Current Status of medical product Regulation and International Collaboration in Taiwan

藥求安全　食在安心

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on Medical Products Regulation
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衛生福利部食品藥物管理署
Food and Drug Administration,
Ministry of Health and Welfare
http://www.fda.gov.tw/

Outline

- Organization and Responsibility of TFDA
- Current Status of Pharmaceutical Regulation in Taiwan
- Current Status of Medical Device Regulation in Taiwan
- International Collaboration
- Future Prospects

Organization and Responsibility of TFDA

Establishment of TFDA

2009.6.3 TFDA Organization Act → 2010.1.1 TFDA Inauguration → 2011~2013 MOHW Restructure → 2013.7.23 TFDA Elevation

4 bureaus:

- Food Safety 食品處
- Pharmaceutical Affairs 藥政處
- Food & Drug Analysis 藥物食品檢驗局
- Controlled Drugs 管制藥品管理局

FDA

2013.07.23 TFDA

FDA

Mission, Vision and Core Value

Quality and Safety of Food and Medical products
(藥求安全 食在安心)

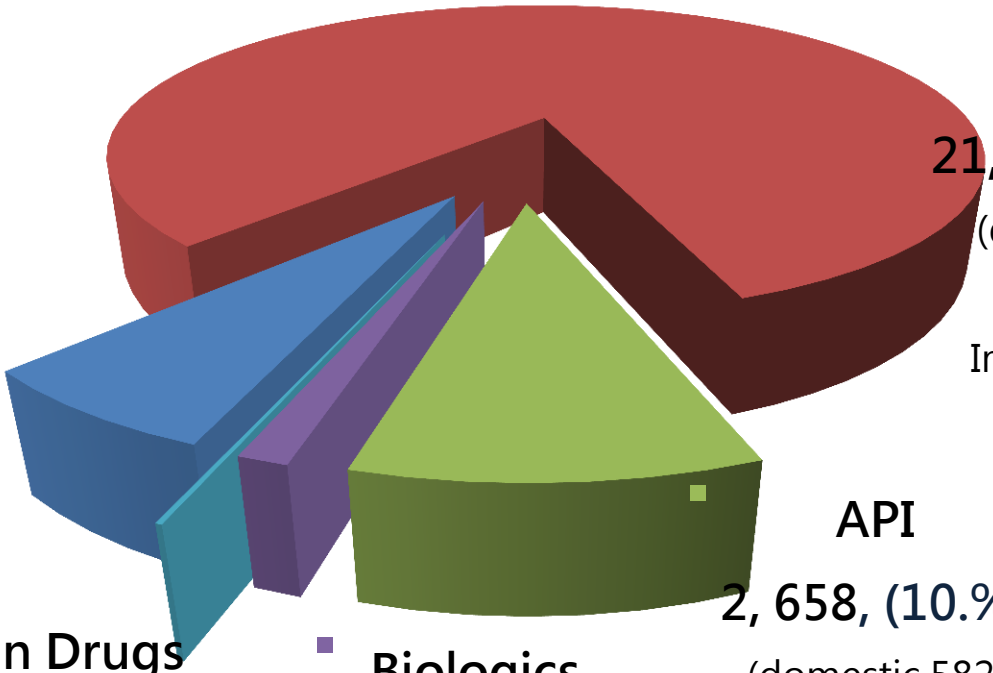
Safe Food

Safe Drug

To safeguard national health
To lead the nation to a new era
of food and drug management

- **Profession (專業)**
- **Service (服務)**
- **Quality (品質)**
- **Innovation (創新)**

Statistics on Pharmaceutical Licenses in Taiwan



Generic Drugs, 21,814; (82.%) (domestic 19, 638(90%); Import 2, 176)

New Drugs 1, 767, (6.6%) (domes 1,275) Import 1259)

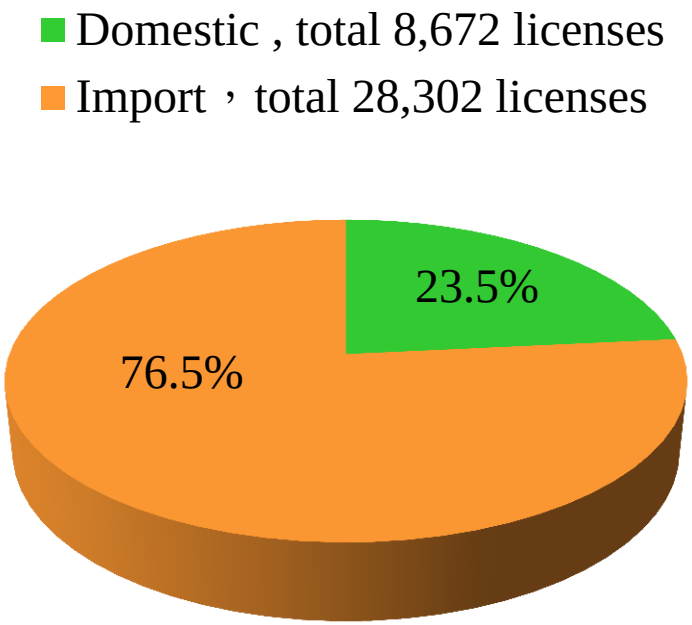
API 2, 658, (10.%) (domestic 582; import 2, 076)

