Asia Regulatory Conference 2013

Day 3: Wednesday, January 30th

Update of New Drug Regulatory Convergence in Taiwan

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Taiwan Profile

- Area: 36,188 Km^2
- Population : 23.23 Millions
- Aging: 10.6% (2009)
- 99% Citizen Covered by NHI – a Single Payer and Single Database (IC Card)
- NHE/GDP: 6.9% (2009)
- 17 Medical Centers, 917 Hospitals (2010)
- Pharmaceutical Market: $4.68 Billion (2010)

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Outline

- Organization and Responsibility of TFDA
- Regulation in IND
- Regulation in NDA
- Regulatory Consultation System for Pharmaceutical Products
  - Domestic Innovation Consultation Project
- International Cooperation
- Future Prospects

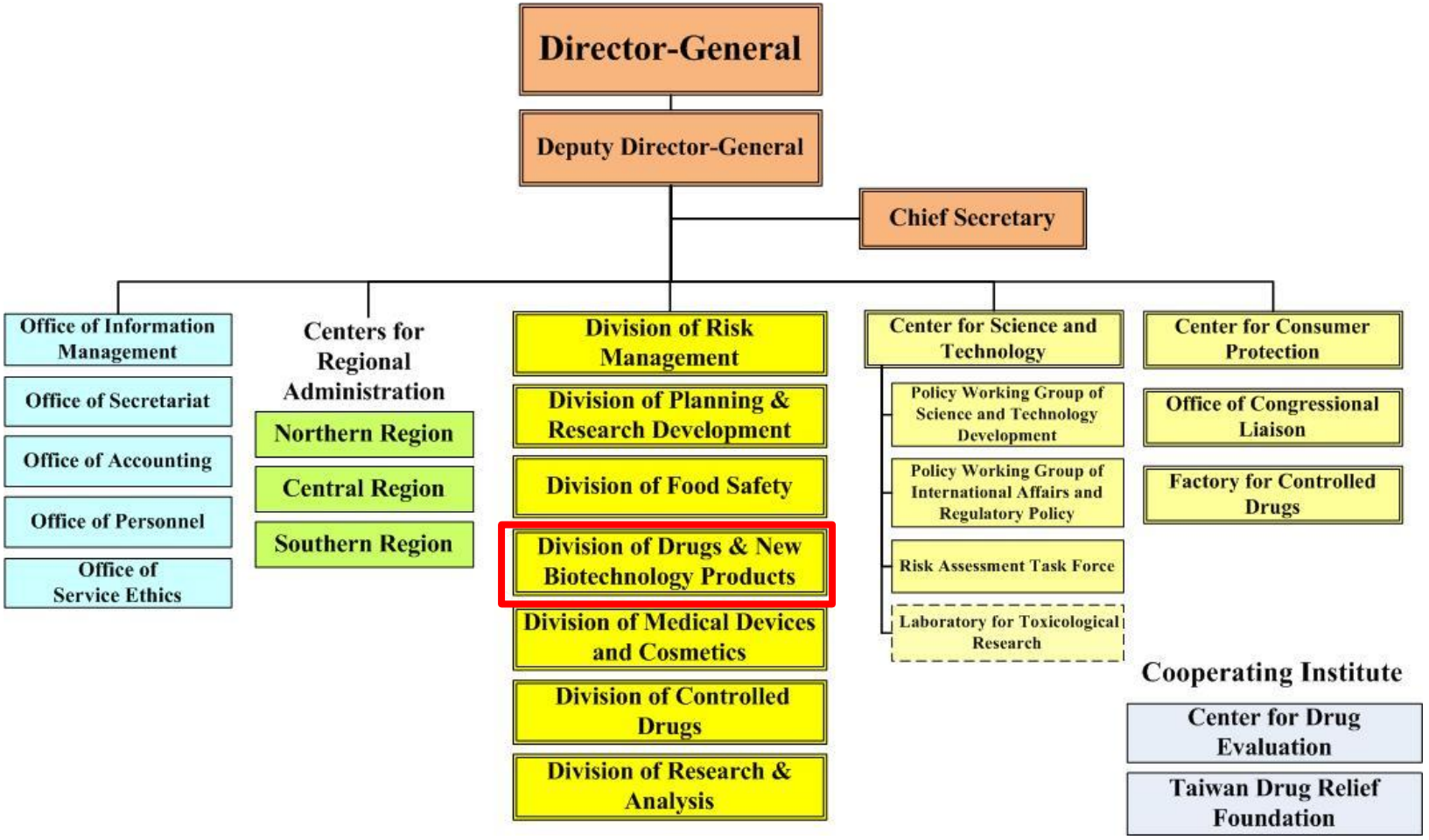
Establishment of Taiwan FDA

Taiwan FDA (TFDA) was inaugurated on Jan. 1, 2010

TFDA supersedes the following 4 bureaus of Department of Health

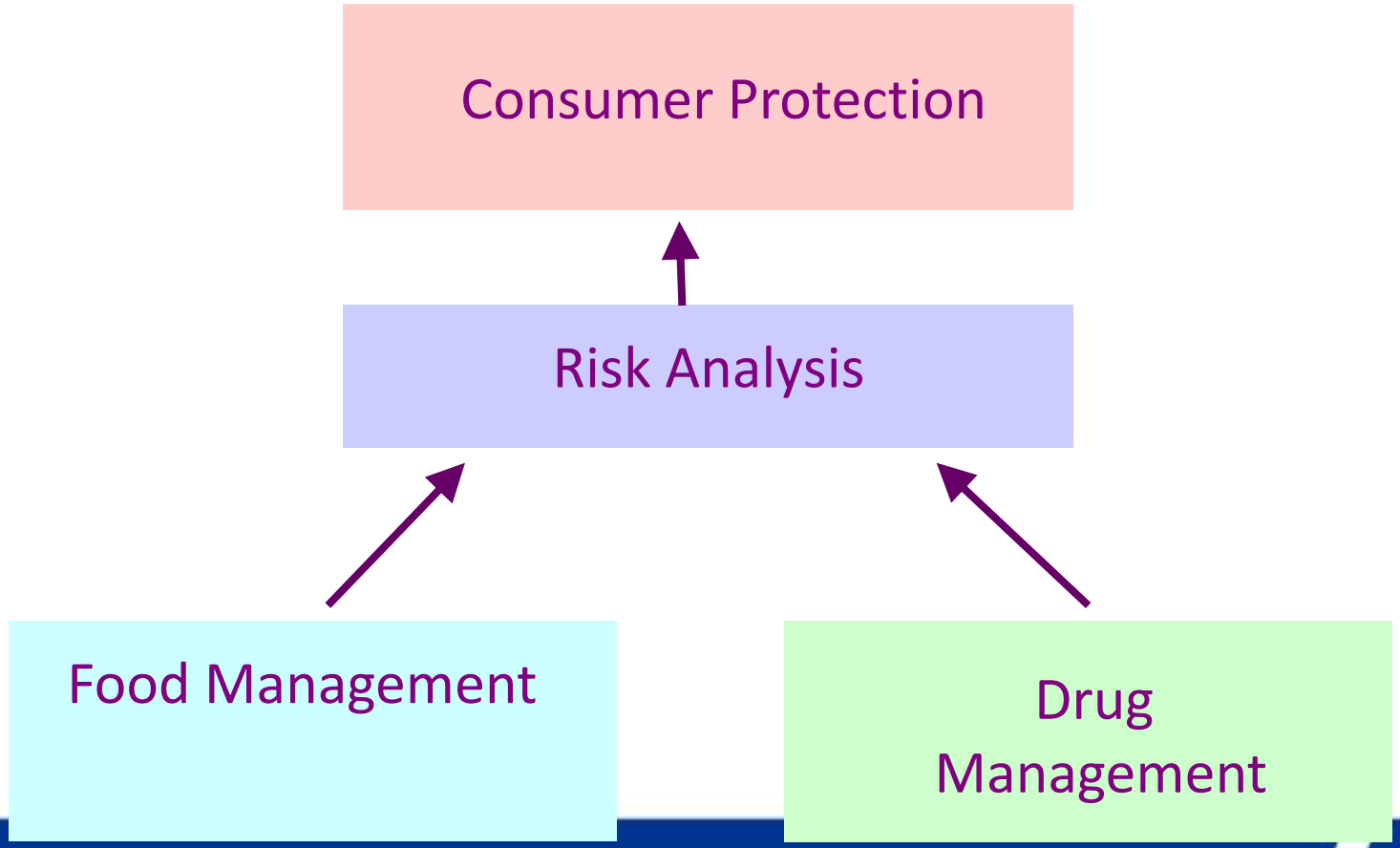
- Bureau of Food Safety
- Bureau of Pharmaceutical Affairs
- Bureau of Food and Drug Analysis
- Bureau of Controlled Drugs

