The 12th Joint Conference of Taiwan and Japan

Regulatory Updates in Taiwan

Oct 7th, 2024

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Taiwan Food and Drug Administration (TFDA)

衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

http://www.fda.gov.tw/

Outline

1. Medicinal Products
2. Medical Devices
3. International Collaboration
4. Future Prospects

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Approval of New Domestic Biosimilars

Currently 39 Biosimilar Products licensed in Taiwan

API	Licenses
Recombinant Somatropin	2
Insulin Glargine	2
Infliximab	2
Trastuzumab	9
Adalimumab	7

API	Licenses
Rituximab	4
Pegfilgrastim	2
Filgrastim	2
Bevacizumab	5
Etanercept	2
Teriparatide	2

Domestic Biosimilar
approved in 2023

NEW

EirGasun (Trastuzumab)
By Eirgenix Inc.

"Guideline for the Registration of Biosimilar Products" revised in April, 2024

Approval of New Domestic Antibiotics

3 of the 16 New Antibiotics reported by WHO* now approved

Name	Approval	API
Recarbrio	**2022**	Imipenem Cilastatain **Relebactam**
Xerava	**2023**	**Eravacycline**
Fetroja	**2024**	**Cefiderocol**

Expedite Review Programs

+

Consultation

NEW

New Domestic antibiotics targeting Gram (-) MDR bacteria

Name	Approval	API
Bobimixyn	**2023**	**Polymyxin b**

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** 2023, WHO "Antibacterial agents in clinical and preclinical development: an overview and analysis"*

Acts for Regenerative Medicine

Regenerative Medicine

Issued in June 2024

Regenerative Medicine Act

NEW

- Regulate regenerative medicine in medical institutions
- To intensify quality management of regenerative medicine therapies

Department of Medical Affairs, MOHW

Regenerative Medicinal Products Act

NEW

- A special law under Pharmaceutical Affairs Act
- To strengthen the whole lifecycle management for regenerative medicinal products

Taiwan Food and Drug Administration, MOHW

Regulatory Updates on Clinical Trials

Dec. 2023	Guideline Using **Digital Health Technologies for Remote Data Acquisition** in Clinical Trials with Medicinal Product
Jan. 2024	Amendments to **GCP Inspection Policies** in the NDA Submission Review Process
Mar. 2024	Guideline toward **Training Requirements for Clinical Research Associates (CRAs)**
May 2024	Guideline for Application of **Computerized Systems and Electronic Data** in Clinical Trials with Medicinal Product
Jul. 2024	ICH guideline E10 on **Choice of Control Group and Related Issues in Clinical Trials (Draft)**
Aug. 2024	ICH guideline E8 (R1) on **General Considerations for Clinical Studies (Draft)**
Sep. 2024	ICH guideline M3 (R2) on **Non-clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals (Draft)** and 17 **Safety guidelines (Draft)**

Real-World Data and Evidence

Guidelines in Taiwan (2020~)

RWD Study Designs- Considerations and Key Points for Registry-based study May 2024 (Draft)

Real World Data Quality Evaluation- Relevance and Reliability Considerations Mar 2021

Basic Considerations in Supporting Drug Research and Development with Real-World Evidence Jul 2020

Precautions for submitting technical documents using RWD/RWE for drug application Jul 2021

Use of Electronic Medical Record Data in Clinical Studies Nov 2020

Guidelines for Using Electronic Healthcare Data to Conduct Pharmacoepidemiologic Safety Studies Mar 2022

RWE Study Designs- Considerations and Key Points for Pragmatic Clinical Trial Jan 2021

Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drugs Oct. 2023

Milestones of OTC Regulation

1970 1980 1990 2000 2010 2020

Pharmaceutical Affairs Act 1970

Pharmaceutical Affairs Act Enforcement Rules 1975

Regulations for Registration of Medicinal Products 1975

OTC Monograph (10 categories) 1996

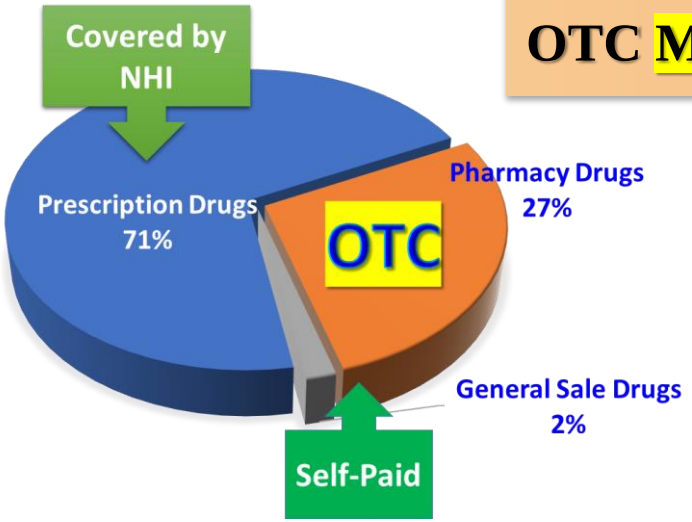
Online sales for general sale drugs 2015

OTC Monograph (16) categories 2018 , **(18)categories** 2019

Checklist for Rx-OTC Switch 2017

Registration guidance for OTC new drug 2020

E-Labeling 2022



2024 Monograph (3) categories *under discussion*

Drug Safety Surveillance

Pharmaceutical Affairs Act

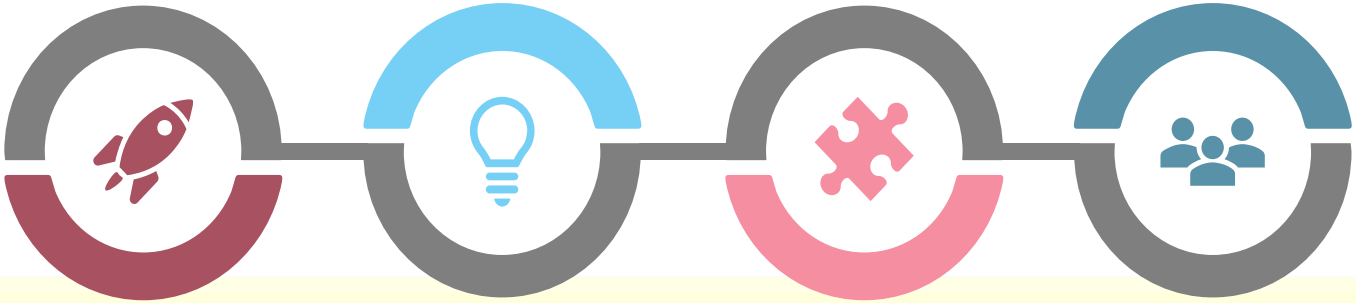
Regulations for the Management of Drug Safety Surveillance

