3rd APEC Funded Seminar of Harmonization of Medical Devices Regulation

Group A

Group A Members

- Regulators – Thailand, Singapore, Vietnam, Brunei, Indonesia, Hong Kong, Chile and Philippines

- Industries – China, Indonesia, Malaysia, Thailand, Singapore, India, Australia, Korea

SG 1

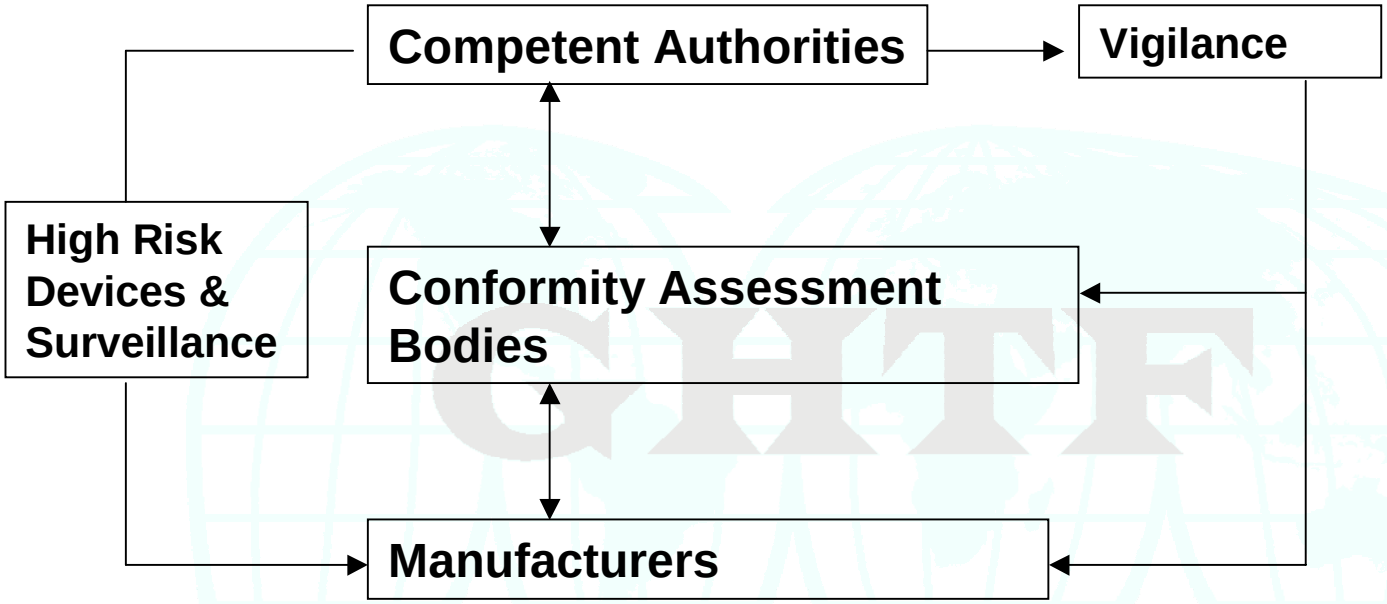
Concerns / Obstacles

- Country specific requirements need to be considered (STED is a good model)
- Staff Competency & Capacity
- Economies without regulations
- Transition period needed to enforce harmonized requirements under current legal framework
- Local Industries lack in knowledge in understanding the GHTF regulatory requirements
- CAB is optional, marketing authorization approval is under CA as country specific
- Understanding of GMDN – CAs, Industries and users

Recommendations

- STED - Minimum recommended requirements for each class of medical devices
- Adopt classification rules and Conformity Assessment Procedures
- Clear item list of MD for each classification, if possible for easier implementation
- Solve grey products such as IVDD, contact lens solution, alcohol prep.
- Training – CA & Industries

