The Medical Instruments Adverse Event Report Framework in Asia Pacific Region

The Working Group on Medical Measurements

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Chinese Taipei

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Look Back on 2015's Presentation (1/2)

- Definition of Medical Devices
- Classification of Medical Devices
- Definition of Adverse Events
- Classification of Adverse Events

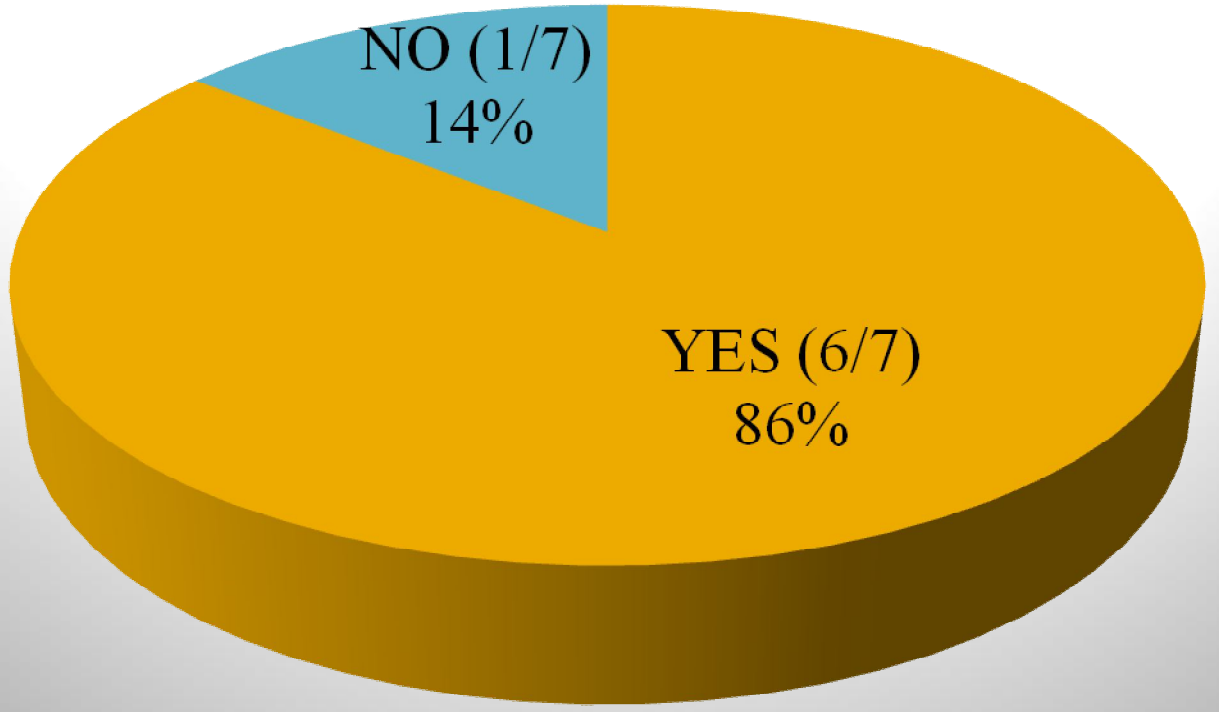
Look Back on 2015's Presentation (2/2)

Adverse Event Report:

- What to report?
- Who to report?
- Whom to report to ?
- When to report?

The Survey on Adverse Event Report (1/10)

Does your economy have a mechanism for reporting medical device adverse events?



The Survey on Adverse Event Report (2/10)

Definition of medical device adverse event?

	Canada	Indonesia	Singapore	Chinese Taipei
Failure of the device or a Deterioration in its effectiveness	●	●		●
Led to the death	●		●	●
Serious deterioration in the state of health of a patient	●		●	●
Discovery of a design flaw		●		
Incorrect or out of specification test result		●		
Others	Incident that occurs outside Canada	Inaccuracy in the labeling	Any debilitating, harmful, toxic or detrimental effect on the body or health of humans	

The Survey on Adverse Event Report (3/10)

In which conditions would an adverse event for a medical device(including medical software) be reported?