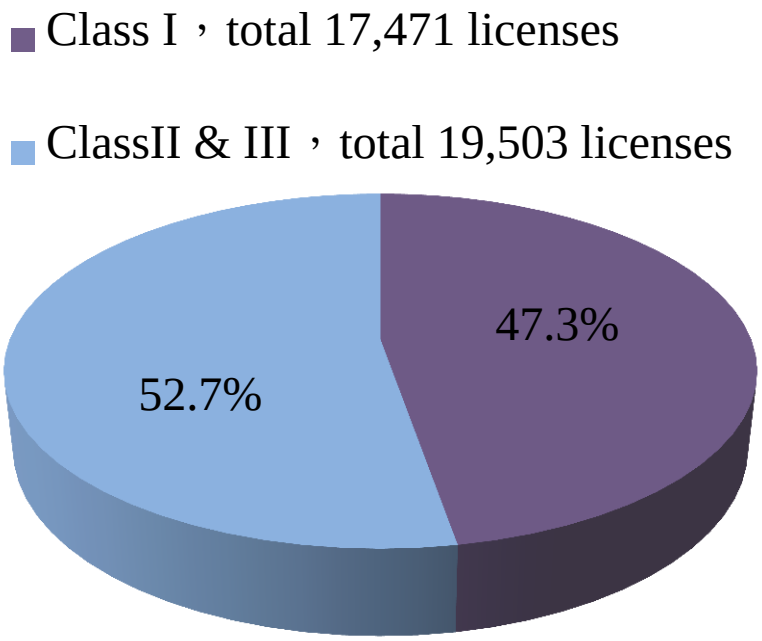
Orphan Drugs 49, (0.2%) (domestic 9; Import 40)

Biologics 357, (1.3%) (domestic 21; Import 336)

