes
  - ☐ Full implementation under the medical device legislation
  - ☐ Partial implementation under the medical device legislation
  - ☐ Full implementation under a voluntary regulatory system
  - ☐ Partial implementation under a voluntary regulatory system
- ☐ No

**Q3** **What are the controls under the medical device post-market surveillance? (please select all that apply)**

- ☐ Adverse Events Reporting ***(Please complete Q4 )***
- ☐ Product Recalls ***(Please complete Q5)***
- ☐ Field Safety Corrective Actions (FSCA) ***(please complete Q6)***
- ☐ Others, please specify: _____

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**Q4 Adverse Event Reporting**

**(a) What is the definition of "Reportable Adverse Event" in your jurisdiction?**

- ☐ Adopt International Medical Device Regulators' Forum (IMDRF)
- ☐ Adopt ASEAN Agreement on Medical Device Directive (AMDD)
- ☐ Country specific definition, please specify: _____

**(b) Is the Adverse Event Reporting mandatory in your jurisdiction?**

- ☐ Yes
  - ☐ It's mandatory under the medical device legislation
  - ☐ It's mandatory under the voluntary regulatory system
- ☐ No
  - ☐ No plans to regulate yet
  - ☐ But plans underway to implement (estimated effect date:_____(year)

**(c) Who are responsible for reporting the Adverse Events to the regulatory authority in your jurisdiction? (please select all that apply)**

- ☐ Mandatory Reporting
  - ☐ Authorized Representative / Registrant
  - ☐ Local Manufacturer
  - ☐ Overseas Manufacturer
  - ☐ Importer
  - ☐ Wholesaler / Distributor
  - ☐ Retailer
  - ☐ Operator, e.g. Healthcare Institutions or Healthcare Professionals
  - ☐ User, including a member of public

- ☐ Voluntary Reporting
  - ☐ Authorized Representative / Registrant
  - ☐ Local Manufacturer
  - ☐ Overseas Manufacturer
  - ☐ Importer
  - ☐ Wholesaler / Distributor
  - ☐ Retailer
  - ☐ Operator, e.g. Healthcare Institutions or Healthcare Professionals
  - ☐ User, including a member of public


**(d) What is the geographical scope for the reporting of Adverse Events to the regulatory authority in your jurisdiction?**

- ☐ Only local Adverse Events (occurring within your jurisdiction) are required to be reported
- ☐ Both local Adverse Events and regional Adverse Events (occurring in a specified region, e.g. EU, ASEAN) are required to be reported
- ☐ Adverse Events occurring globally are required to be reported

**(e) Was/Is there phased implementation for Adverse Event reporting controls?**

- ☐ Yes
  - ☐ 1st phase: Local reporting, 2nd phase: Global reporting
  - ☐ 1st phase: Voluntary reporting, 2nd phase: Mandatory reporting
  - ☐ 1st phase: Higher risk classes of devices, 2nd phase: Lower risk classes of devices
  - ☐ 1st phase: Lower risk classes of devices, 2nd phase: Higher risk classes of devices
  - ☐ Others, please specify: _____
- ☐ No

**(f) Does the regulatory authority categorize the Adverse Event Reports received? (please select all that apply)**

- ☐ Yes, cases are categorized according to the following factor(s) for risk-based follow-up actions:
  - ☐ Medical device risk classification
  - ☐ Medical device type / category (e.g. orthopaedics implantables, percutaneous coronary intervention devices)
  - ☐ Severity of harm i.e. death, serious injury, threats to public health, etc.
  - ☐ Others, please specify: _____
- ☐ No, cases are reviewed and handled on case-by-case basis

**(g) Does the regulatory authority conduct Adverse Event trending? (please select all that apply)**

- ☐ Yes, and factor(s) being considered for the trending procedure is/are
  - ☐ Medical device risk classification
  - ☐ Medical device type / category (e.g. orthopaedics implantables, percutaneous coronary intervention devices)
  - ☐ Others, please specify: _____
- ☐ No

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**Q5 Product Recall**

**(a) Is there any definition of "Product Recall" in your jurisdiction?**

- ☐ Yes, please specify: _____
- ☐ No

**(b) Is the product recall mandatory in your jurisdiction?**

- ☐ Yes
  - ☐ It's mandatory order from the regulatory authority under the medical device legislation
  - ☐ It's mandatory order from the regulatory authority under the voluntary regulatory system
- ☐ No
  - ☐ No plans to regulate yet
  - ☐ But plans underway to implement (estimated effect date:_____(year)

**(c) Who are responsible for conducting the product recall in your jurisdiction? (please select all that apply)**

- ☐ Authorized Representative
- ☐ Local Manufacturer
- ☐ Overseas Manufacturer
- ☐ Importer
- ☐ Wholesaler / Distributor
- ☐ Retailers

**(d) Does the regulatory authority categorize the product recall when the cases are identified? (please select all that apply)**