(a) Fault with the device that caused (or could have caused) injury/death

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
A malfunction or deterioration in the characteristics or performance	●	●	●		●	●
Inadequate design or manufacture	●	●	●	●	●	●
Inaccurate labeling, instruction for use and/or promotional materials	●	●	●		●	●
Other information becoming available (for example, manufacturers testing results on device are published)		●	●		●	●
Unclean/unsterile device	●	●	●	●	●	●
Dislodgement/misconnection/ removal of device	●	●	●	●	●	●
Incorrect assembly or use of device	●	●	●	●	●	●

The Survey on Adverse Event Report (4/10)

In which conditions would an adverse event for a medical device(including medical software) be reported?

(b) Fault with a device that resulted in the following outcome for a person

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
Death	●	●	●	●	●	●
Serious injury or deterioration to a patient, user, or other person	●	●	●		●	●
Hospitalization (initial or prolonged)	●	●	●	●	●	●
Disability or permanent damage	●	●	●		●	●
Congenital anomaly/birth defect	●	●	●		●	●
Required intervention to prevent permanent impairment or damage (devices)	●	●	●		●	●

The Survey on Adverse Event Report (5/10)

Which authority takes responsibility for dealing with medical device adverse events?

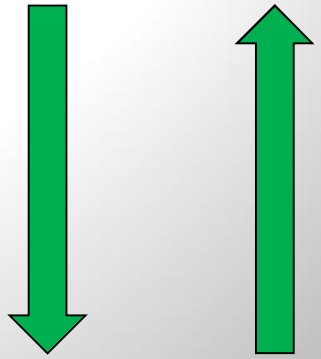
- *Health authority* (100%)

The Survey on Adverse Event Report (6/10)

Who should report adverse events?

- *Manufacturers and Importers*
- *Clinicians*
- *User Facilities*
- *Customers/Users*

Mandatory



Voluntary

The Survey on Adverse Event Report (7/10)

Who must report an adverse event?

	Canada	Indonesia	Malaysia	Mongolia	Singapore	Chinese Taipei
Manufacturers and Importers	●	●	●		●	●
User Facilities				●		●
Clinicians		●		●		●
Customers/Users				●		

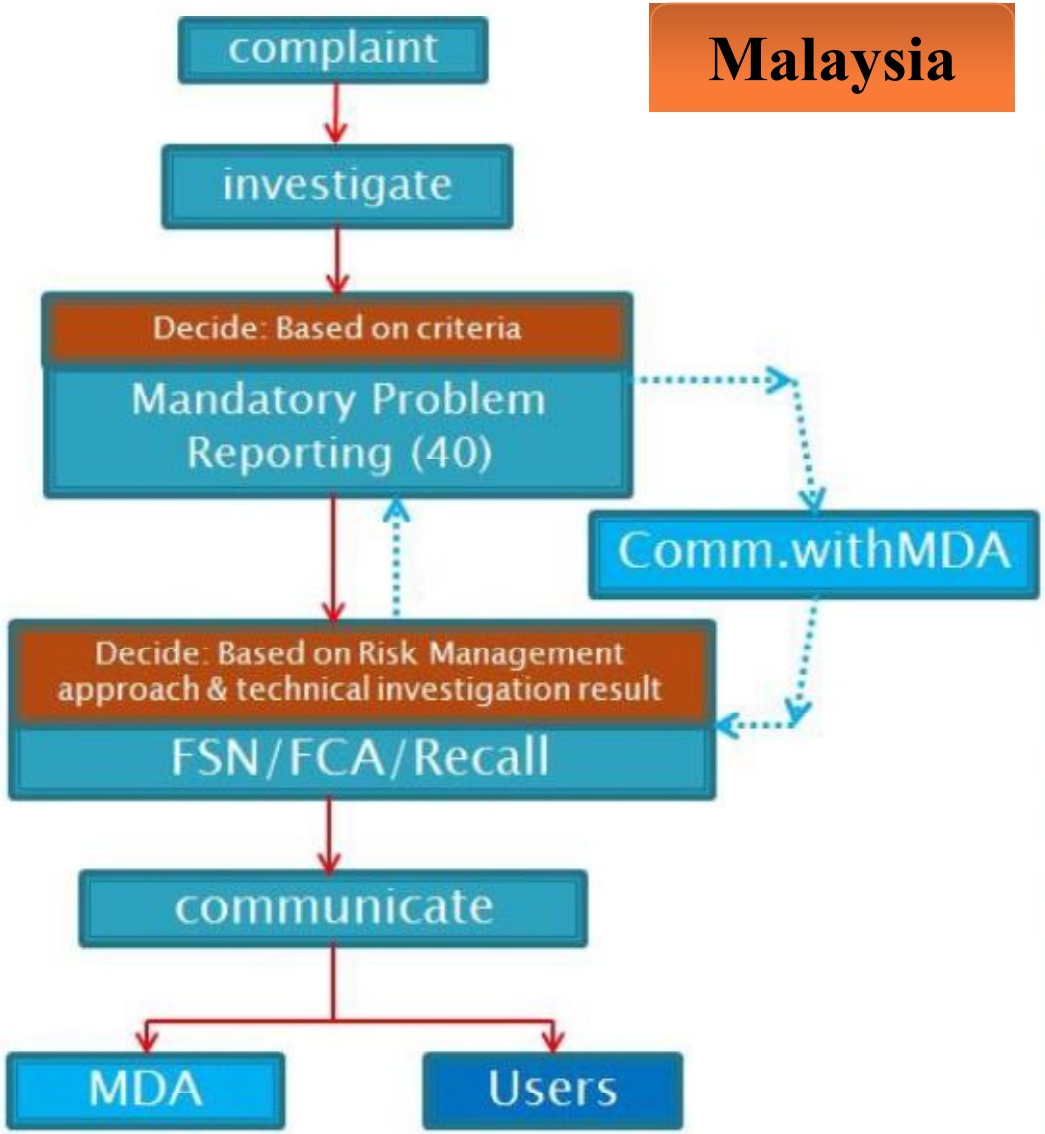
The Survey on Adverse Event Report (8/10)