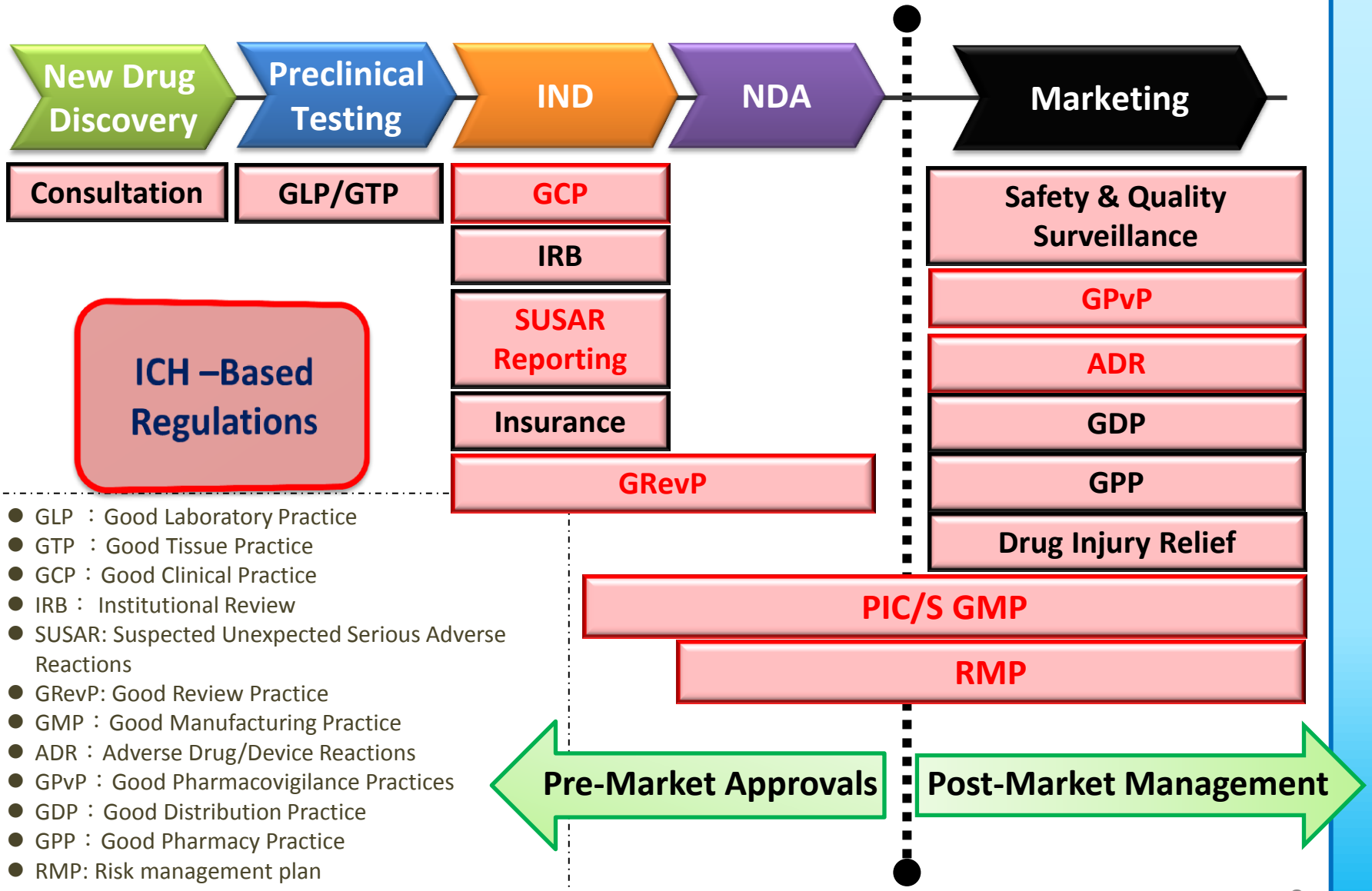
total: 26,654

Statistics on Medical Device Licenses in Taiwan



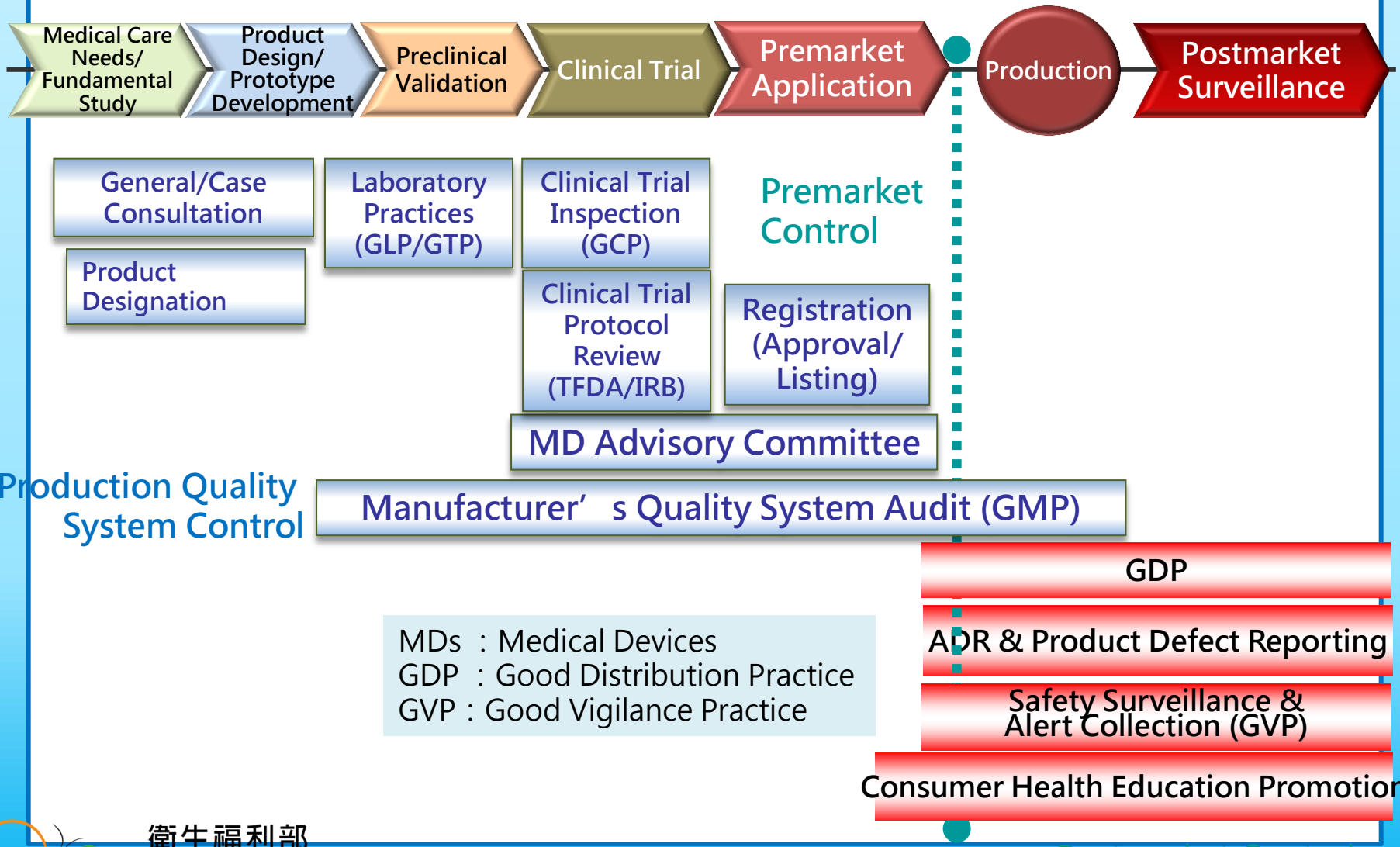


Medicinal Product Life Cycle Management



- GLP ：Good Laboratory Practice
- GTP ：Good Tissue Practice
- GCP：Good Clinical Practice
- IRB： Institutional Review
- SUSAR: Suspected Unexpected Serious Adverse Reactions
- GRevP: Good Review Practice
- GMP：Good Manufacturing Practice
- ADR：Adverse Drug/Device Reactions
- GPvP：Good Pharmacovigilance Practices
- GDP：Good Distribution Practice
- GPP：Good Pharmacy Practice
- RMP: Risk management plan

Medical Device Life Cycle Management



MDs ：Medical Devices
GDP ：Good Distribution Practice
GVP：Good Vigilance Practice

Current Status of IND Regulation in Taiwan

IND: Investigational New Drug

Current Status of IND Regulation in Taiwan

- Objectives
  - To enhance IND **review efficiency**
  - To strengthen **clinical trial quality**
  - To promote multi-regional clinical trials (**MRCT**) in Taiwan

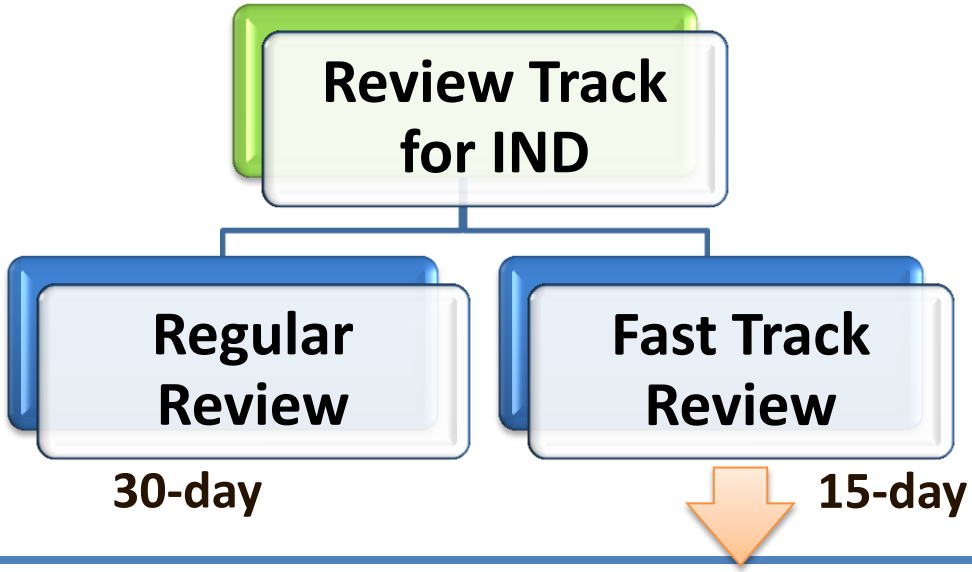
Strategies to improve IND Regulation in Taiwan