Food and Drug Administration
Department of Health, Taiwan

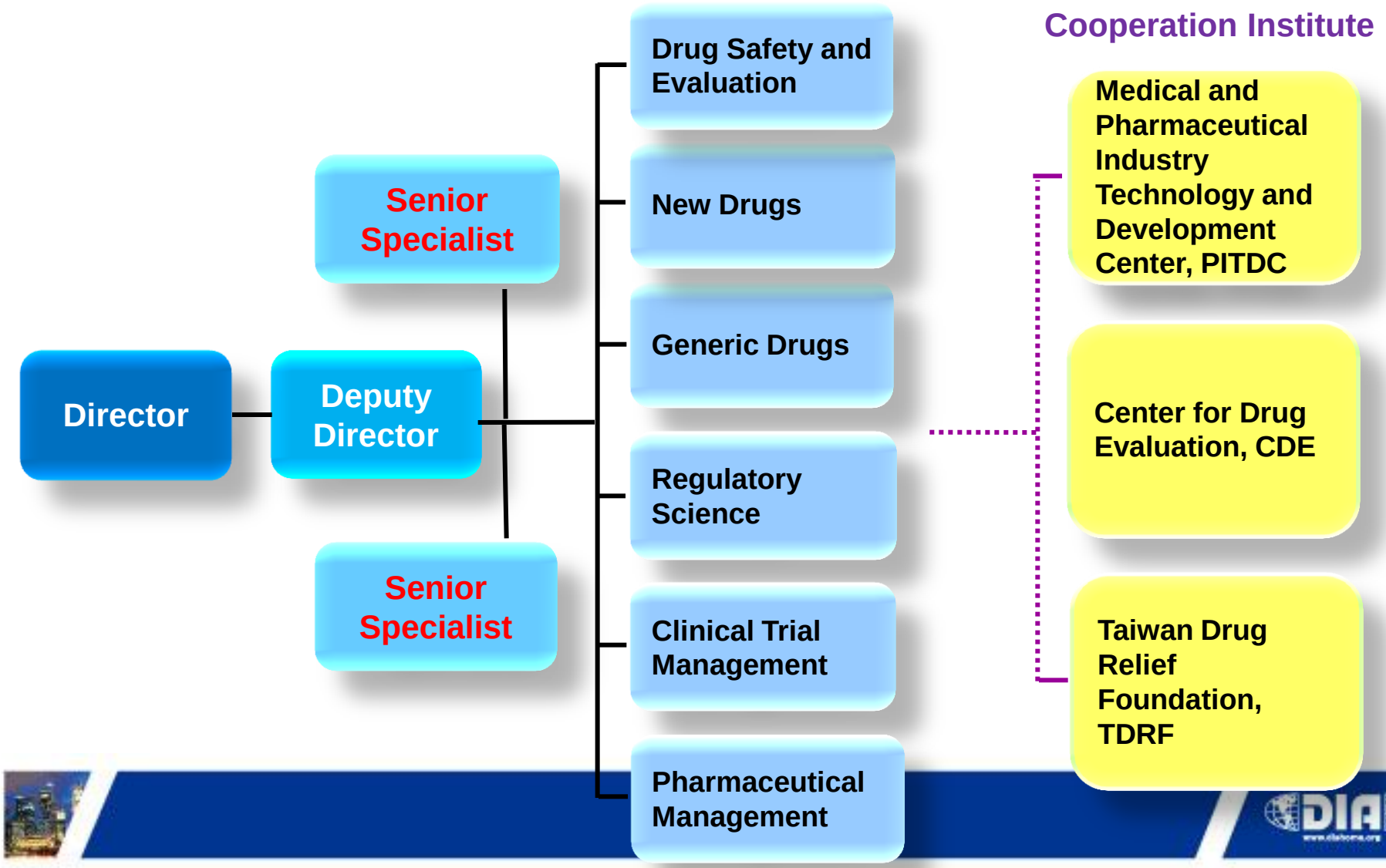


Core Value of TFDA

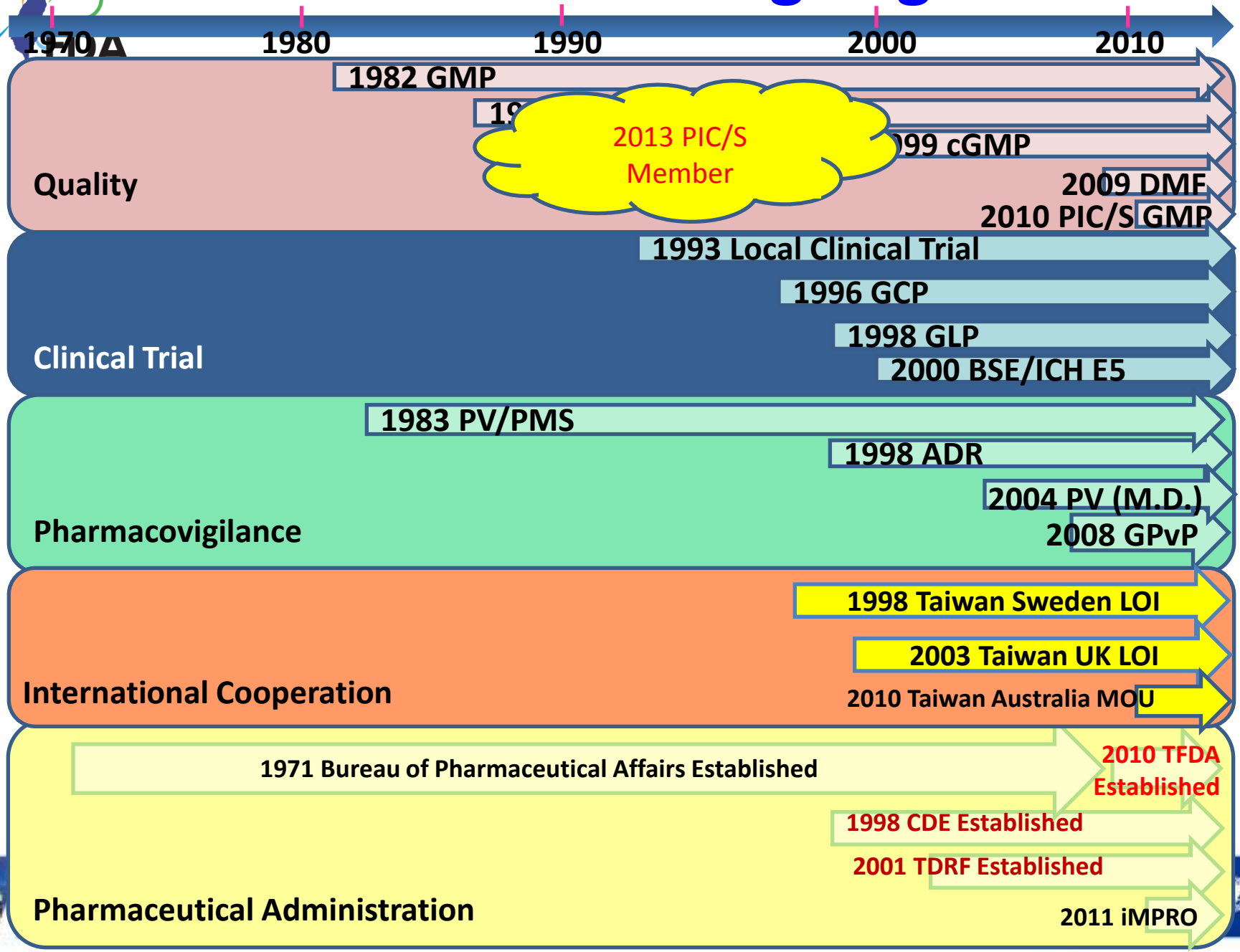
