AHWP
Technical Committee

Survey Report 2002

Purpose of Survey

- To obtain input from Asian regulators on their efforts to harmonize the regulation of medical devices with the Global Harmonization Task Force (GHTF) recommendations and guidance;
- To obtain suggestions for possible regional collaboration and training.

Survey Questionnaires

- I. Status of medical device regulations
- II. What are primary concerns about medical devices offered in their economies?
- III. Which existing regulatory systems in other economies have they evaluated as models for their own system?
- IV. GHTF guidance documents:

  Status of adoption and implementation in member economies.

Survey : Feb - Apr 2002

Asian member economies:

- Brunei Darussalam
- PRC
- Hong Kong
- South Korea
- Indonesia
- Malaysia
- Philippines
- Thailand
- Chinese Taipei/Taiwan
- Singapore

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FINDINGS:

I. Status of medical device regulations

- 6 economies currently regulate medical devices (cn, id, kr, ph, tw, th);

  3 independently developed from drug regulations;
  2 intending to introduce new regulations

- 2 economies in the process of promulgating regulations (sg, 02/03; my, 04);

- 1 economy, studying various regulatory systems (hk).

FINDINGS:

II. Primary concerns about medical devices

Member economies with regulatory systems in place:

- Safety and efficacy of a medical device
- Quality and safety, supported by substantiated documents
- Post-market surveillance
- Labelling not in accordance with requirements; nonsubmission of Certificates of Free Sale and cGMP from the country of origin issued by the regulatory authority
- Safety, efficacy & quality; Adverse events reporting; modern technology
- Quality, safety and effectiveness

Member economies with developing regulatory systems:

- Quality, safety and effectiveness; low-risk alternative therapy medical devices with unsubstantiated treatment claims
- Ensure devices imported and manufactured locally meet international standards concerning quality, safety and effectiveness; to facilitate marketing authorization and export of locally manufactured devices
- Public safety, use of medical device by non-medical professionals

FINDINGS:

III. Which existing regulatory systems were evaluated as models

Member economies with regulatory systems in place:

- USA and Europe model;
- Code of Federal regulation for classification of medical devices, TGA regulation;
- US FDA and Japanese regulations;
- None in particular;
- US, EU;
- Modified from US FDA regulatory system.

Member economies with developing regulatory systems:

- EU, Canada, Australia, GHTF guidance documents;
- EU directives, Australia, GHTF guidance documents;
- GHTF founding members' models and economies of APEC.

FINDINGS:

IV. Status of adoption & implementation of GHTF guidance documents (12)

SG1: * Essential Principles of Safety and Performance of Medical Devices;
* Labelling for Medical Devices;
* Role of Standards in the Assessment of Medical Devices.

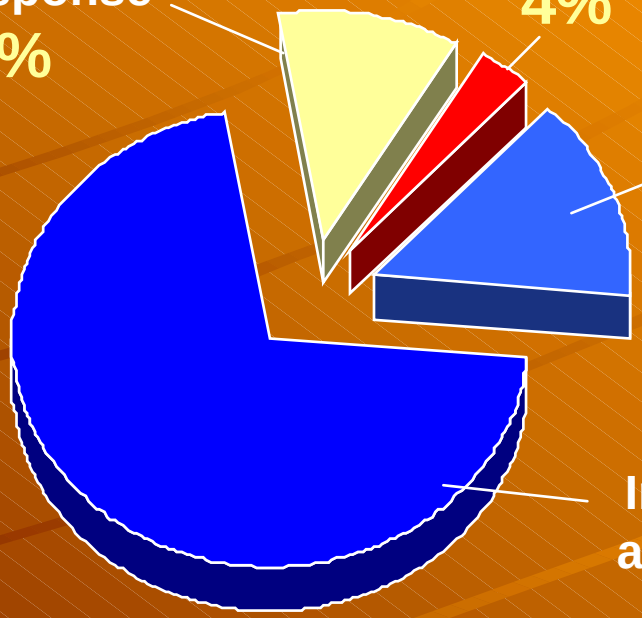
SG2: * Global Medical Device Competent Authority Report;
* Minimum Data Set for Manufacturer Reports to Competent Authority;
* Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices;
* Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative.

SG3: * Guidance on Quality Systems for the Design & Manufacturing of Medical Devices;

SG4: * Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies;
* Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements;
* Audit Language Requirements;
* Training Requirements for Auditors.

FINDINGS:

IV. Status of adoption & implementation of GHTF guidance documents (continued)

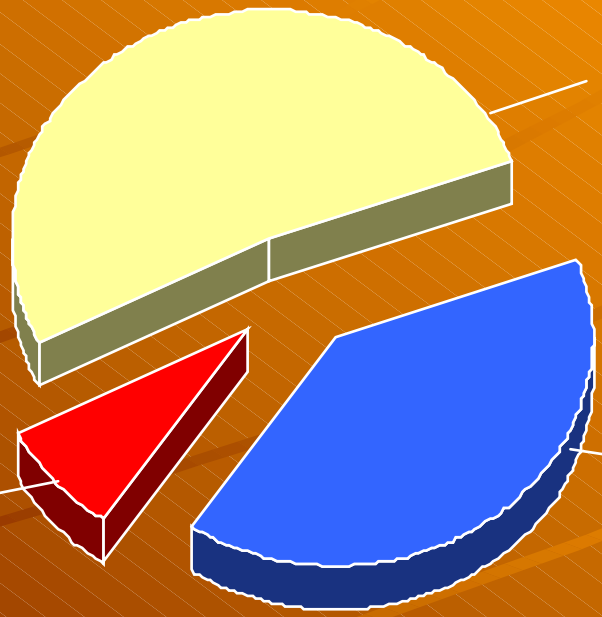


SG1: Essential Principles of Safety and Performance of Medical Devices
SG2: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative
SG1: Labelling for Medical Devices
SG1: Role of Standards in the Assessment of Medical Devices
SG2: Global Medical Device Competent Authority Report
SG2: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

FINDINGS:

IV. Status of adoption & implementation of GHTF guidance documents (continued)

TRAINING



No response
52%

No
8%

YES
40%

SG2: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative

SG4: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies

SG4: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

SG4: Training Requirements for Auditors

SG1: Role of Standards in the Assessment of Medical Devices

SG2: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices

Thank You.