- Strategies
  - Establish fast track review pathway
  - Establish world-class clinical trial environment
    - Conducting GCP inspection
    - financial support from government
    - Autonomous improvement in clinical trial quality of applicants
  - Relax CPP requirement
  - Provide NHI drug price incentive

** CPP: Certification of Pharmaceutical Products*

Enhance IND review efficiency

- Establishing fast track review pathway



Applicable for:

1. IND with the Same **US FDA-Approved** IND Number (July, 2004)
2. Multinational multicenter trials **simultaneously conducted in one of the medically advanced countries** + Taiwan's medical center hospital also involved (Aug, 2010)

Strengthen clinical trial quality -GCP Inspection in Taiwan

ICH-GCP

- **Regular inspection**
  - First-in human, pivotal, phase IV (30 ~ 40 cases/ yr)
  - with 1~2 cases/yr unacceptable (3~7% unaccepted)
- **For-cause inspection** (~3 cases/yr)
  - Clinical trial with GCP violation and safety concern
  - Clinical trial with serious adverse event (SAE) occurred

Strengthen clinical trial quality - Qualified Clinical Trial Sites for IND

- Only teaching hospitals are qualified to conduct IND in Taiwan
  - 26 sites with government funding

Total Teaching Hospitals (qualified clinical sites) , 131					
Excellent Center*	6	Excellent Center of Oncology*	8	General Clinical Research Center*	12

- **International recognition certificate and accreditation**
  - 23 sites (Ethics committees and IRB) in Taiwan have received SIDCER # / FERCAP# Recognition certificate (2005-2012)
  - 2 sites in Taiwan have earned AAHRPP# Accreditation (~2013)

#SIDCER: Strategic Initiative for Developing Capacity in Ethical Review
#FERCAP: The Forum for Ethical Review Committees in the Asian and Western Pacific Region
#AAHRPP:The Association for the Accreditation of Human Research Protection Programs

MOU between Taiwan Centers of Excellence and the International Pharmaceutical Companies

Taipei Veterans General Hospital
- 2009 Sanofi Aventis
- 2010 GSK
- 2011 Norvatis

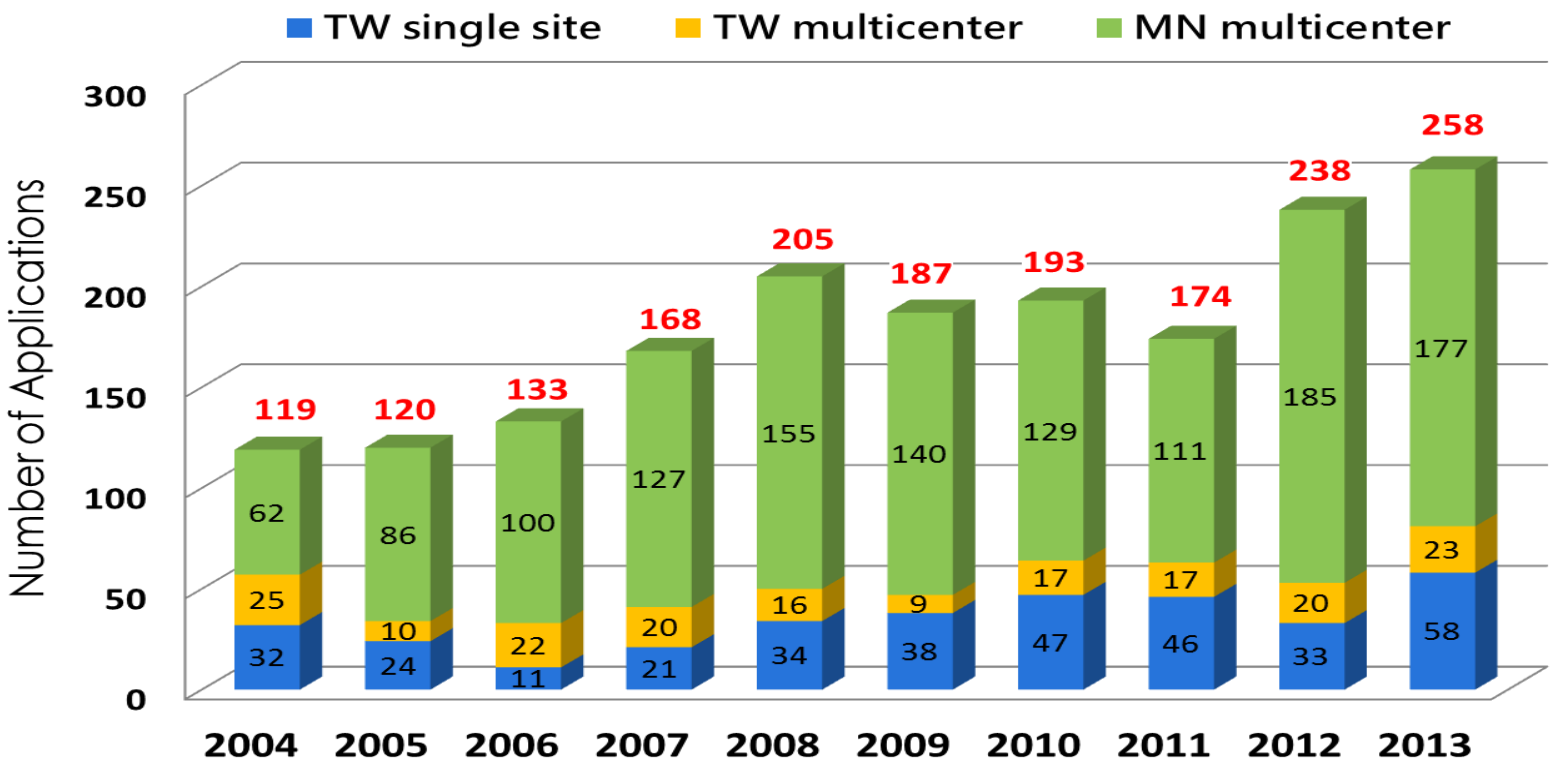
China Medical University Hospital
- 2010 Norvatis