from Product Center to Consumer Center



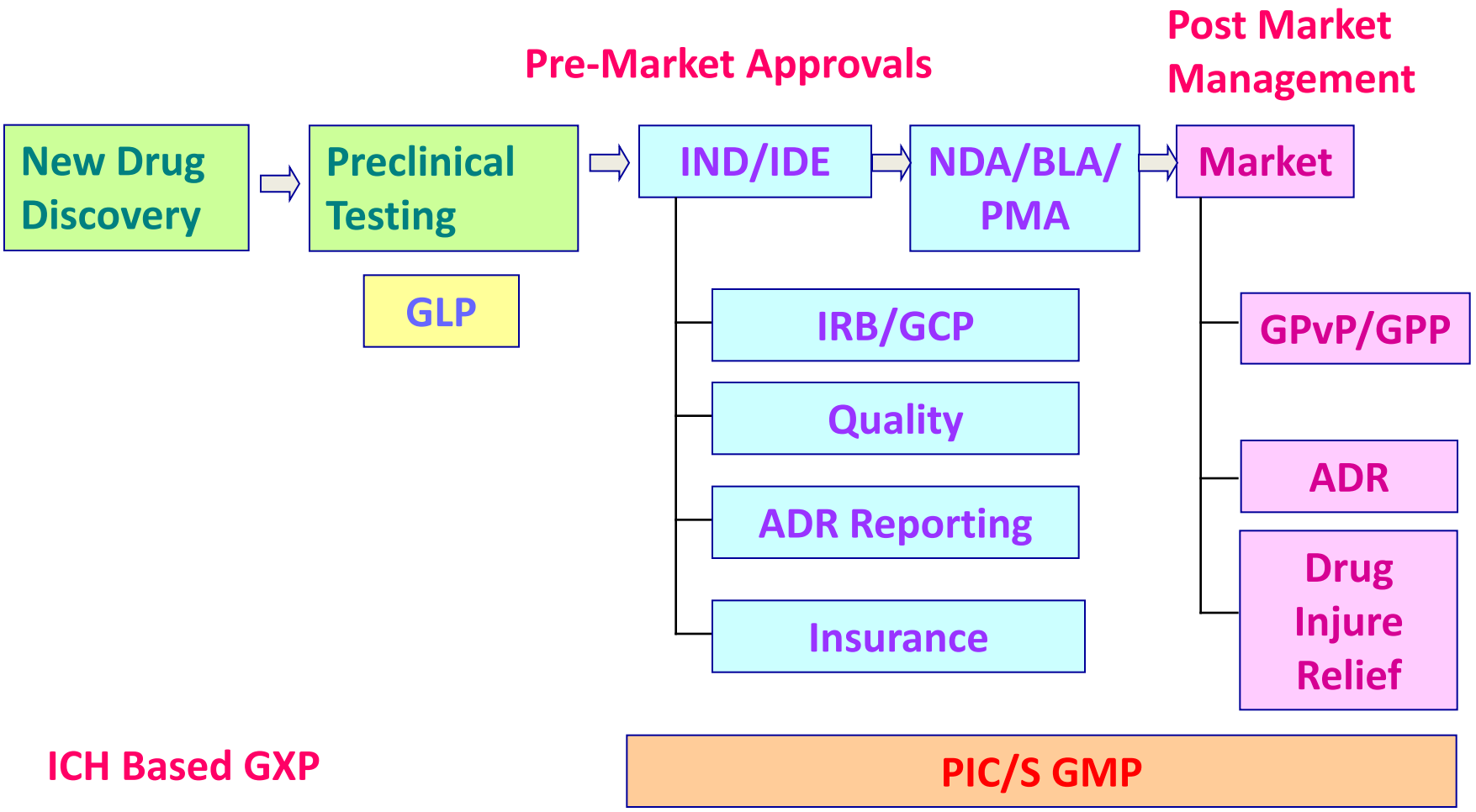
Division of Drugs and New Biotechnology Products



