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

1927-2017 FICCI @90

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

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

1927-2017 FICCI @90

Post-market Surveillance of Medical Device
How far have we gone towards Harmonization

Asian Harmonization Working Party
Technical Committee
Work Group 4 Chair

Jennifer MAK

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

1927-2017 FICCI @90

Content

- Introduction
  - Adverse Event (AE)
  - Field Safety Corrective Action (FSCA)
  - Product Recall
- PMS Survey and Results
- Observations
- Way Forward

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Post-market Surveillance (PMS)

- Providing ongoing assessment and monitoring on the safety and effectiveness of the medical device after a device has been introduced to the market

- Fundamental PMS Elements
  - Adverse Event (AE) Reporting
  - Field Safety Corrective Action (FSCA)
  - Product Recall

Adverse Event (AE)

- Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including abnormal laboratory finding, in patients, users or other person ***(Medical Device Regulation EU 2017/745, Article 2 (57))***

- Reportable AE
  - Public health concern
  - Death or serious injury
  - Death or serious injury if re-occurred

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

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Field Safety Corrective Action (FSCA)

- 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

- Actions include product recall, device modification, implant alert, device precaution and user warning

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

Product Recall

- Permanent removal from the market and / or destruction of devices, when the device has or may have a safety problem

- A form of FSCA

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

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PMS Survey

- Time: July – Sep 2017
- Survey Format: Hard copy and online version of questionnaire
- Participants: AHWP member economies and representatives from other jurisdictions

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PMS 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 and Yemen
  - **Non-AHWP Jurisdictions** - Australia, Europe, Germany, Japan, Papua New Guinea, Peru and USA

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

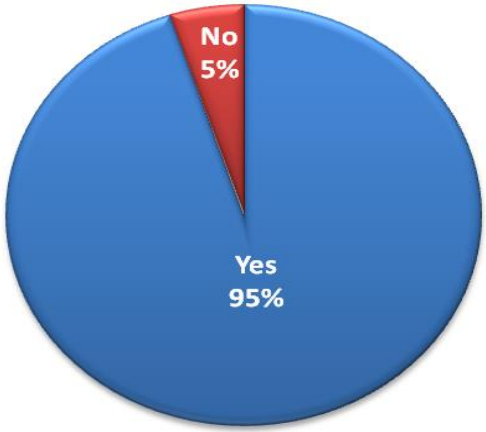
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

Are we adopting the same approach in PMS?

Medical Device Legislation

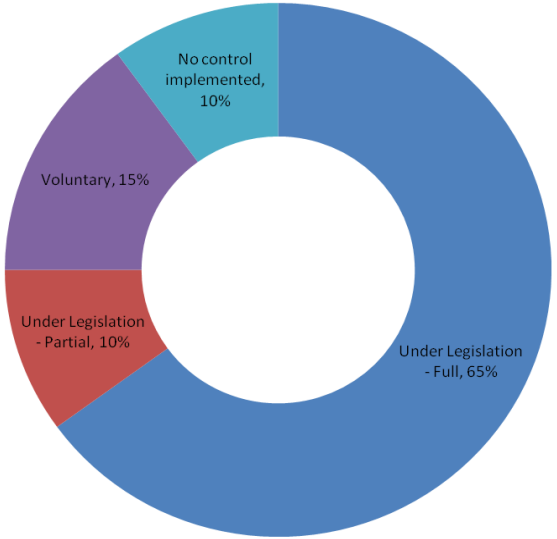
- A majority (95%) has medical device legislation implemented in their jurisdictions



Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PMS Implementation

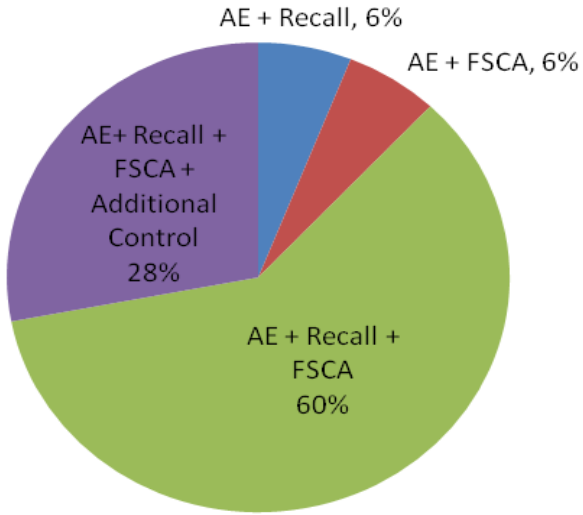


- Under Medical Device Legislation – 75%
  - 65% fully implemented
  - 10% partially implemented
- Under Voluntary PMS System – 15%

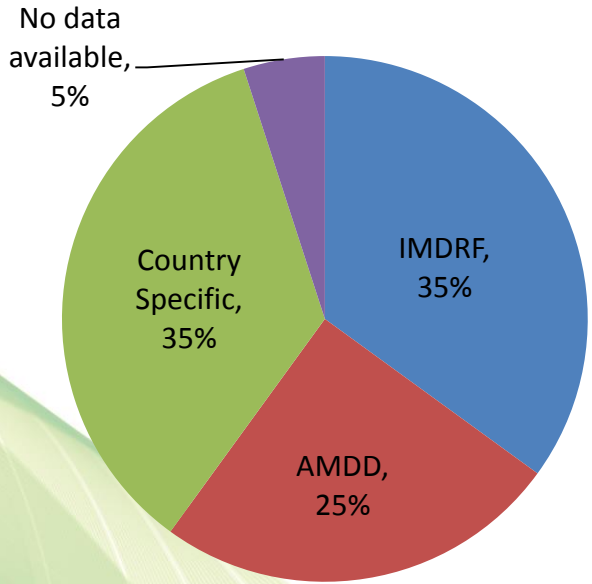
Elements of PMS

- PMS scope in 88% of the jurisdictions covers AE reporting, FSCA and product recall

- In 28% of the jurisdictions, PMS strengthened via imposing additional controls, e.g. testing of product samples, compliance audit of manufacturers and periodic post-market reviews



Interpretation (Definition) of Reportable AE



- About 1/3 adopting IMDRF's recommendations
- About 1/3 having own country's specific definition
- About 1/4 adopting ASEAN's recommendations

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Definition of FSCA

- About 2/3 having own country's specific definition
- About 1/3 not having any definition

Definition of Product Recall

- 3/4 having own country's specific definition
- 1/4 not having any definition

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

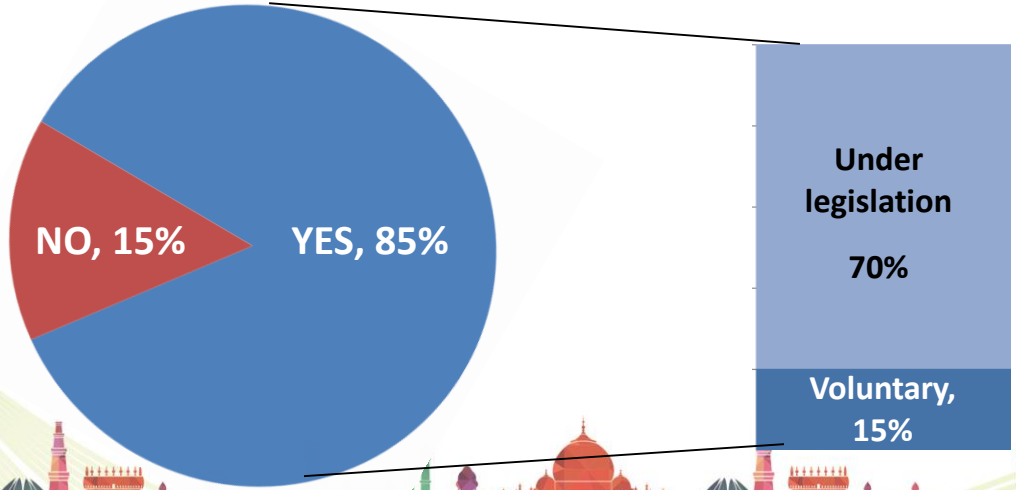
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

Are we using the same reporting criteria?