Cheng Kung Medical Hospital
- 2010 Norvatis, MSD
- 2011 Norvatis

National Taiwan University Hospital
- 2007 GSK
- 2009 Norvatis, Boehringer Ingelheim
- 2012 Pfizer, Bayer, MSD

Chung Gung Medical Hospital
- 2010 Norvatis
- 2012 GSK
- 2013 MSD

IND Applications in Taiwan



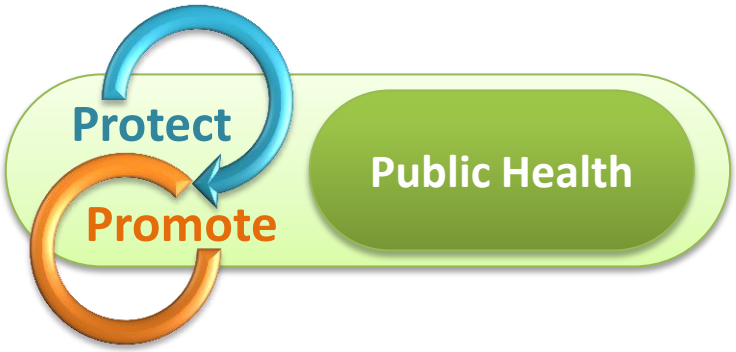
An Increase in multiregional trials

Current Status of NDA Regulation in Taiwan

NDA: New Drug Administration

NDA Regulation in Taiwan

- Objectives:
  - Refine NDA review strategy
  - Optimize NDA regulations
  - Facilitate innovative medicine industry
    - Regulation Paradigm shift from protection to promotion



Assure QUALITY, SAFETY, EFFICACY of Medicinal Products

Help to Speed the Development of Innovative Medicine

Optimize NDA regulations

Biologics:

Biosimilar products	● Guideline for Review and Approval of Biosimilar Products (2008) ● Points to Consider for Review and Approval of Biosimilar Products (2010) ● Guideline for Review and Approval of Biosimilar Monoclonal Antibodies (2013)
Vaccines	● Guideline for Review and Approval of Pandemic influenza vaccines (2010)
Cell therapy products	● Guidance for IND applications for human cell therapy products (2014)

Botanical Products

● Guideline for Review and Approval of Botanical Products (2013)

Nanomedicine

● Approval requirement for liposomal drugs (annex of Regulations for Registration of Medicinal Products)
● Guidance for CMC requirement of liposomal products (under construction)

Facilitate innovative medicine industry -Regulatory Consultation System

Regulatory Consultation System for Medicinal Products

- **Online Information**
- **Consultation by Request**
- **Active Consultation**
  - **Domestic Innovative Consultation** (Early Harvest Lists)
  - **National Research Program for Biopharmaceuticals (NRPB)**
  - **Seeds regulator training widespread consultations service**
- **Industrial Communication Platform**

Adopt and adapt the PIC/S GMP in Taiwan

- Official PIC/S member since 2013
- All manufacturers shall fully comply with the current version of PICS/GMP standard by **2014.12.31**
- Current status:

Total domestic manufacturers	**141**
PICS	*80*
Under revision	*38*
Waiting to be evaluated	*2*
Planning to stop manufacturing	*13*
unclear	*8*

84%

PIC/S GMP
與國際接軌

cGMP
(validation)

GMP

1980s' → 1990s' → 2007.12~

Current Status of Medical Device Regulation in Taiwan

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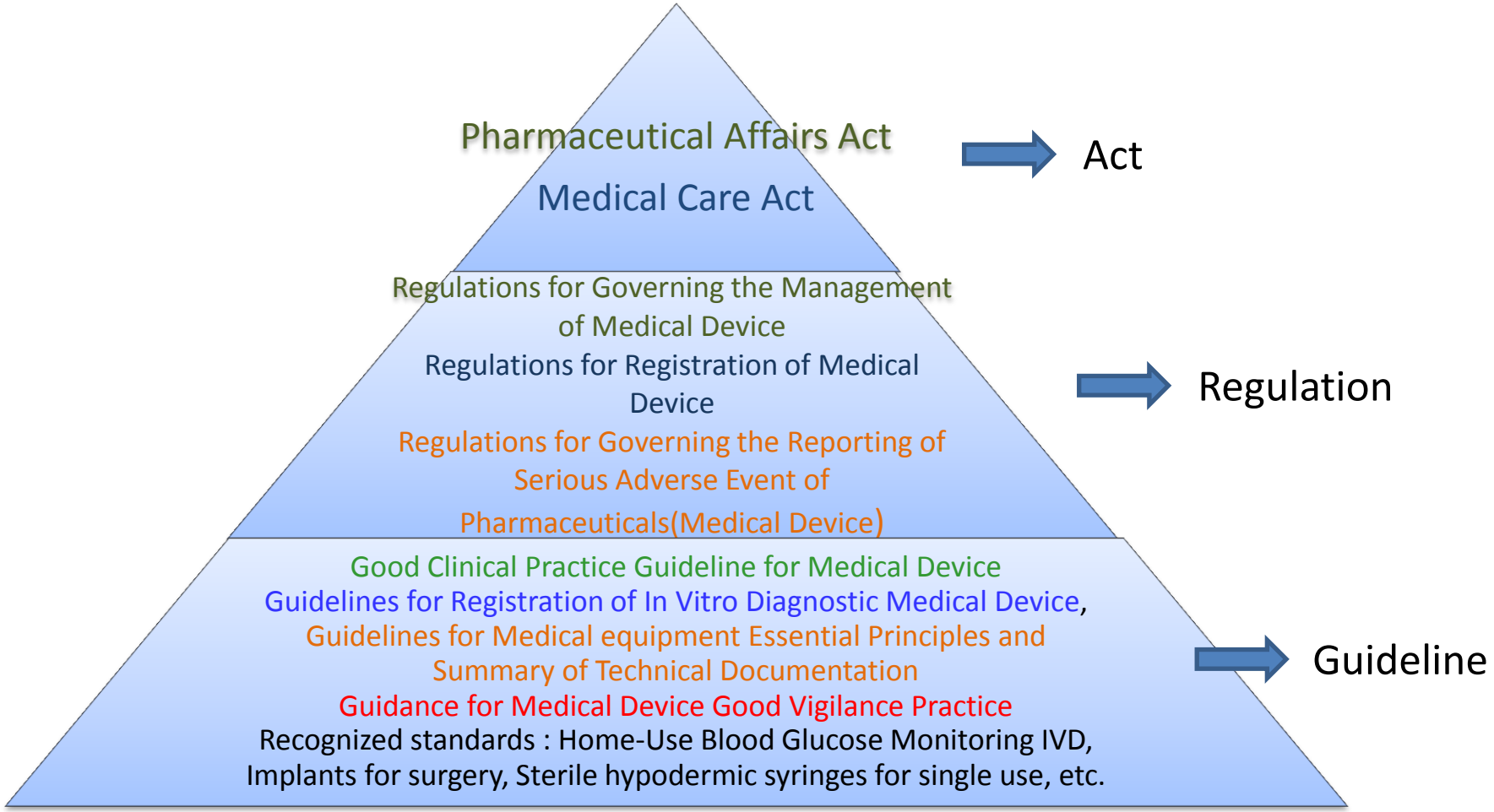
Regulations for Medical Device in Taiwan