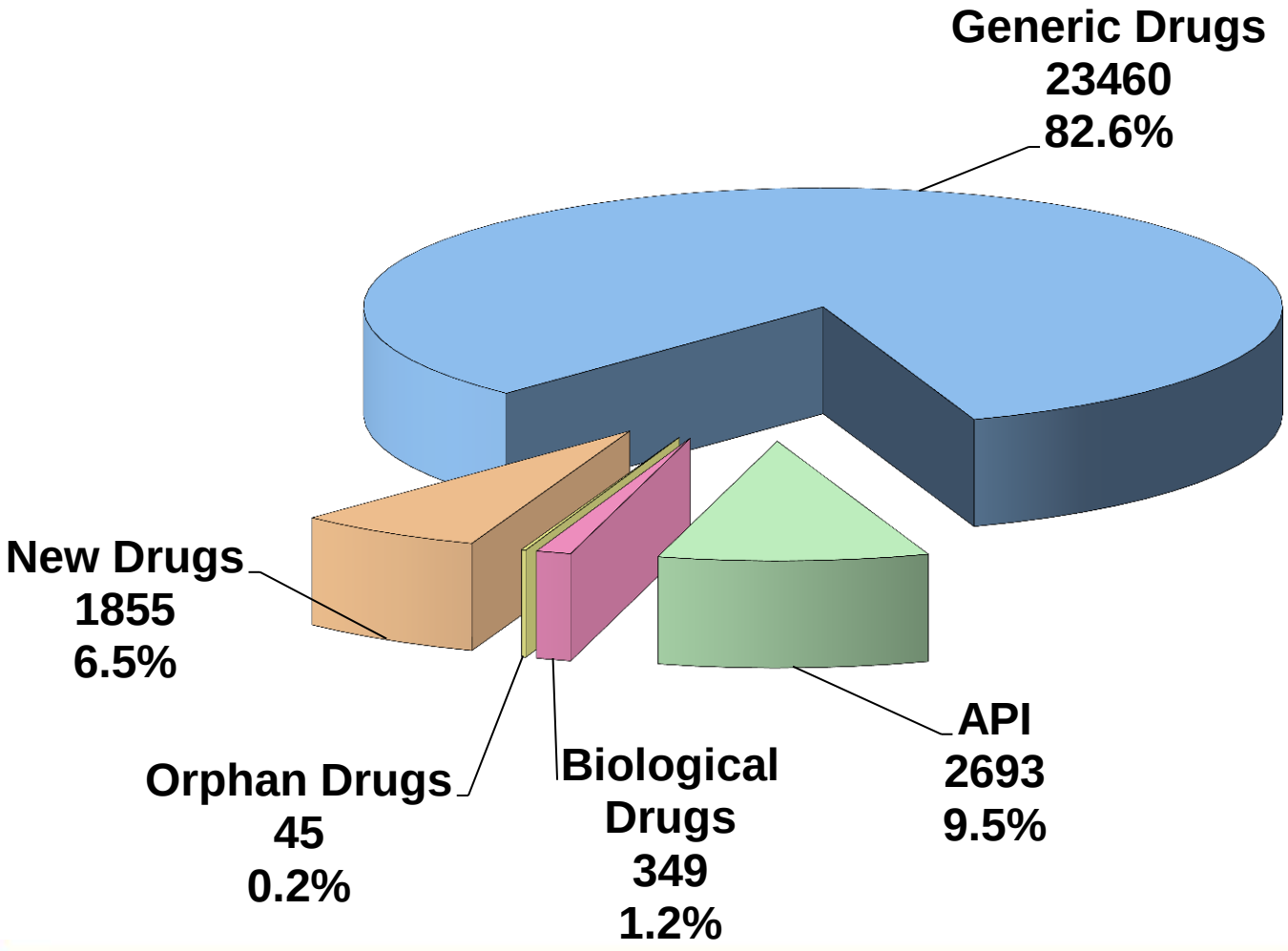
Milestone of Drug Regulation



Pharmaceutical Regulation



Statistics of Pharmaceutical Licenses (2012)