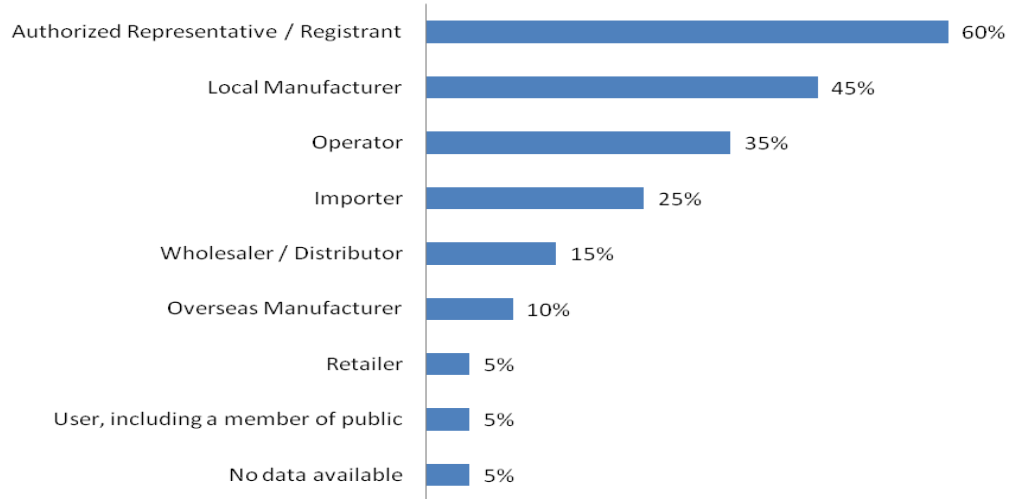
Reporting Criteria of AE (1)

- Mandatory reporting of AE required in 85% of the jurisdictions either under the medical device legislation (70%) or the voluntary PMS system (15%)



Reporting Criteria of AE (2)

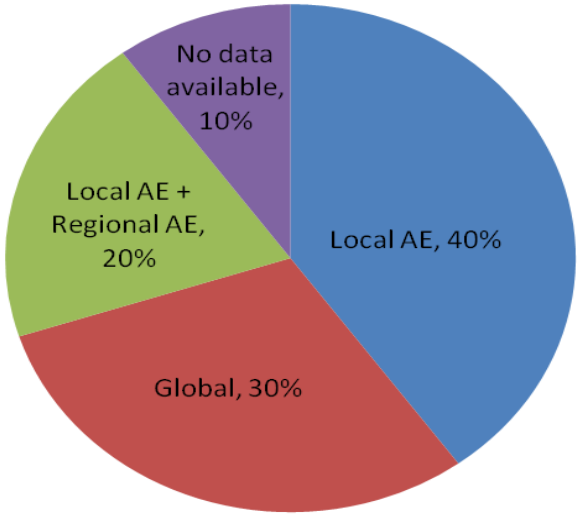
- Authorized representative and local manufacturer being the major parties responsible for the mandatory AE reporting