Amendment on Pharmaceutical Affairs Act

Article 13 - Definition of Medical Devices

- The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, **software, reagent for in vitro use**, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, **regulating fertility**, or which may affect the body structure or functions of human beings, and **do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body**.

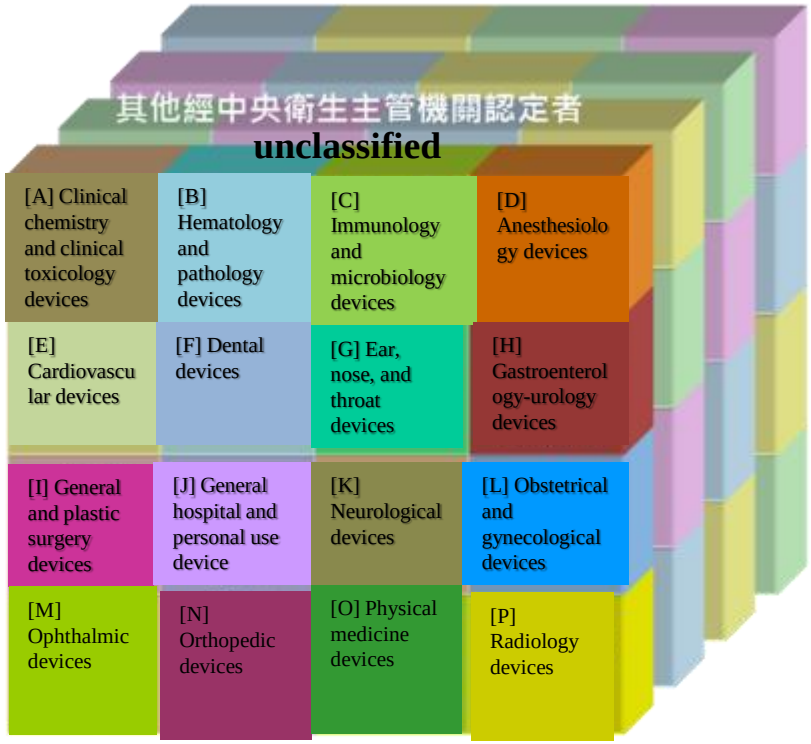
藥事法第13條條文修正如下：

本法所稱醫療器材、係用於診斷、治療、減輕、直接預防人類疾病、調節生育、或足以影響人類身體結構及機能，且**非以藥理、免疫或代謝方法**作用於人體，以達成**其主要功能**之儀器、器械、用具、物質、軟體、體外試劑及其相關物品。

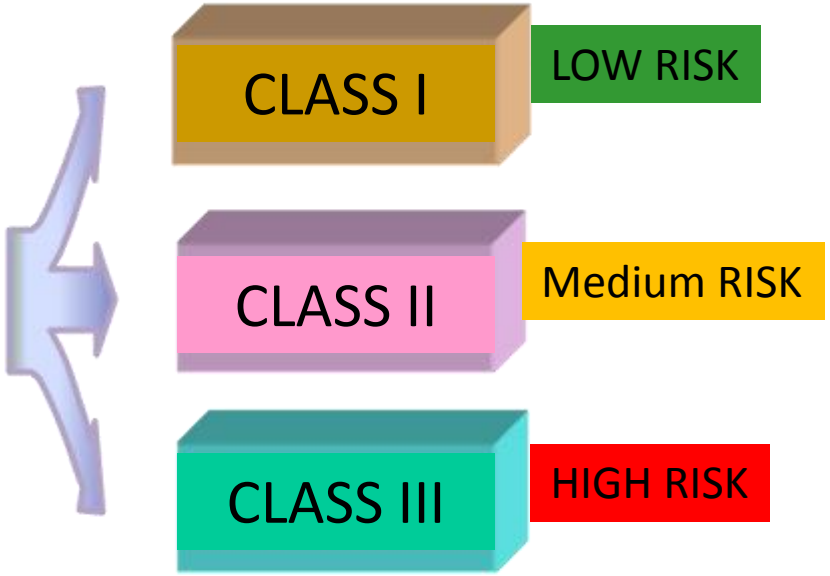
前項醫療器材，中央衛生主管機關應視實際需要，就其範圍、種類、管理及其他應管理事項，訂定醫療器材管理辦法規範之。

Medical device category

- Pursuant to Article 3 of Regulations for Governing the Management of Medical Device ， medical devices classified by intended use and mode of action with seventeen categories.