Amended on April 15, 2022
Effected on January 1, 2023

Regulations for Reporting Severe Adverse Reactions of Medicaments

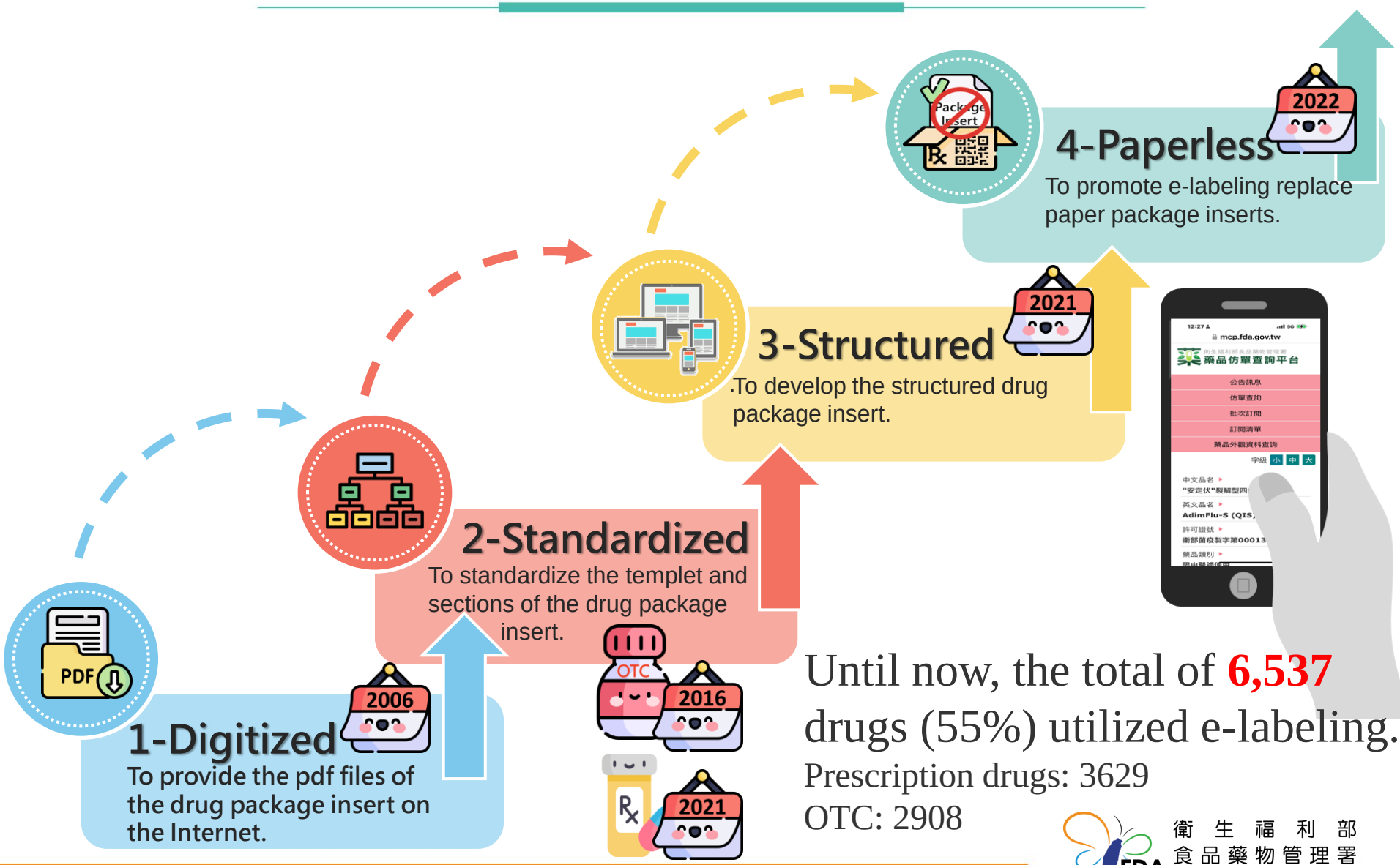
2022/9/2 Draft amendment

Scope	**Documents**	**Action**	**Inspection**
→ All licenses	→ All safety data	→ Report in 3 days	→ GPvP compliance



To ensure the safety of medication for the public, TFDA continued to enhance the drug safety surveillance system, conduct **educational training** on drug safety surveillance related issues, and carry out **Pharmacovigilance inspections**.

Policy on e-Labeling Implementation



Until now, the total of **6,537** drugs (55%) utilized e-labeling.

Prescription drugs: 3629

OTC: 2908

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Illegal Sale Drugs Online

Sell Drugs Online

passive

Passively accept reports from the public

- In 2023, a total of 1,478 cases of illegal online sales of drugs on the Internet were seized.
- 62 illegal overseas websites were published on the official website.

proactive

Searching illegal sale of drugs over the internet

- TFDA actively search the online platform illegal online sale of drugs and ask online platform operators to remove them from the shelves.

