Case Studies in Postmarket Reliance Implementation

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

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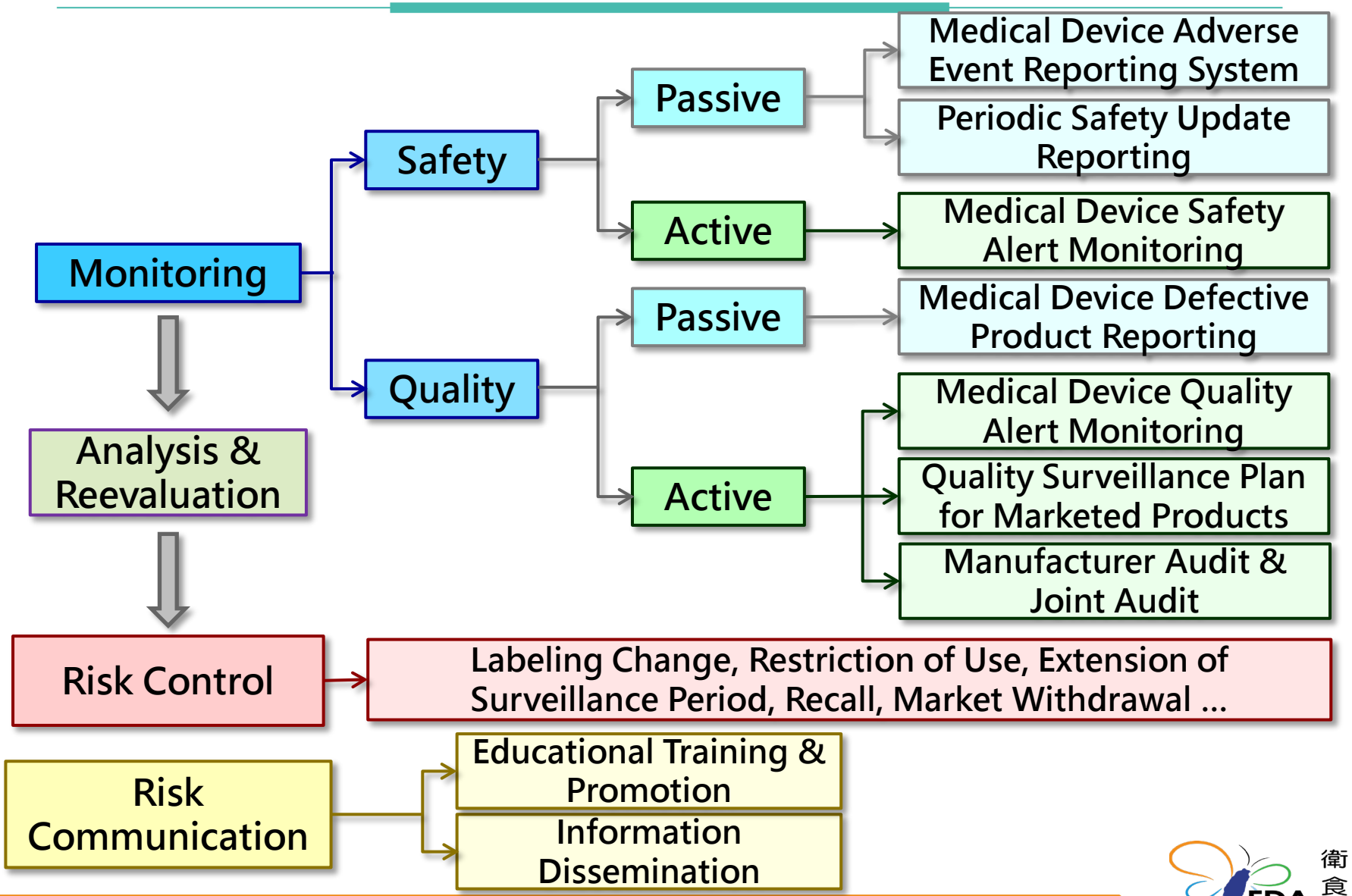
Outline

- Medical device post-market risk management in Taiwan
- Case study example
  - Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)
  - Actions in response
  - Key elements in evaluation
- Takeaway points

Medical Device Post-Market Risk Management



Medical Device Safety Alert Monitoring

- Active monitoring of global alerts
  - Collect safety information announced by the United States, Canada, United Kingdom, Japan, etc.
  - Check to see if any domestic products are affected
  - Take responsive actions
- Passive collection of domestic reports
  - According to the Medical Devices Act, upon the finding that a medical device is likely to cause harm to the health of human body, the registered firm shall proactively report to the central competent authority and undertake corrective and preventive measures.
  - Those who fail to comply shall be fined between NT$20,000 and NT$500,000.

Global Safety Information Monitoring

swissmedic Schweizerisches Heilmittelinstitut

香港特別行政區政府 衛生署

Health Canada

国家药品监督管理局 National Medical Products Administration

ECRI Institute

MHRA Regulating Medicines and Medical Devices

HSA Health Sciences Authority

FDA

SFDA

Australian Government Department of Health Therapeutic Goods Administration

BfArM Bundesinstitut für Arzneimittel und Medizinprodukte

Pmda JAPAN

more ...

Case Study Example

Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)

2017

- Breast implants: Update - Breast Implant Associated-Anaplastic Large Cell Lymphoma (U.S. FDA 2017/3/26)
  - FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL)
- Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) (UK MHRA 2017/7/26)

2019

- Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) - Letter to Health Care Providers (U.S. FDA 2019/2/6)
- Health Canada advises Allergan of its intent to suspend its licences for Biocell breast implants as a precautionary measure (Health Canada 2019/4/4)

Actions in Response to BIA-ALCL Safety Info

1. Referred to and relied on safety information of various countries, issued letters to alert medical associations, stayed vigilant for ALCL related symptoms in breast implant patients
2. Announced an informed consent form of breast implant surgery (its content includes a risk statement on BIA-ALCL and requirement for clearly informing the patient), added BIA-ALCL adverse reaction information into the labeling
3. Launched a retrospective study project to investigate potential domestic BIA-ALCL cases
4. Convened an expert meeting and asked device firm to submit product safety evaluation data
5. In coordination with foreign recall action, asked domestic firm to conduct recall operation and revoked product license per the firm's request
6. Initiated a domestic clinical surveillance plan and received the first BIA-ALCL case report

Key Elements in Safety Info Evaluation

- Confirm if there are any affected domestic products
- Address the recommendations in foreign evaluation reports (BIA-ALCL as an example):
  - Consider ethnic differences in foreign study reports
  - Probe into product's safety and efficacy according to its risk and benefit profile
  - Identify whether related actions could cause supply and demand imbalance of medical device market
- Refer to the following when taking responsive actions:
  - Collect opinions from related device firms
  - Consult external healthcare professionals
  - Release information timely to dispel public concerns
  - Collaborate with relevant government agencies

Takeaway Points

- Reliance on safety information from foreign regulatory counterparts enhances domestic market surveillance/vigilance
- Communication with all relevant stakeholders is necessary and essential to ensure appropriate actions are timely taken
- Global network for postmarket information exchange would bring together expertise from different parts of the world to contribute to device and patient safety improvement

Thank you

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