What is the procedure of the medical device adverse events report in members economy?

- **Canada:**

  Support Officers are responsible for processing and data entering reports while the Problem Report Information Specialists (e.g. nurses) are responsible for assessing and coding the reports. This data, including both mandatory and voluntary incident reports, is analyzed for trends by scientific evaluators who initiate risk mitigation activities such as label changes and public communications, while corrective actions (e.g. recalls) are initiated by the group responsible for regulatory compliance and enforcement.

MDA expectations – Establishment responsibilities



Malaysia

Complaint handling procedures **(39)**

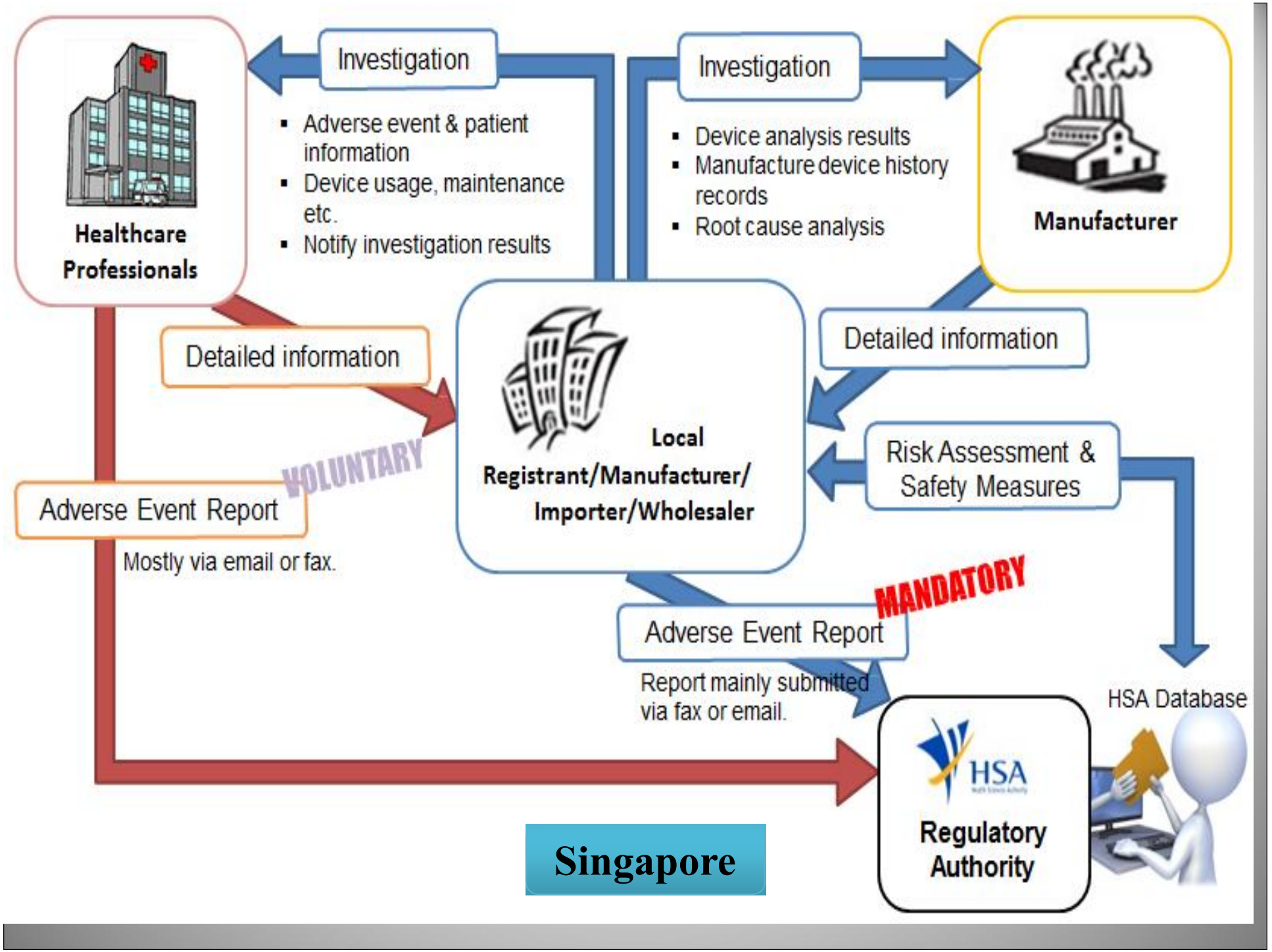
Distribution records **(37)**

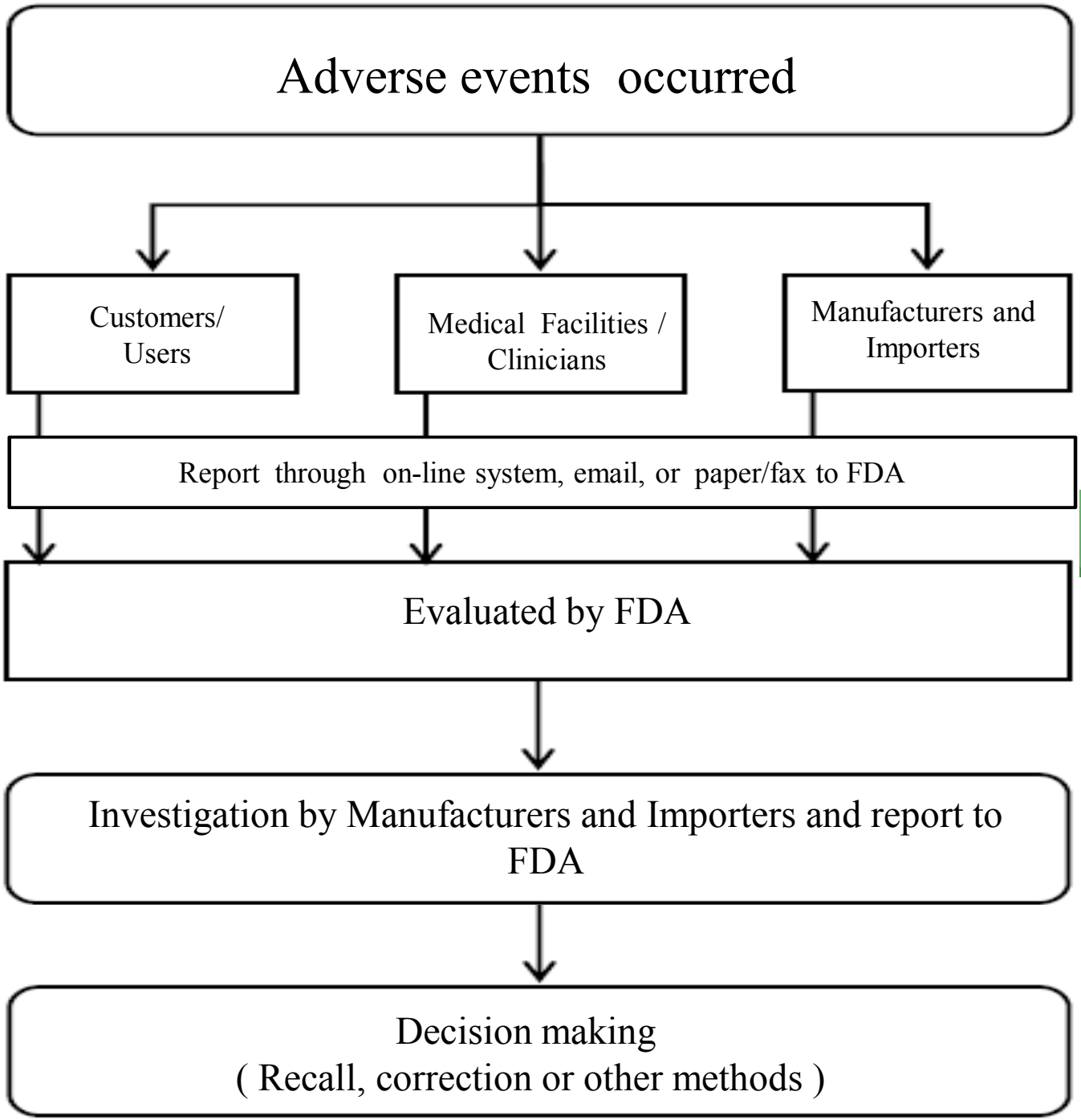
1. Inside / outside Malaysia ?
2. Device available in Malaysian market?
3. Any incident recorded fulfilled the criteria as in **(40)** ? :