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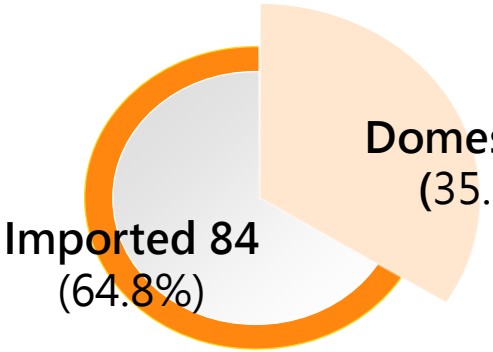
2023.09-2024.08 Regulatory Updates on Medical Devices

Sep. 2023	Amendments of the “Guidance for Medical Device Post-market Surveillance Practice”
Nov. 2023	Amendments on partial articles of the “Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration” as well as Appendix 1 of Article 5, Appendices 2 and 3 of Article 6
Jan. 2024	Amendments of the “Guidance for Pre-clinical Testing of Endosseous Implant and Abutment” and the “Guidance for Pre-clinical Testing of Electrosurgical Devices for General Surgery”
Apr. 2024	Amendments of the “Directions of Case Counseling for Domestically Developed AI/ML Medical Devices ”
May. 2024	Promulgation of "The List of Essential Medical Devices Under Article 34 of Medical Devices Act"
Sep. 2024	Promulgation of "Application Guidelines and Drafting Instructions for Predetermined Change Control Plans of Medical Device Software Utilizing AI/ML Technologies"

Strategies for Promoting the SaMD Industry

Total 129 cases



(From 2020 to September2024)

Training Courses

- Meeting industry needs
- **160+** Courses
- **21** Workshops
- MDs e-learning platform

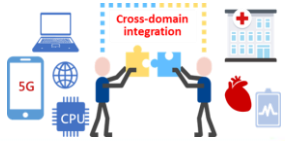
Guidelines Developed

- Regulatory environment
- **19** documents published
  - ✓ **12** guidelines (5 related to AI-SaMDs)
  - ✓ **1** reference template
  - ✓ **6** FAQs

AI/ML Platform

- Information and matchmaking
- Views : 490,000+

(From 2021 to September 2024)



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SaMD: Software as a Medical Device