Note: Operator refers to Healthcare Institutions or Healthcare Professionals

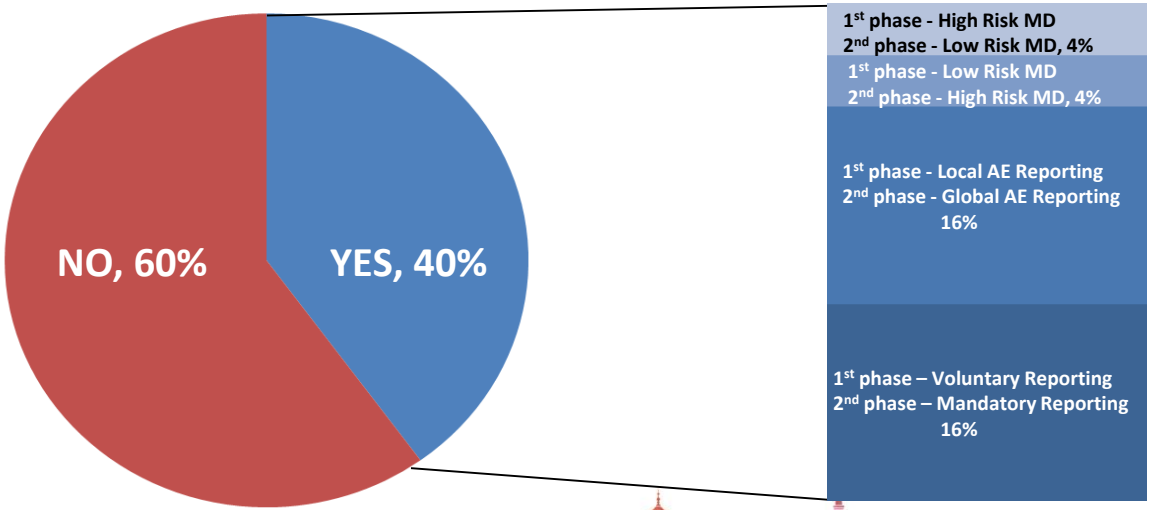
Reporting Criteria of AE (3)

- Different geographical scopes of reportable AE required in the jurisdictions
  - 40% requiring Local AE reporting
  - 30% requiring Global AE reporting
  - 20% requiring both Local and Regional AE reporting



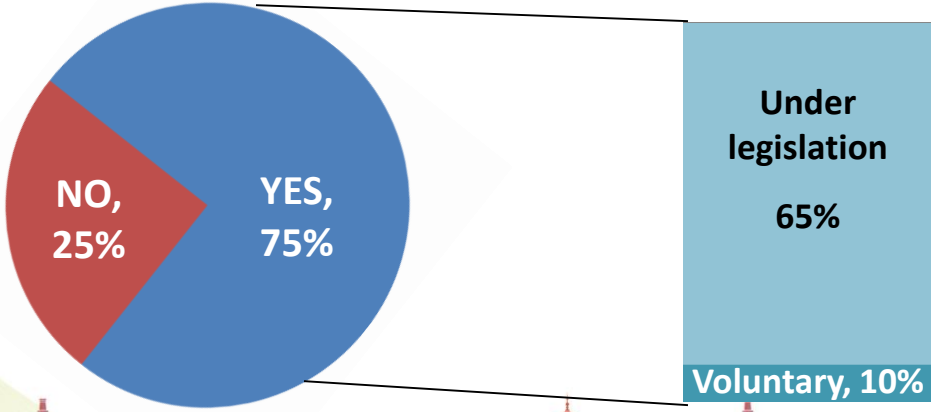
Reporting Criteria of AE (4)

- AE reporting implemented in two phases in 40% of the jurisdictions



Reporting Criteria of FSCA (1)

- Mandatory reporting of FSCA required in 75% of the jurisdictions either under the medical device legislation (65%) or the voluntary PMS system (10%)