- ☐ Yes, cases are categorized according to the following factor(s) for risk-based follow-up actions:
  - ☐ Medical device risk classification
  - ☐ Medical device type / category
  - ☐ Severity of harm, i.e. death, serious injury, threats to public health, etc.
  - ☐ Likelihood of risk
  - ☐ Distribution of nonconforming devices
  - ☐ Duration of exposure to population
  - ☐ False-positive or false-negative results
  - ☐ Patient tolerance of risk
  - ☐ Risk factors for healthcare professionals or caregivers


- ☐ Others, please specify: _____
- ☐ No, cases are reviewed and handled on case-by-case basis

**Q6 Field Safety Corrective Actions (FSCA)**

**(a) Is there any definition of "Field Safety Corrective Actions" in your jurisdiction?**

- ☐ Yes, please specify: _____
- ☐ No

**(b) Is the FSCA mandatory to be reported and conducted in your jurisdiction?**

- ☐ Yes
  - ☐ It's mandatory under the medical device legislation
  - ☐ It's mandatory under the voluntary regulatory system
- ☐ No
  - ☐ No plans to regulate yet
  - ☐ But plans underway to implement (estimated effect date:_____(year)

**(c) Who are responsible for reporting and conducting the FSCA in your jurisdiction? (please select all that apply)**

Reporting FSCA

- ☐ Authorized Representative
- ☐ Local Manufacturer
- ☐ Overseas Manufacturer
- ☐ Importer
- ☐ Wholesaler / Distributor
- ☐ Retailer

Conducting FSCA

- ☐ Authorized Representative
- ☐ Local Manufacturer
- ☐ Overseas Manufacturer
- ☐ Importer
- ☐ Wholesaler / Distributor
- ☐ Retailer


**(d) Does the regulatory authority categorize the FSCAs reported? (please select all that apply)**

- ☐ Yes, cases reported are categorized according to the following factor(s) for risk-based follow-up actions:
  - ☐ Medical device risk classification
  - ☐ Medical device type / category
  - ☐ Severity of harm, i.e. death, serious injury, threats to public health, etc.
  - ☐ Likelihood of risk
  - ☐ Distribution of nonconforming devices
  - ☐ Duration of exposure to population
  - ☐ False-positive or false-negative results
  - ☐ Patient tolerance of risk
  - ☐ Risk factors for healthcare professionals or caregivers
  - ☐ Others, please specify: _____
- ☐ No, cases are reviewed and handled on case-by-case basis

**Q7 The approximate number of cases handled annually by the regulatory authority in your jurisdiction:**

- ☐ Adverse Events Reporting (Case handled annually: _____ )
- ☐ Product Recalls (Case handled annually: _____ )
- ☐ Field Safety Corrective Actions (Case handled annually: _____ )

**Q8 The number of officer in the post-market team in the regulatory authority in your jurisdiction:**

- ☐ < 10 officers
- ☐ 10 – 25 officers
- ☐ 25 – 50 officers
- ☐ 50 – 100 officers
- ☐ > 100 officers

Approximate breakdown:

Adverse Events: _____ officers

Product Recalls / FSCA: _____ officers

Others, please specify: _____: _____officers

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Q9 What are the education or professional backgrounds of the officers in your jurisdiction? (please also specify the number of officers)

***Adverse Events***

- ☐ Engineer, (_____ officers)
- ☐ Medical Practitioner (_____ officers)
- ☐ Nurse (_____officers)
- ☐ Pharmacist (_____ officers)
- ☐ Scientist (_____ officers)
- ☐ Others, please specify _____ (_____ officers)

***Product Recall / FSCA***

- ☐ Engineer (_____officers)
- ☐ Medical Practitioner (_____ officers)
- ☐ Nurse (_____ officers)
- ☐ Pharmacist (_____ officers)
- ☐ Scientist (_____ officers)
- ☐ Others, please specify _____ (_____ officers)

Q10 How many local medical device manufacturers (i.e. Establishment licence of medical device manufacturing) are in your jurisdiction?

- ☐ < 100
- ☐ 100 – 500
- ☐ 500 – 1,000
- ☐ 1,000 – 3,000
- ☐ > 3,000

Q11 How many medical device distributor / importer are in your jurisdiction?

- ☐ < 100
- ☐ 100 – 500
- ☐ 500 – 1000
- ☐ 1,000 – 3,000
- ☐ > 3,000

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Q12 How many healthcare facilities (hospitals, clinics, clinic labs, nursing homes) are in your jurisdiction?

- ☐ < 5,000
- ☐ 5,000 – 10,000
- ☐ 10,000 – 20,000
- ☐ > 20,000

**Remark:**

1. **Thank you for your time an effort to complete this survey. Please note that the information collected in this survey will be used by AHWP TC WG4 as a reference for developing work or formulating the future activities for PMS.**
2. **Please return this questionnaire to WG4 by sending emails to secretariat@ahwp.info and so1_mdco@dh.gov.hk**

**-THE END -**