Status of Approved AI-SaMDs in Taiwan

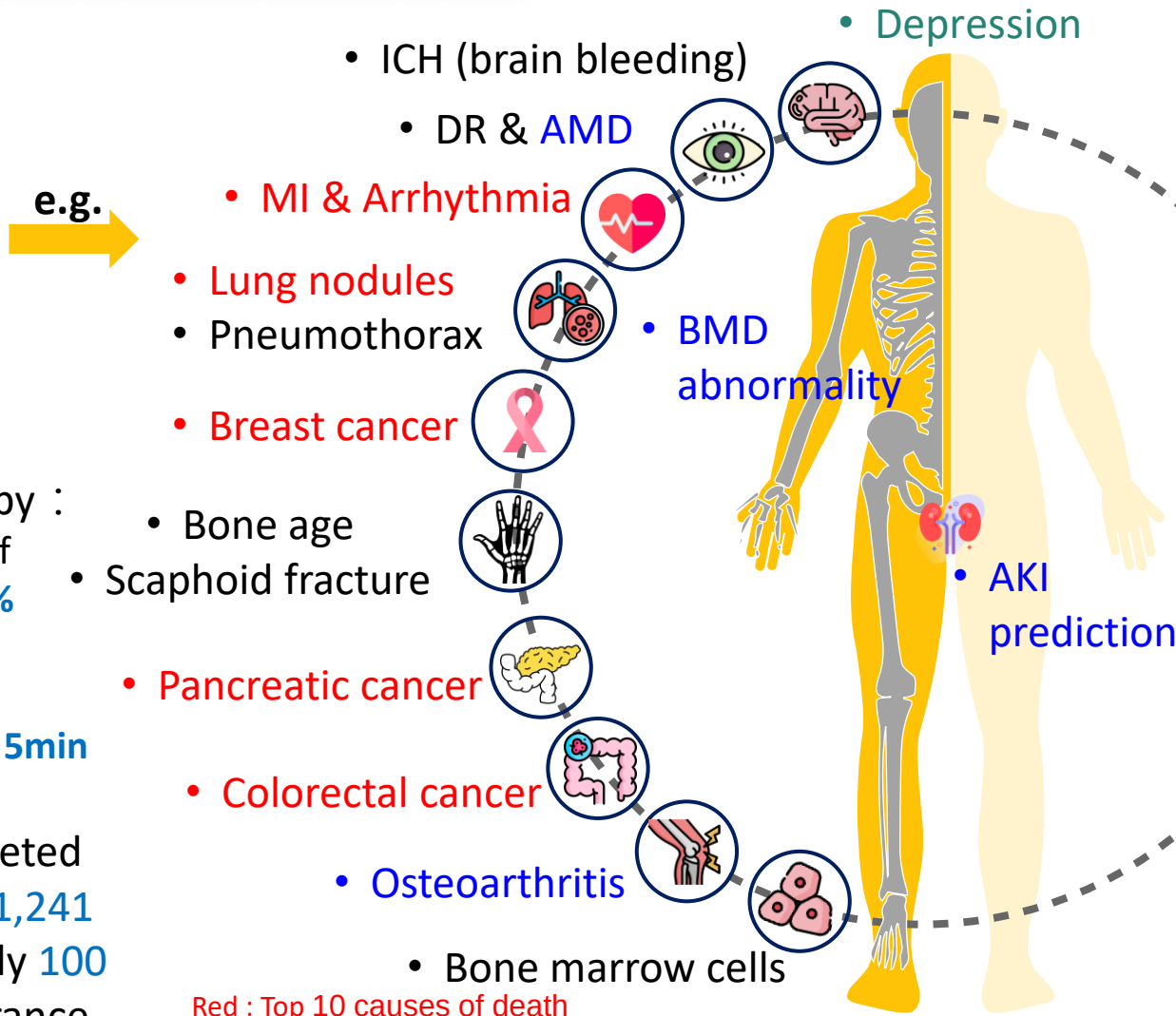
Consultation Service

- ↓ Product time-to-market
- For **domestic** AI-SaMDs
- **24** AI-SaMDs launched

Clinical Efficacy

- Organ contouring in radiotherapy：
  - ✓ Improve the protection rate of healthy organs: **3.7% → 12.9%**
  - ✓ Reduce patient discomfort: **63% → 52%**
  - ✓ Save contouring time: **1hr → 5min**
- Early screening for lung cancer
  - ✓ Over 18,000 people completed the screening, identifying 1,241 positive cases, saving nearly 100 million NTD in health insurance expenses."

e.g.



Red : Top 10 causes of death
Blue : Aging-related
Green: Mental health

ICH: Intracranial hemorrhage
MI: Myocardial infarction
DR: Diabetic retinopathy
AMD: Age-related macular degeneration
BMD: Bone mineral density
AKI: Acute kidney injury

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International Cooperation

Asia-Pacific Economic Cooperation

- RHSC Good Registration Management Priority Work Area Center of Excellence (CoE) for Regulatory Science (since 2016)
- RHSC Medical Device Priority Work Area Center of Excellence (CoE) for Regulatory Science (since 2019)

IMDRF International Medical Device Regulators Forum

- Affiliate Member (2023)
- WG Members
  - QMS (2023)
  - AI/ML (2023)
  - Clinical Evidence for IVDs (2024)

ICMRA International Coalition of Medicines Regulatory Authorities

- Associate Member (2023)

Global Harmonization Working Party GHWP Towards Medical Device Harmonization

- Work Group 2 - Pre-market: IVDD Chair (since 2012)
- Work Group 3 - Pre-market: Software as a Medical Device Chair (2023)
- Work Group 9 - UDI & Nomenclature Member (since 2019)

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

- Affiliate Member (since 2023)

Collaboration with Japan

Pharmaceutical Working Group

1. Developed Position Paper and Q&As for New Drug Review Scheme; 6 cases were adopted and 5 were completed.
2. Established the Information Sharing model of post-marketing surveillance information.