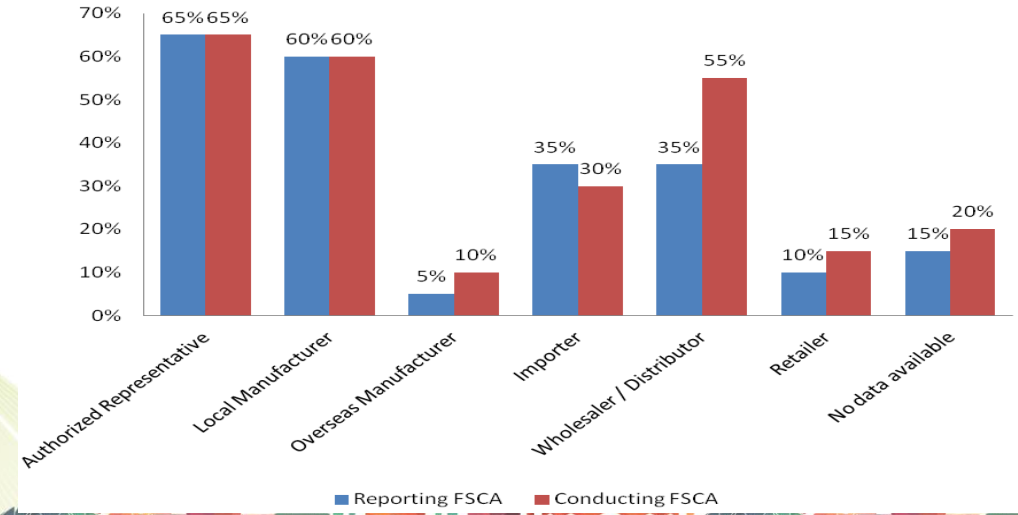


Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

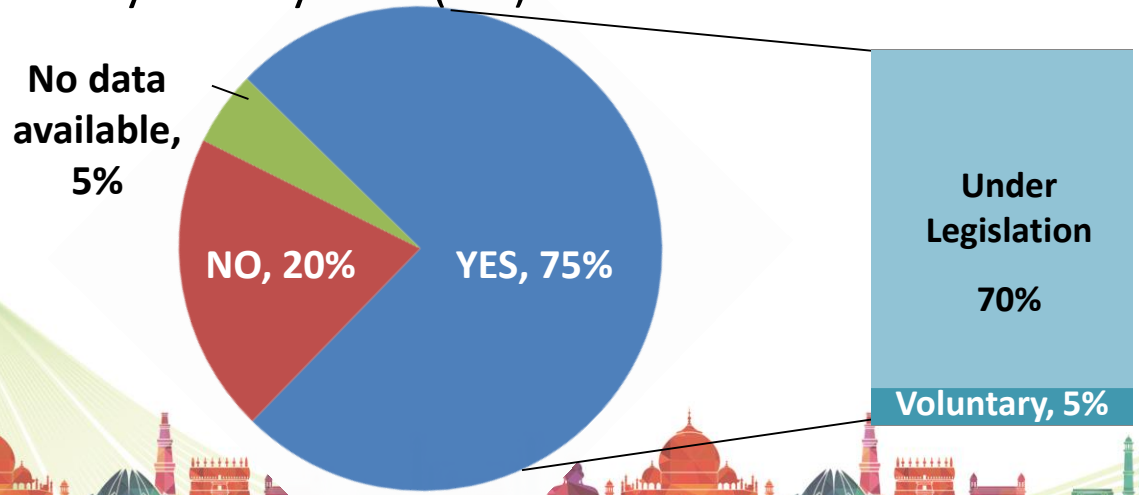
Reporting Criteria of FSCA (2)

- Authorized representative and local manufacturer being the major parties responsible for reporting and conducting FSCA