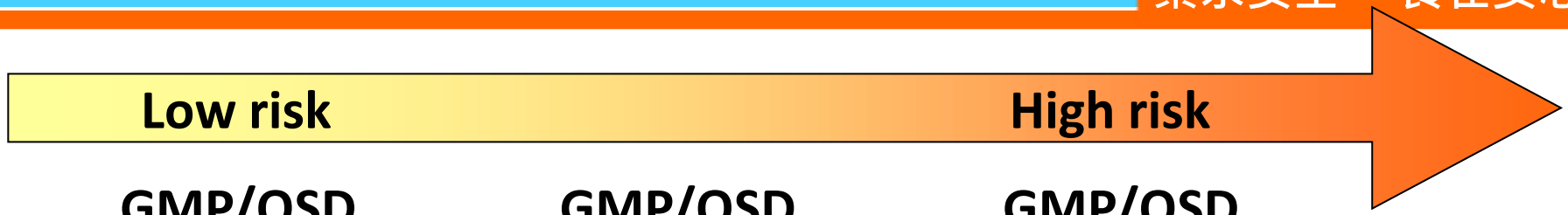


Seventeen categories



According to the degree of risk points three levels

Risk Based Regulation



GMP/QSD

Class 1

affidavit

On-site registration

* Self-declaration can be accepted to instead of GMP/QSD compliance letter for Non-sterile Class 1 products without measurement function

GMP/QSD

Class 2

Technical Document

Preclinical testing and QC documents can be waived if with both EU and US marketing approval.

GMP/QSD

Class 3

Technical Document

Clinical reports are required for most of the cases.

→ **Documents required for Registration**

QSD: Quality system documentation

Strengthening Regulatory Oversight of Pharmaceutical Firms and Distribution Channel

Notice "Pharmaceutical firms may sale Class 1 medical devices by internet and matters regarding registration".

→ It not only ensures consumers' convenient access of medical devices, but also takes the safety of medical devices into account.

Draft medical device Good Distribution Practice (GDP)

→ Ensure product quality in distribution. Strengthen regulatory oversight of pharmaceutical firms.

Build a unique device identification (UDI) system information platform for high risk medical devices.

→ Improve the mechanism for regulatory oversight of high risk medical devices to ensure users' safety.

Recent Changes in Medical Device Regulation

- Amend Regulations for Governing the Management of Medical Device: The amendments were announced in January 2014.
  - The manufacturing of medical devices class I without measuring function or not sterilized shall comply with simplified GMP.
- Amend Regulations for Registration of Medical Device: The amendments were announced in September 2014.
  - The EP/STED documents are mandatory for class 3 products..
  - Medical devices previously regulated as drugs must conform with the requirements of medical device GMP within 3 years of grace period.

Current Status of Post-Marketing Management in Taiwan

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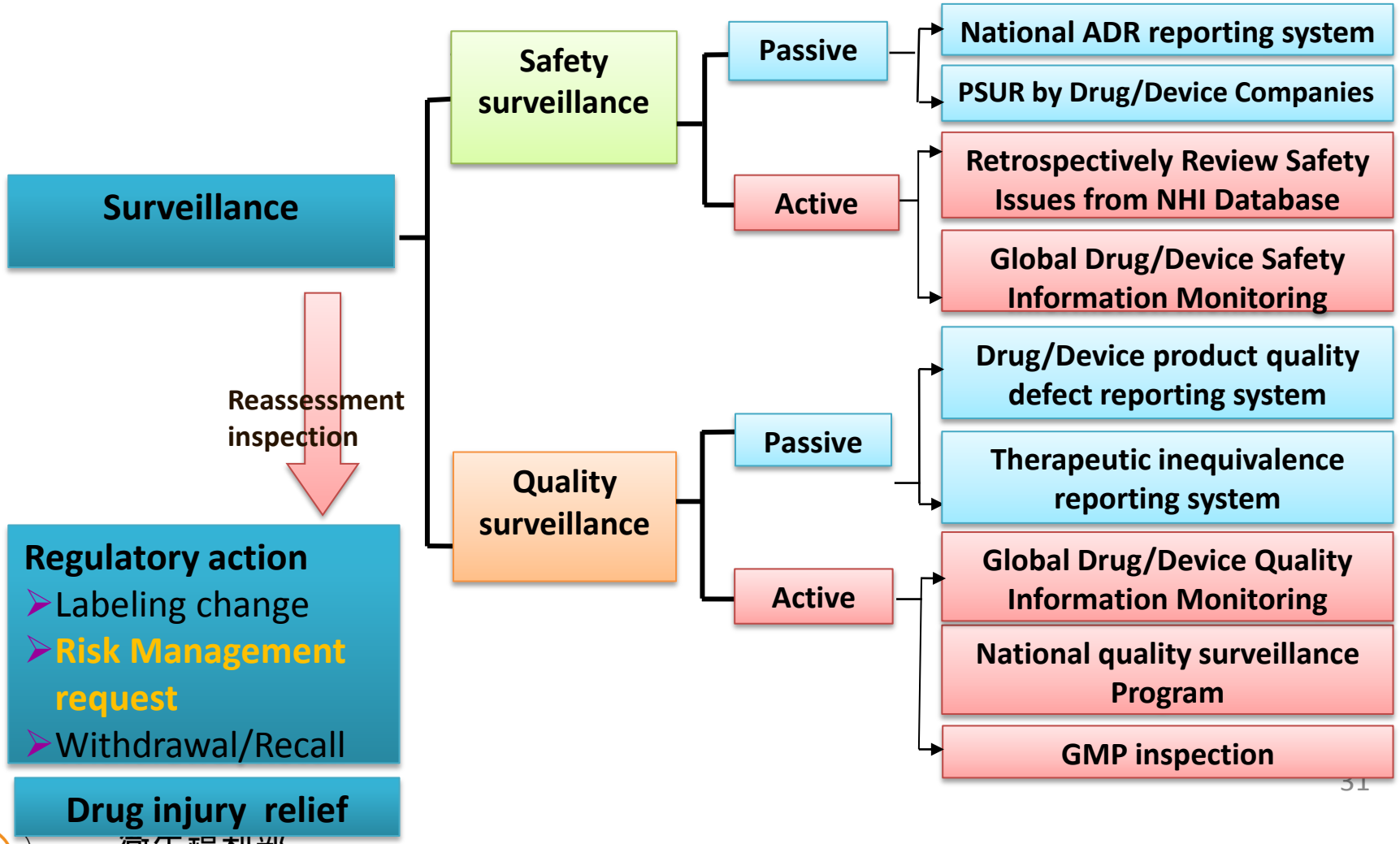
Post-marketing Safety and Quality Surveillance ~~Medical Products