Roles of Regulatory Authorities

- **Protect the Public Health**
  - Evaluate Prudently Based on Good Review Practice
  - Assure Drug Quality, Safety, and Efficacy
- **Promote the Science and Innovation**
  - Create Consultation Mechanism
  - Increase Consistency and Transparency
  - Streamline and Reform Regulations and Review System

Regulation in IND

Laws and Regulations

- Laws:
  - Pharmaceutical Affairs Act and Enforcement Rules (1970, 1973)
  - Medical Care Act and Enforcement Rules (1986, 1987)
  - Human Biobank Management Act (2010)
  - Human Research Act (2011)
- Regulations:
  - Regulations of Medicament Manufacturer Inspection(1973)
  - Regulations for Good Clinical Practice (1996)
  - Regulations on Human Trials (2009)

Establishment of a Modern Clinical Trial Environment in Taiwan

- **Goal**
  - Establishment of Software and Hardware to Meet International Standard
  - Introduce Early Phase Multi-National, Multi-Center Trial, Concurrently with Global Drug Development
  - Strengthen Quality of Clinical Trial
- **Government Funding Research Centers :**
  - Grant $22 million (2011)
  - Good Clinical Research Center, GCRC(12);Center of Excellence(5); Cancer Center of Excellence(8)
- **Qualified Clinical Trial Sites for IND**：134 Teaching Hospitals
- **Training for Clinical Trial Professionals**
  - Include Medical Care Institutions, CROs, and Sponsors
  - Require 30 Hours in 6 Years of Human Related Training for PIs
- **Inspection**
  - Enhance IRB Quality
  - Establish a Clinical Trial GCP Inspection System in Line with International Standard
  - Encourage Voluntary Non-Clinical Studies GLP Inspection

Conform to International Regulations on Protection of Human Subjects

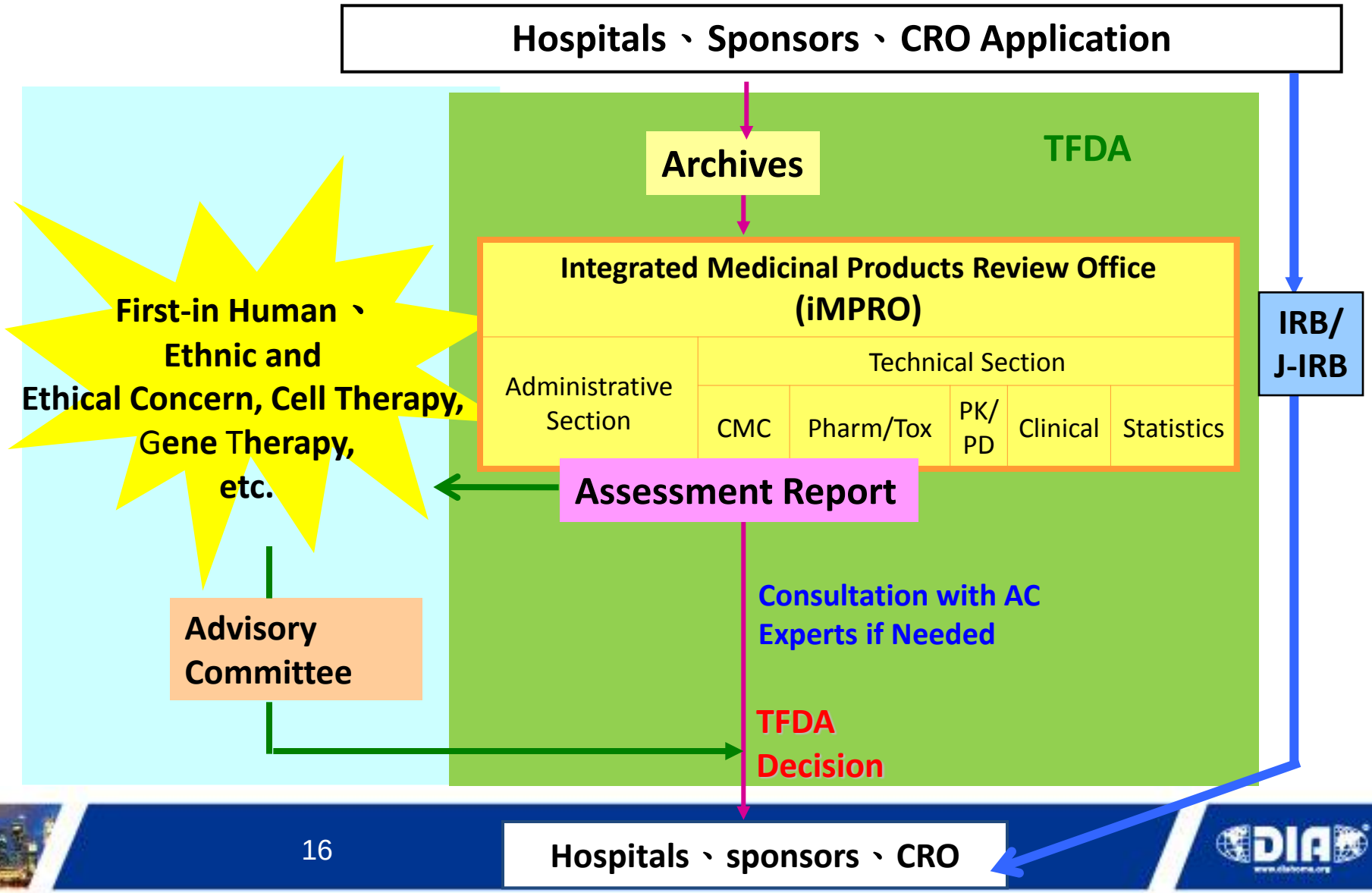
- Declaration of Helsinki and ICH-GCP
- SIDCER / FERCAP Recognition Program
  - Establish a Forum for Regional Network
  - Promote Protection for Human Subjects