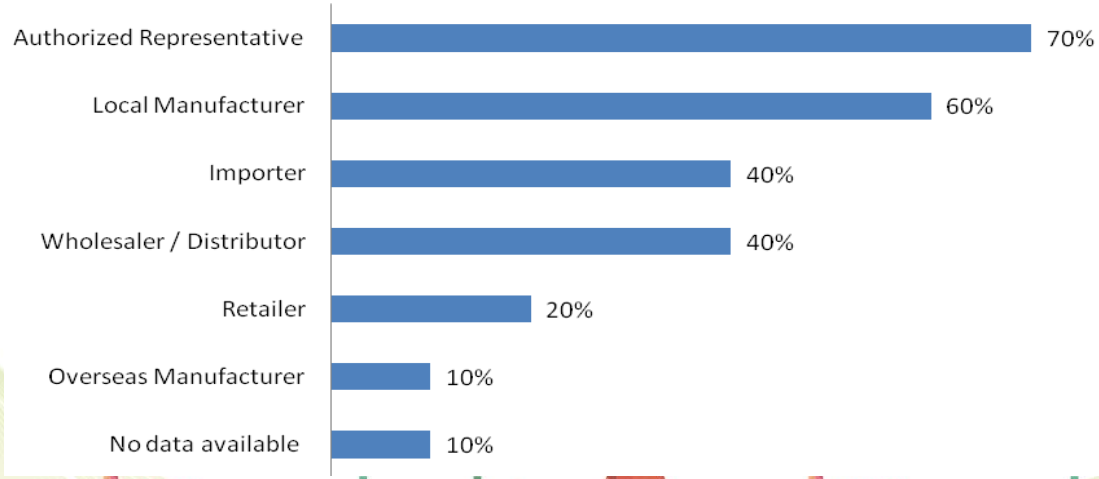
Reporting Criteria of Product Recall (1)

- Mandatory reporting of product recall required in 75% of the jurisdictions either under the medical device legislation (70%) or the voluntary PMS system (5%)



Reporting Criteria of Product Recall (2)

- Authorized representative and local manufacturer being the major parties that responsible for the product recall reporting



Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

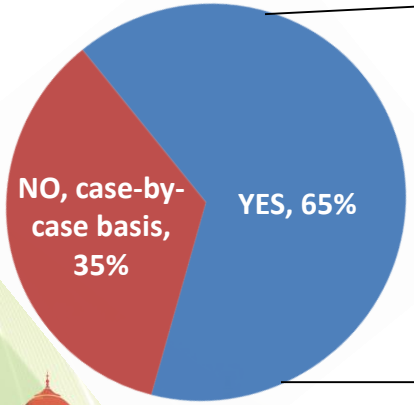
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

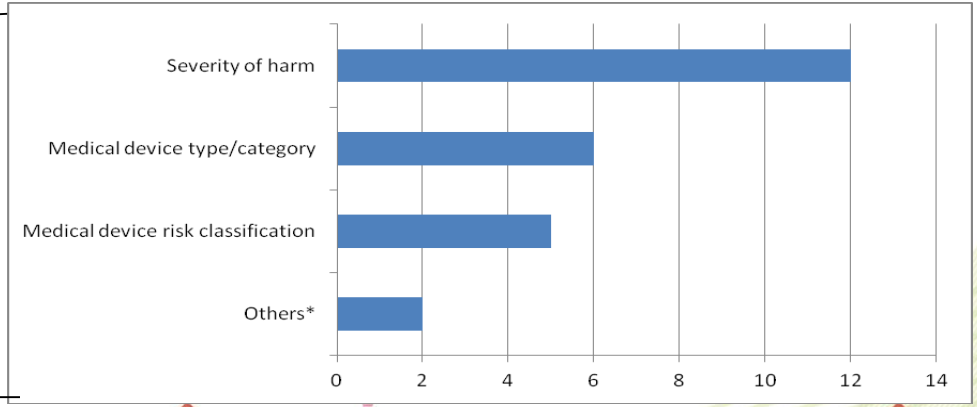
1927-2017 FICCI @90

Are we using the same criteria in managing the cases?

Managing AE cases (1)

- AE cases being categorized in 65% of the jurisdictions
- The severity of harm, i.e. the degree of harm to the patients, operators or end-users, being the most common parameter used in AE categorization