Risk Management Plan

By careful design, monitor and control, the implementation of Risk management plan :

- Provides early access to new drugs (especially in non-CPP cases)
- Prevents unnecessary marketed drug withdraw
- Ex. Currently 29 NDAs and 4 marketed ingredients (Carbamazepine, TNF-Alpha Blockers, Rosiglitazone, Pioglitazone) in Taiwan require RMP conduction.

International Collaboration

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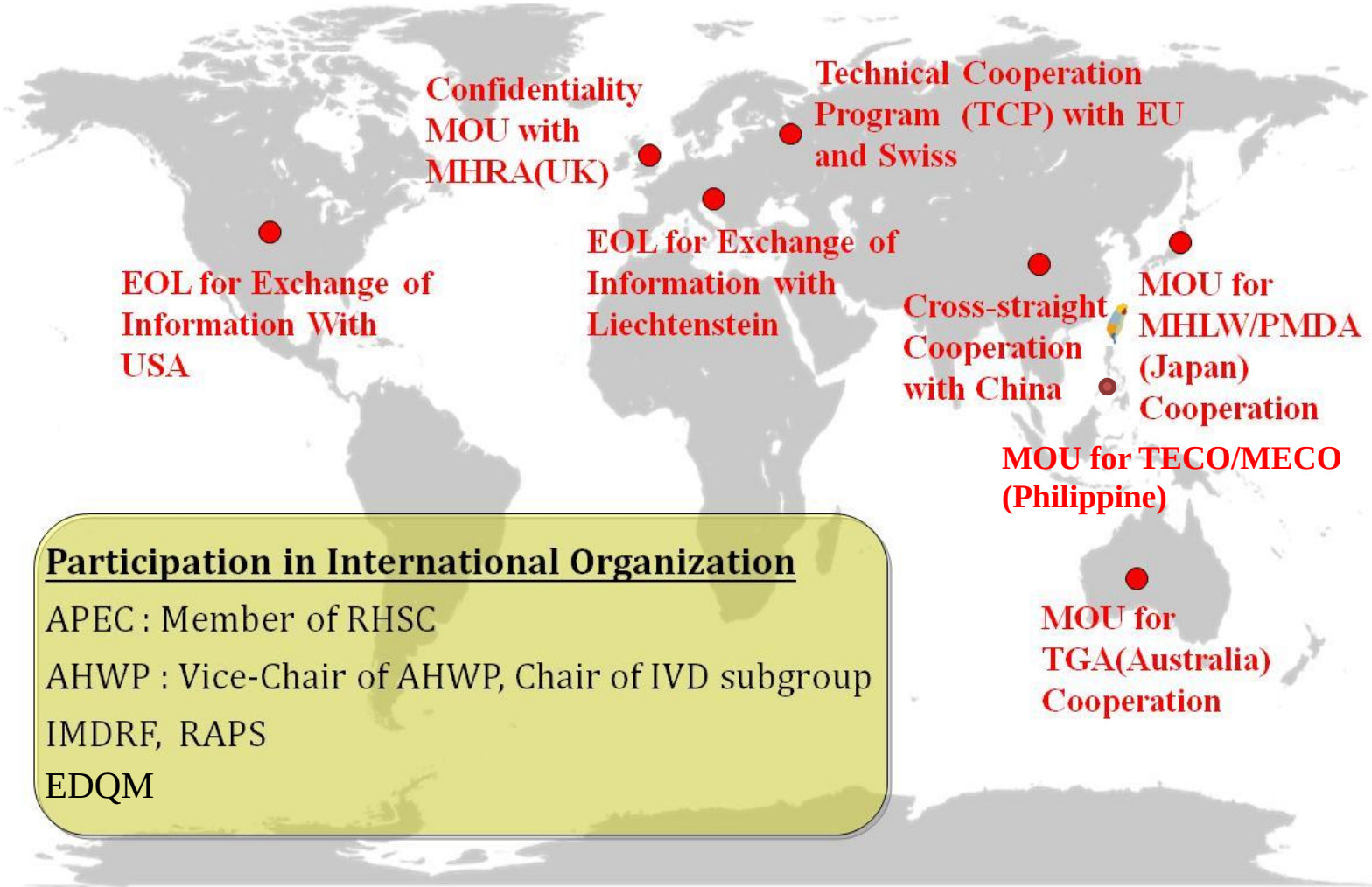
International Cooperation



Participation in International Organization

APEC : Member of RHSC

AHWP : Vice-Chair of AHWP, Chair of IVD subgroup

IMDRF, RAPS

EDQM

Organization breakthrough and innovation-1

Increase administrative efficiency

Future Prospects

Consumer Protection

- Win-Win-Win

Government
Smart Administration

Industry
Competences Enhancement

Thank You for Your Attention

Chiang Kai-shek Memorial Hall

Taipei 101

Yehliu Geopark

Sun Moon Lake

North-East coast of Taiwan

Pingxi Flying Lanterns

Penghu

Night Markets

Temples

For more information, please go to: http://www.fda.gov.tw

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