SIDCER Recognition Program

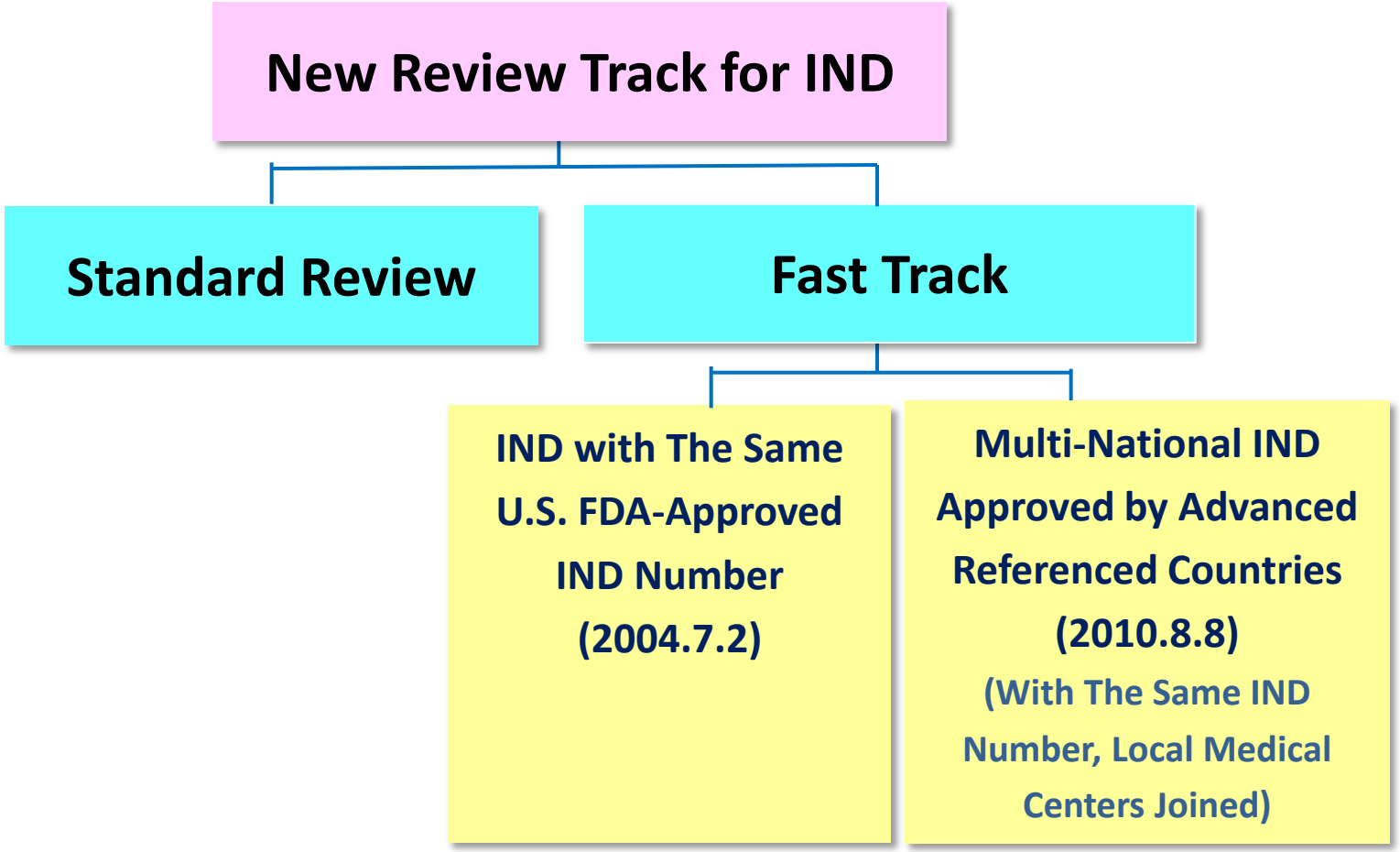
(Recognized IRBs/ECs)

