IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

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Safety notices and Vigilance

Opportunities and challenges – Industry perspective

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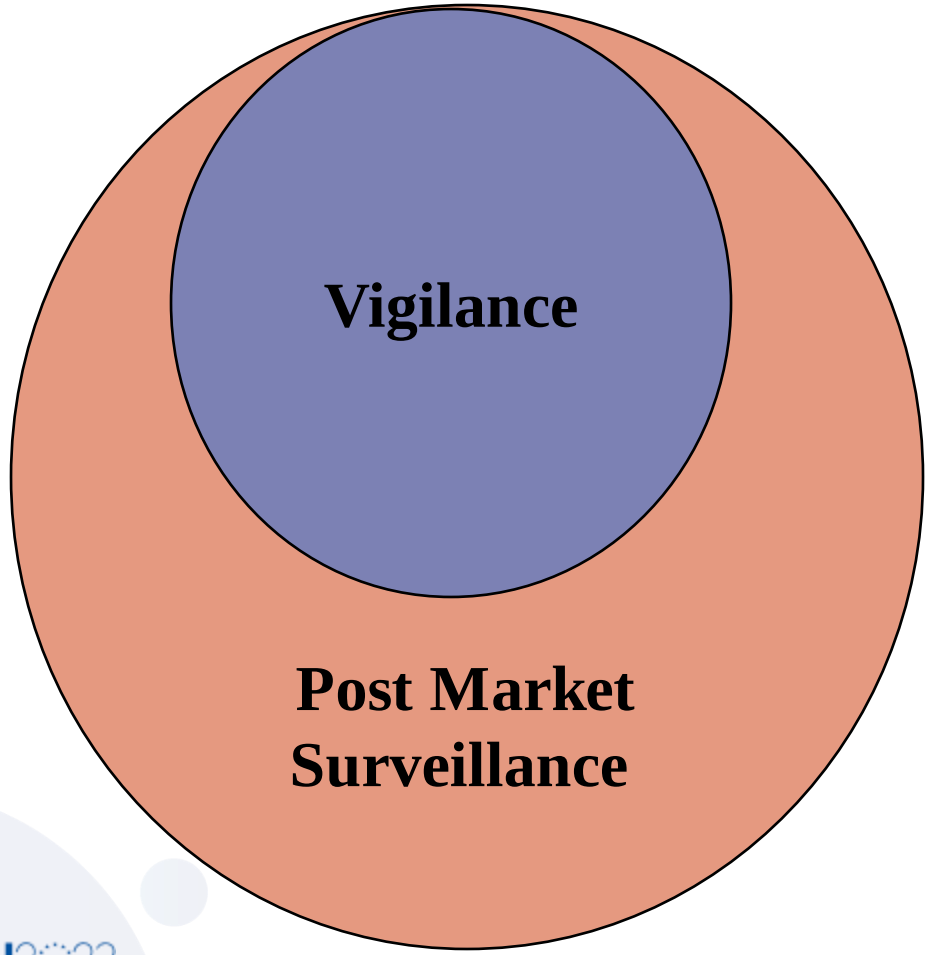
OVERVIEW

- Postmarket Surveillance/ Vigilance
- Summary PMS activities & Links to International Standards
- Regional/Markets Key challenges
- Key Opportunities

Postmarket surveillance/ Vigilance



Vigilance:
<u>reacting</u> to adverse event

Post Market surveillance:
<u>proactive</u> collection of information

Vigilance:

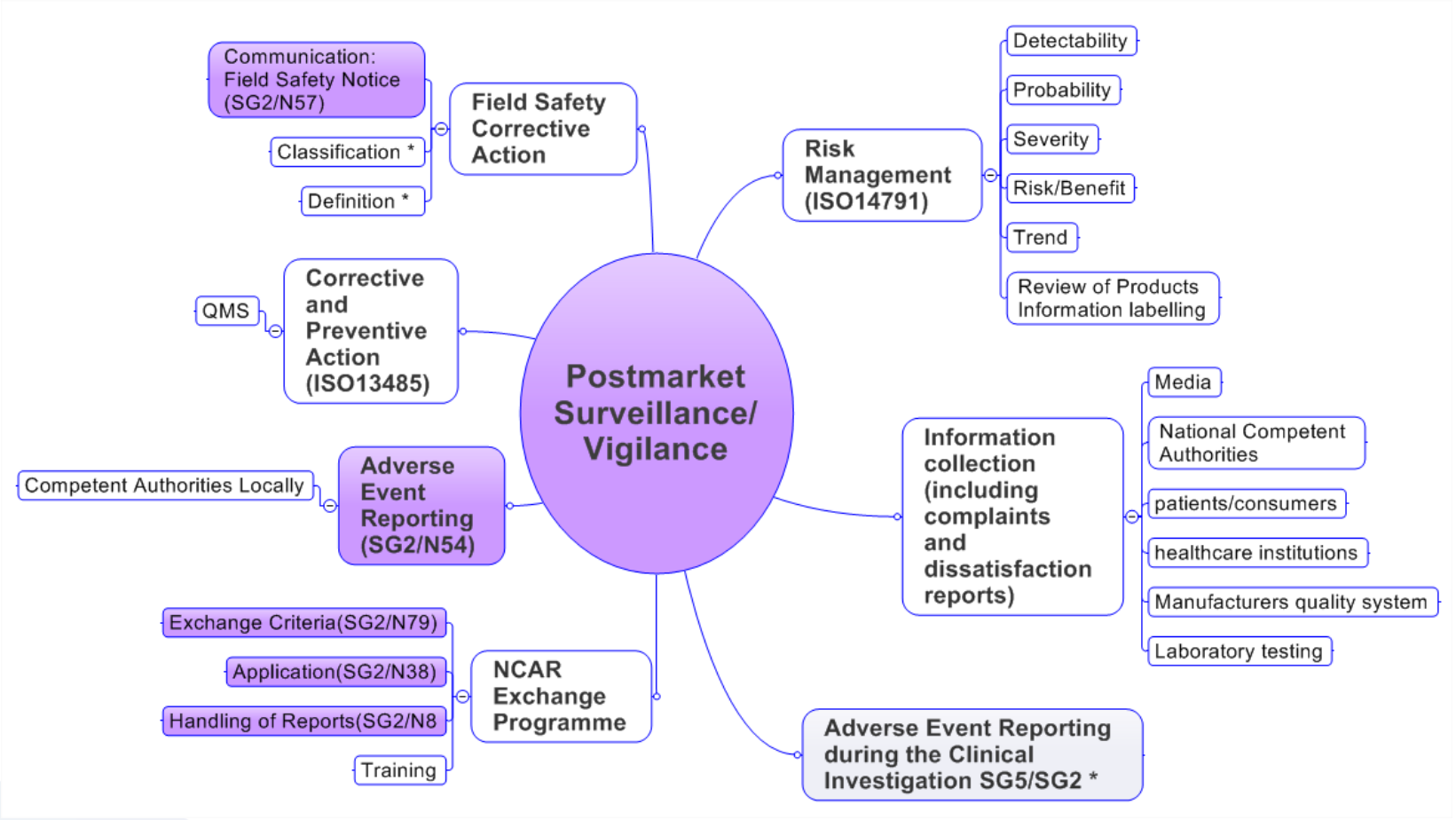
The reporting and investigation of adverse events. Both the manufacturer and the Regulatory Authority play major roles.

Post market surveillance:

Post market collection of info on the quality, safety and performance of a MD by Regulatory Authorities or Manufacturers.

→ Injury prevention, Product improvement, Regulatory measures, ….

Summary PMS activities & Links to International Standards (*)



(*) Reference: section 9.2 of GHWG-GRM/N1R13 (2011)

Regional/Markets Key challenges

- Different Definitions
  - Adverse Events
  - FSCA
- Different AE reporting criteria
- Foreign AE report requirements
- No common AE/FSCA reporting forms
- Different reporting timelines
- Different Annual/PSUR reports requirements
- Multiple UDIs systems

Example SAE Reporting Timelines

China

- Not later than 7 days for events that led to death or serious deterioration in state of health,
- Not later than 20 days for events that led to serious injury that happen in China.
- Not later than 30 days for events that led to serious injury that happen overseas

Japan

- Unlabeled serious incidents or near incidents – 15 days
- Labeled serious incidents or near incidents – 30 days
- Unlabeled medium level incidents or near incidence – 30 days
- Serious incidents by infectious diseases that could be caused by using medical devices – 15 days.

Australia

- Death or serious deterioration in health: 10 days

Hong Kong SAR

- Deaths, serious injuries, or events of serious public health concern: 10 elapsed calendar days

Singapore

- Not later than 10 days for events that led to death or serious deterioration in state of health,

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Example Not reportable Criteria

China

- There are no definite provisions for "Not Reportable Events"

Australia

- Events occurred outside Australia.
- by the user prior to its use
- Adverse incident caused solely by patient conditions
- Use of a medical device beyond its service life
- Protection against a fault functioned correctly
- Remove likelihood of occurrence of death or serious injury
- Expected and foreseeable side effects that are documented in manufacturer's instructions for use or labelling
- Adverse events described in an advisory notice
- Reporting exemptions granted by the Therapeutic Goods Administration

Hong Kong SAR

- Incidents occurred outside of Hong Kong
- Deficiency of a new device found by the user prior to its use
- Adverse incident caused by patient conditions
- Use of a medical device beyond its service life
- Protection against a fault functioned correctly and where no death or serious injury occurs
- Remote likelihood of occurrence of death or serious injury
- Expected and foreseeable side effects
- Adverse incidents described in an advisory notice previously sent to users
- Use errors
- Adverse incidents cause by abnormal use

Singapore

- Events occurred outside Singapore.

Japan

- There are no definite provisions for "Not Reportable Events" except for mishandling or user error.

Key Opportunities

- Harmonization definition/criteria/timelines/reporting forms
- Consider annual safety report requirements over foreign AE reporting requirements
- Consider Post Market requirements to be part of Renewal/ Recertification/ New medical device regulation requirements

THANK YOU / QUESTIONS

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