Conformity Assessment



SG 2 – AE Reporting

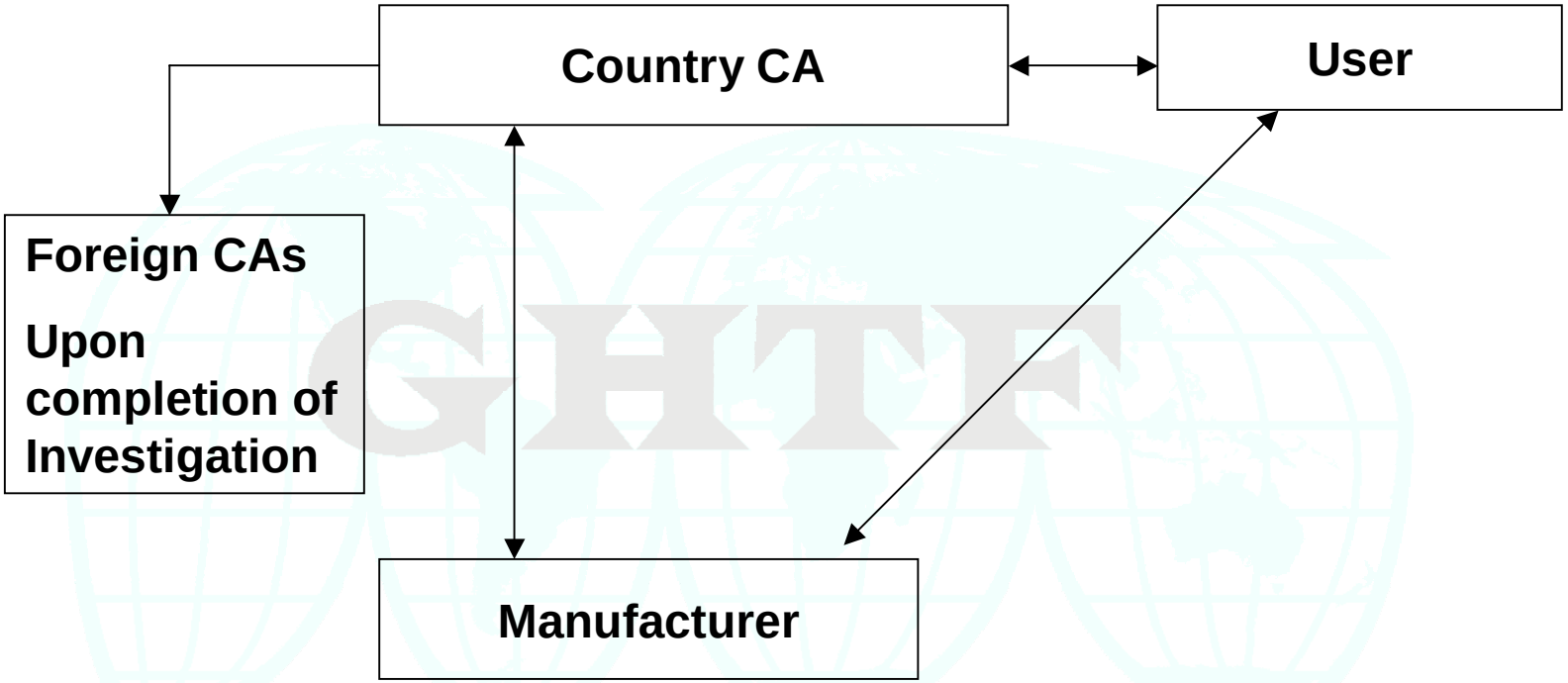
Concerns / Obstacles

- Industries worry CA takes action before completing the investigation of AE.
- Encourage voluntary report from health profession or user
- Many CAs lack in vigilance system

Recommendations

- Common reporting format
- Common reporting timeframe
- Data Exchange for AE reports between CAs
- CAs to set up appropriate vigilance system
- Networking among CAs

AE Reporting Model



SG 3 / SG 4

Concerns / Obstacles

- Auditors Competency
- Auditors trained in GMP (drug) instead of Quality Management System auditing.
- Resource planning and transition period before enforcement

Recommendations

- Auditors training for CAs, CABs and Industries
- Accreditation of Auditors for CAs, CABs and Industries.
- Auditors recognition among member countries

Note: The group considers the GHTF guidance documents are good model.

Summary

RECOMMENDATIONS FOR GHTF GUIDELINES CONSIDERATION

1. Member Countries National law and legislation
2. Products availability, accessibility and affordability
3. Equity of healthcare service (public benefits)
4. Industry and Regulatory readiness for implementation and impact
5. Resources
   - Financial
   - Infrastructure
   - Manpower
   - Etc.,
6. Prevailing situation (e.g. health status, social, political, economic, education, etc.,)
7. Action plan with priority setting and reports back to individual country for consideration on adoption and implementation of harmonized requirements