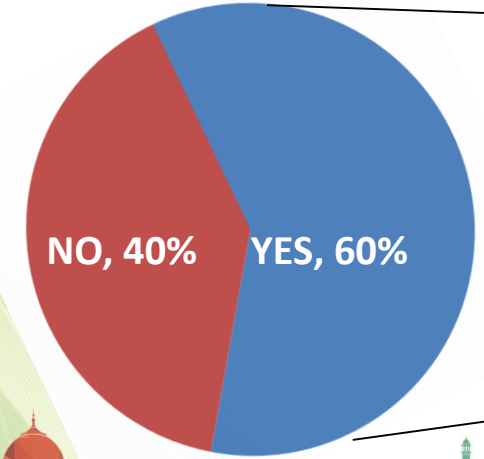


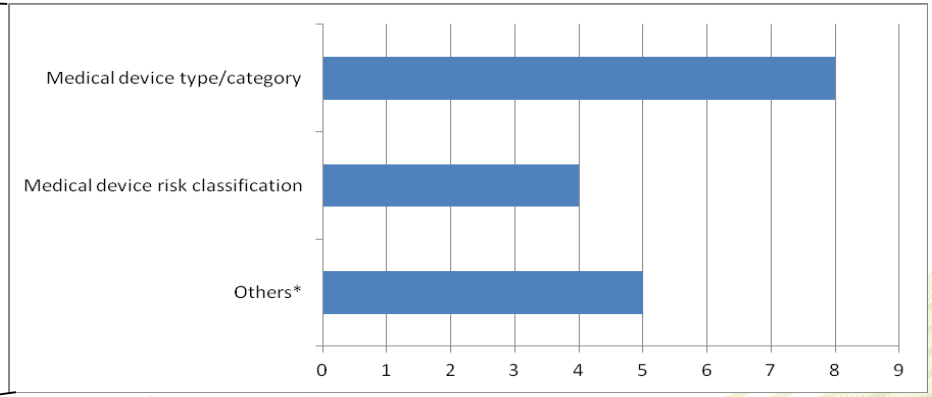


*Others: Guidance documents or possibility of occurrence

Managing AE cases (2)

- AE trending being conducted in 60% of the jurisdictions
- Medical device type / category being the most common parameter used in AE trending

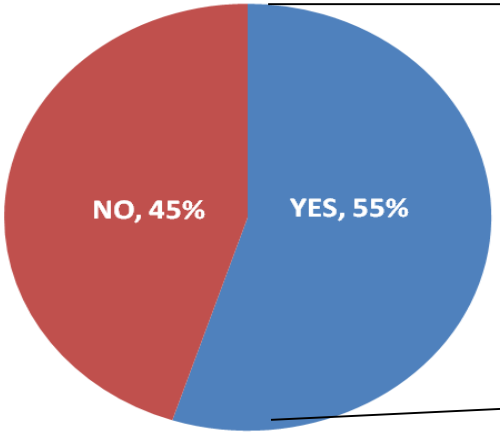


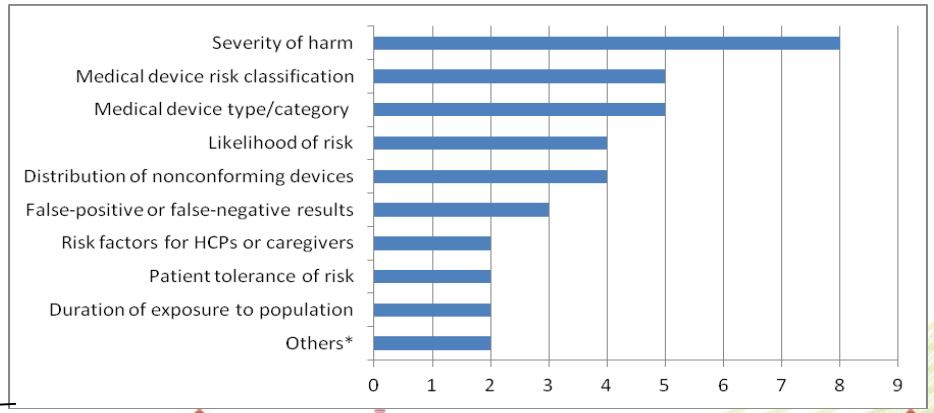


*Others – possibility of occurrence, severity of harm, case-by-case basis or other parameters, e.g. GMDN

