Actions of Medical Device Post-Market Surveillance

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Outline

• Total product life cycle management system
• Purpose of post-market surveillance
• Post-market risk control mechanism
  – Spontaneously AE reporting system
  – Medical device closely safety monitoring
  – Re-evaluation of marketed medical devices
  – Post-market regulatory controls
• Stakeholders in post-market surveillance
• Policies and implementation
• Summary and prospects
Total Product Life Cycle Management System

Medical Care Needs / Fundamental Study

Product Design / Prototype Development

Preclinical Verification

Clinical Trial

Premarket Application

Production

Post-market Surveillance

General / Special Case Consultation

Good Laboratory Practice (GLP/GTP)

Clinical Trial Inspection (GCP)

Clinical Trial Protocol Review (authority/IRB)

Registration (Approval/Listing)

Medical Device Advisory Committee

Manufacturer’s quality system audit (GMP)

Pre-market Control

Product Source Control

GLP : Good Laboratory Practice
GTP : Good Tissue Practice
GCP : Good Clinical Practice
IRB : Institutional Review Board
GMP : Good Manufacturing Practice
ADR : Adverse Device Reaction
GVP : Good Vigilance Practice
GDP : Good Distribution Practice

Adverse Device Reaction (ADR)/Defective Product Reporting
Safety Surveillance (GVP) & Alert Collection
Good Distribution Practice (GDP)
Unique Device Identification (UDI)
Consumer Health Education and Awareness

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Purpose of Post-Market Surveillance

• The ultimate goal: to continually ensure the safety, effectiveness and quality of marketed medical devices with reasonable risk / benefit profiles
• Benefits
  – Patients and healthcare facilities: safety
  – Authority: protection of public health
  – Manufacturers: improvement of products from the feedback of real-world experience
### Post-Market Risk Control Mechanism of Medical Devices

#### Monitoring
- **Safety**
  - **Reactive**
    - Adverse event (AE) reporting system
  - **Proactive**
    - Medical device safety monitoring (with periodic safety update reports, PSUR)

- **Quality**
  - **Reactive**
    - Defective product reporting system
  - **Proactive**
    - Monitoring of domestic and global quality alerts
    - Post-market quality surveillance program (sampling/testing)
    - Manufacturer inspections, joint post-market audits

#### Risk analysis/Re-evaluation
- **Risk control**
  - Amended labeling, restricted use, extended monitoring duration, recalls, product withdrawals, etc.
  - Educational training

#### Risk communication
- Awareness promotion and dissemination of information

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Spontaneously AE Reporting System

- Reporting of adverse event (AE)/defect product via online system, mail or fax
- Medical device safety monitoring via Periodic Safety Update Reports (PSUR)
- Vigilance/surveillance activities via online system

**Domestic licenses holders and manufacturers**
- AE/defect product report
- AE report in clinical trials
- Periodic safety update reports (PSUR)
- Voluntary notice of recall

**Local health authority**
- Transfer AE report from consumers

**Consumers and healthcare professionals**
- AE/defect product report
- AE report in clinical trials

**Vigilance activities of global safety/quality information**
- Alerts and recalls from foreign government websites
- Safety Alert Dissemination System (SADS) of AHWP

**Awareness of AE reporting system by device users and healthcare providers** can be promoted to improve the collection of post-market data which are meaningful and useful for evaluation.

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Trend of AE Reports in Chinese Taipei

Most reported items in 2016
- AE: Cardiovascular devices (e.g., vascular stent)
- Defective devices: general and plastic surgery devices (e.g., i.v. set)

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Medical Device Closely Safety Monitoring

• For brand-new devices or long-term implants with high risk
  – limited use experience in clinical trials
  – assessment of long-term effects
  – other arising issues of safety and effectiveness

• The License holder shall actively collect safety information available both domestically and globally during the 3-year period, and submit the Periodic Safety Update Reports (PSUR) every 6 months

• PSUR will be reviewed by Medical Device Safety Evaluation Committee to assess safety and effectiveness
Patterns of Safety Monitoring

- 189 products designated for safety monitoring till 2016
- Categories:

  - Cardiovascular devices: 31.2%
  - General and plastic surgery devices: 44.4%
  - Neurological devices: 7.41%
  - Ophthalmic devices: 4.76%
  - Dental devices: 4.76%
  - Others: 7.41%
Re-evaluation of Marketed Medical Devices

• Information monitoring or collecting
  – Reports of AE / product defect
  – periodic safety update reports
  – vigilance activities

• Risk analysis and assessment
  – device defect or use error
  – single-case or systematic problem
  – device-specific or device type-specific problem
  – relation to manufacturing process

• Post-market regulatory controls
• Dissemination of safety information
Post-Market Regulatory Controls

- Notify manufacturer to take appropriate action, such as:
  - Product correction (e.g., labeling change);
  - Sales restriction (till correction verified); or
  - Market withdrawal
- Perform audit inspection or sample testing
- Issue a public announcement (safety alert or recall notice)
- Inform targeted healthcare providers
- Escalate safety monitoring of the reported product or same type of product
Stakeholders in Post-Market Surveillance

Health Authority
- Pre-market assurance of product safety and effectiveness
- Re-evaluation of AE report and safety monitoring
- Vigilance/surveillance activities
- Regulatory controls

Healthcare Facilities
- User training
- Safety information disclosure to patient
- AE report

Manufacturers
- Training program
- Safety information disclosure in IFU and labeling
- AE report
- Field safety notice
- Preventive action

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Policies and Implementation

• Legal obligation and actions in laws and regulations
  – Mandatory serious AE reporting and safety monitoring
  – Re-evaluation for product safety and effectiveness
• Guidance for healthcare facilities and manufacturers
• Proactive actions
  – Vigilance activities of global information
  – Educational training
    • Seminars to improve the quantity and quality of AE reports
    • An experience sharing platform for clinical engineers
  – Discretionary studies for long-term effects
• Other resources
  – Voluntary accreditation of clinical engineers
  – Management of medical devices in healthcare facilities
Summary

Post-market surveillance

- Spontaneously AE reporting system
- Closely Safety monitoring
- Vigilance activities of global information
- Training
- Manufacturer inspection
- Post-market quality audit
- Discretionary studies

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