a. Failure of device and deterioration in its effectiveness, inadequacy of labelling / IFU
b. Has led to death or serious deterioration of health of a patient, user or others? Or could do so if it reoccur?
c. Serious threat to public health?

FCA may include **(41)**:
- Return of device to the establishment,
- Modification of the device,
- Exchange of the device,
- Destruction of the device,
- Specific advice on the use of the device,
- It may involve recall as part of the action needed **(42).**

Overall, this is how the MDA expect the establishment monitor the safety and performance of a medical device – all vigilance report is recorded and evaluated (38)


Healthcare Professionals
Investigation
Adverse event & patient information
Device usage, maintenance etc.
Notify investigation results
Investigation
Device analysis results
Manufacture device history records
Root cause analysis
Manufacturer
Detailed information
Detailed information
Local Registrant/Manufacturer/ Importer/Wholesaler
Risk Assessment & Safety Measures
VOLUNTARY
Adverse Event Report
Mostly via email or fax.
MANDATORY
Adverse Event Report
Report mainly submitted via fax or email.
HSA Database
HSA
Regulatory Authority
Singapore



Chinese Taipei

The Survey on Adverse Event Report (9/10)

Does the authority have a time frame for processing adverse event report?

Canada

Manufacturers and importers are required to report serious incidents related to a medical device:

- Within 10 days: if an incident leads to death or a serious deterioration of health.
- Within 30 days: if an incident were to reoccur, could end in death or serious deterioration of health.
- All other types of reports from industry and public or health care professionals are considered voluntary reports and have no specific time requirements for reporting.

Chinese Taipei

- The recall or correction period is between 1 ~ 6 months, depending on the level of severity.
- Regulation: Regulations for Medicament Recall (medical devices recalls included).

The Survey on Adverse Event Report (10/10)

How many **medical device adverse events occurred in 2015** in your economy?

Medical Device	Estimate proportions
Medical syringes (R 26)	**Medium ~ Small**
Clinical electrical thermometers with maximum device(R 115)	**Medium ~ Small**
Mechanical non-invasive sphygmomanometers (R 16-1)	**Small**
Non-invasive automated sphygmomanometer(R 16-2)	**Small**
Westergren tubes for measurement of erythrocyte sedimentation rate(R 78)	**Small**
Electrocardiographs - Metrological characteristics - Methods and equipment for verification(R 90)	**Small**
All other Devices	**Large**

Summary

- *Most members have a mechanism for reporting medical device adverse events*
- *Health authority is the sole competent agency*
- *Manufacturers/importers and user facilities are mandatory to report(clinicians)*
- *Customers/users are voluntary to report (clinicians)*
- *Condition of the medical device adverse events of most members are the same*
- *Not every member has a time frame for adverse event report*
- *More adverse events reported concerned devices are not covered by OIML Recommendations*

2017 Working Plan

- Collecting the Legal Measures Mechanism on Medical Devices in Asia Pacific region
  - Objects
    1) To understand the legal measures on medical devices in Asia Pacific region
    2) To accelerate medical devices put on market among APLMF member economies
    3) To address the importance of accurate medical devices to diagnosis and treatment if possible
  - Approach
    - Design and disseminate a survey to collect the mechanisms of the legal measures on medical devices in Asia Pacific region

- Questions?
- Comments?

Thank you!