Medical Devices Working Group

Exchanged review principle on AI-enabled medical devices:

- Computer-assisted diagnosis (CADx)
- Computer-assisted detection (CADe)

Progress for the QMS Working Group of Medical Devices

2014
- Establishment of **QMS WG**.

2018
- **MOC** was signed on November 30.

2019
- **Abbreviated mode** start up.

2020
- **Q&A for MOC** was published on December 21.

2024
- Till September, 2024, **68 manufacturers were approved** under abbreviated mode.

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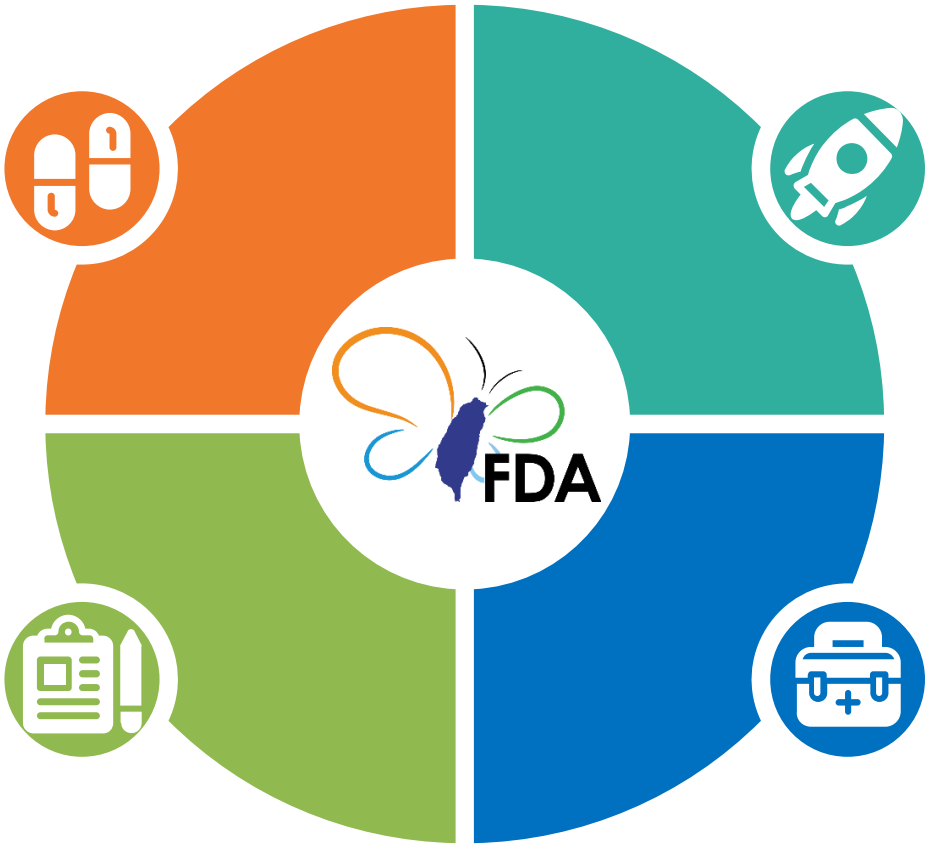
Future Prospects between Taiwan and Japan

Enhance the Qualitative collaboration



Broaden the international regulatory science in each work process

Deepen the exchange of mutual regulatory information

Collaborate on regulatory reliance

Thank You!

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