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Regulations for PMS in India- Present & Proposed

Ms. Sumati Randeo

Head Regulatory, Compliance & Government Affairs

Abbott Vascular India

ASIAN HARMONIZATION WORKING PARTY

Federation of Indian Chambers of Commerce and Industry

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POST MARKET SURVEILLANCE REGULATIONS IN ASIAN COUNTRIES

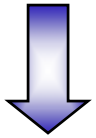
AE Requirements		India	Singapore	Hong Kong	China
Time Frame for Reporting	Public treat	Within 2 days	Within 48 hrs	Within 10 days	At once, Immediately
	Serious Injury or Death	Within 15 days	Within 10 days	Within 10 days	10 days (Provincial center for Medical device Adverse Events Monitoring)
	Other Averse Reports	Within 15 days	Within 10 days	Within 30 days	10 days
Alignment to GHTF Reporting Requirements		Regulators are reviewing the recommendations for adoption of GHTF	Yes	Yes	Yes

CURRENT POST MARKET SURVEILLANCE REPORTING REGULATIONS IN INDIA

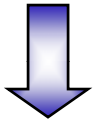
- Present reporting system is in accordance to Schedule Y of the Drugs and Cosmetics Act.
- Periodic Safety Update Reports (PSURs) are furnished to the CLA.
- PSURs are submitted every 6 months for the 1ST two years and for subsequent two years its submitted annually.
- PSURs submitted within 30 calendar days of the last day of the reporting period.
- In case of serious unexpected Adverse Event, it must be reported within 15 days after the Manufacturer becomes aware of the event.
- Since the PSURs and Adverse Event Reporting Form under Schedule Y are drug specific, it does not suit the device reporting requirements. But Sch Y Guidelines adopted as – Good Practices.

CHALLENGES FACED

Adverse Event Definition

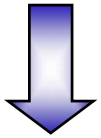


Adverse Event Reporting Form



Whom to submit?

Time Frame for Submission?



Reporting

PROPOSED PMS REGULATIONS

- It is proposed to adopt GHTF Guidelines for Adverse Event Reporting (AER) as covered by draft Schedule MIII.
- Objective:
  - Improve the protection of health and safety of patients, users.
- AER must be submitted to the CLA.
- Assessing link between device and event, the manufacturer should take in to account:

  i. Opinions and available information from Healthcare professionals

  ii. Information concerning previous, similar events

  iii. Other information held by applicable stakeholders

ADVERSE EVENTS TO BE REPORTED UNDER SCHEDULE MIII

- **The following basic reporting criteria is considered a reportable adverse event.**

1. The Manufacturer becomes aware of information regarding an event that has occurred with his listed device(s).
2. The Manufacturer's device is associated with the event.
3. The event led to one of the following outcomes:
   - Death of a patient, user or other person;
   - Serious injury of a patient, user or other person;
   - No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs.
4. Unanticipated event of Medical Device
   - Unanticipated event that results in death or serious injury / serious public health concern.
   - When the manufacturer notes a change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern.
   - When the manufacturer initiates corrective action to prevent death or serious injury or serious public health concern.

EVENTS EXEMPTS FROM REPORTING UNDER SCHEDULE MIII

- **The following exemptions need not be reported**

1. Deficiency of a new device found by the user prior to its use.
2. Adverse event caused by patient conditions.
3. Use of a medical device beyond its service life.
4. Protection against a fault functioned correctly and where no death or serious injury occurs.
5. Remote likelihood of occurrence of death or serious injury.
6. Expected and foreseeable side effects.
7. Adverse events described in an advisory notice previously sent to users, and where no serious injury or death occurs.
8. Adverse events caused by abnormal use of medical devices.

TO WHOM, WHEN AND HOW TO REPORT?

- To Whom?
  - All reportable Adverse Events is to be reported to the CLA in a form of a report form within the specified time frame.
- Time Frame:
  - Adverse events that result in death or serious injury or of a serious public health concern must be reported by the Manufacturer to the CLA promptly, but not later than 15 days after the Manufacturer becomes aware of the event.
- How to report?
  - Medical Device Adverse Event Report Form on the same lines as N54 form of GHTF SG2 is proposed to be used.

STRIVING TOWARDS BETTERMENT

- “We cannot solve problems by using the same kind of thinking we used when we created them”- A. Einstein

- There is no excuse, for not doing things better!

THANK YOU