Managing FSCA

- FSCA cases being categorized in more than half of the jurisdictions
- The severity of harm being the most common parameter used in FSCA categorization

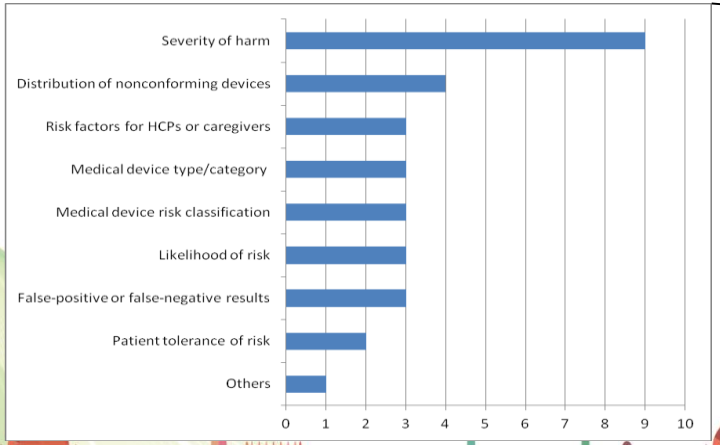


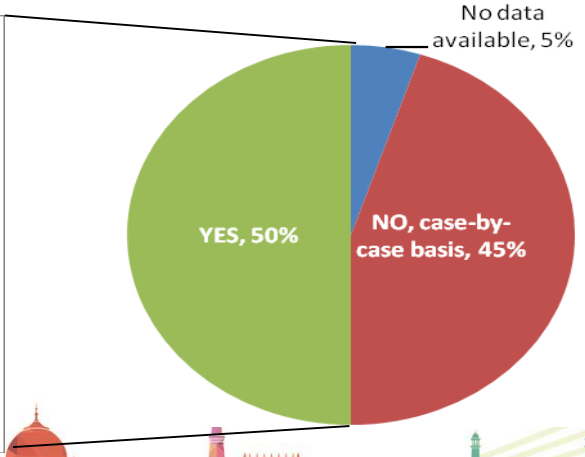


*Others: Guidance Documents or review on case-by-case basis in some cases; HCPs = Healthcare professionals

Managing Product Recall

- Product recall cases being categorized in half of the jurisdictions
- The severity of harm being the most common parameter used in product recall categorization





*Others: Guidance Documents; HCPs = Healthcare Professionals

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

1927-2017 FICCI @90

Observations and Way Forward

Observations (1)

- Similar control framework in PMS shared in the jurisdictions , covering the 3 fundamental elements:
  - AE Reporting
  - FSCA
  - Product Recall
- Depending on the resources available and public health concerns of the regulatory authority, PMS being strengthened by imposing additional controls in individual jurisdiction

Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Observations (2)

- Reportable AE interpreted (or defined) similarly in many jurisdictions

- However, different approaches in managing AE tend to be adopted in the jurisdictions, probably due to
  - the unique infrastructure of the local medical device industry
  - the local public health concerns; and
  - the resources available

Observations (3)

- In some jurisdictions, country specific definitions for FSCAs and Product Recall being used rather than adopting the ones recommended in the IMDRF or AHWP guidance documents

- Product recall is included within the definition of FSCA as suggested in IMDRF or AHWP guidance documents; yet FSCA and product recall found being handled in separate systems in many jurisdictions

- Despite the lack of harmonized standards in managing FSCA and product recall, a similar approach in managing FSCA and product recall still shared by the jurisdictions, which mainly based on the severity of harm

Way Forward

The survey data indicate that PMS in the jurisdictions has been going towards harmonization. To help go further in the direction, we may consider:

- More experience sharing and communications on PMS work amongst the regulatory authorities from different jurisdictions, and also with the industry;
- Developing more PMS related guidance e.g. guidelines or good practice in managing FSCA and product recall;
- Further gap analysis conducted aiming to identify and narrow down the differences of the PMS measures implemented without compromising public health in different jurisdictions

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

1927-2017 FICCI @90