Year	Taiwan	South Korea	China	Thailand	Others	Total
2005-2011	24	24	17	11	11	87

Standard Review Process for IND



New Review Track for IND



Clinical Trials Network in Taiwan

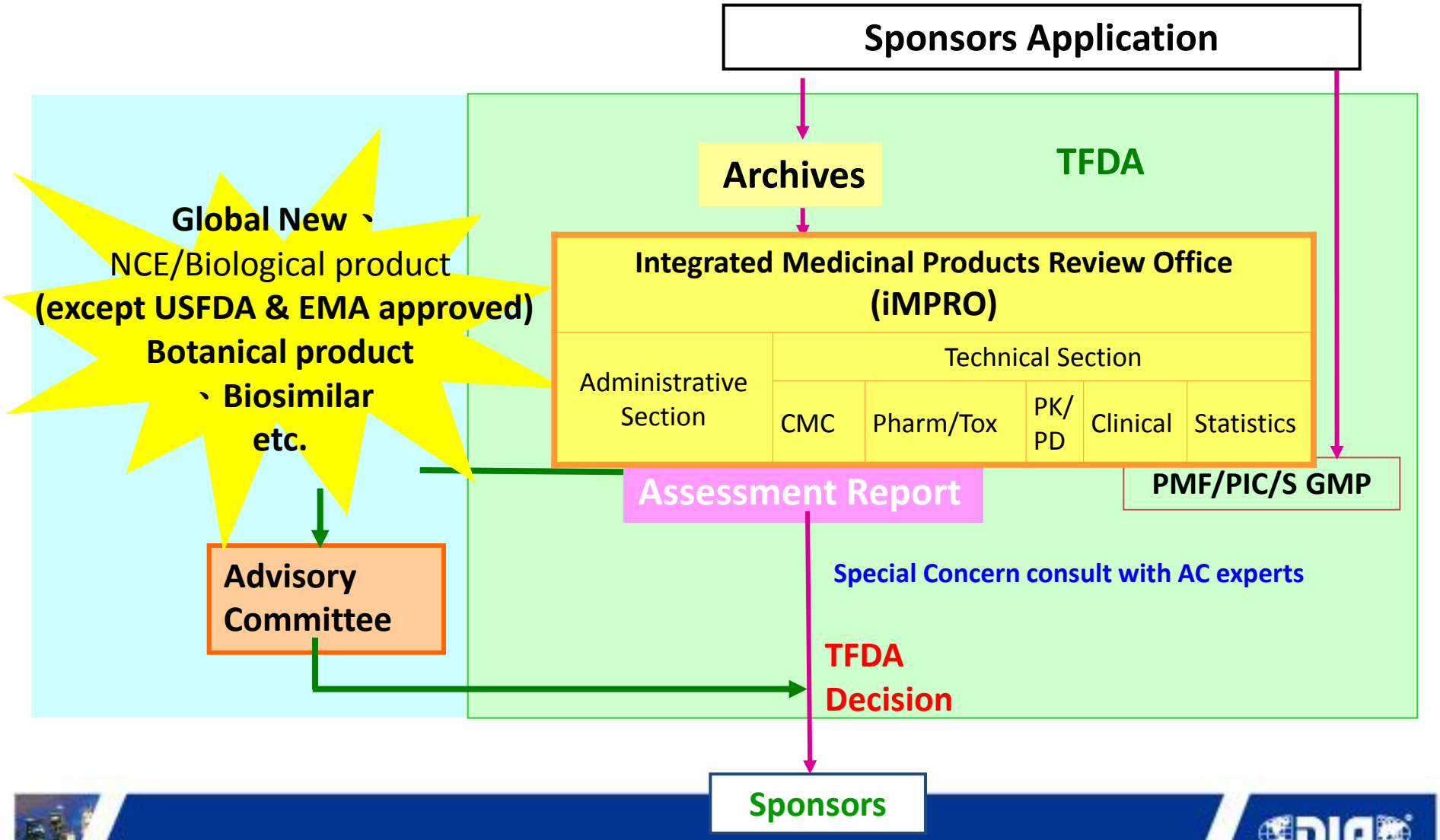
http://www.cde.org.tw/ct_taiwan/index.htm

Regulation in NDA

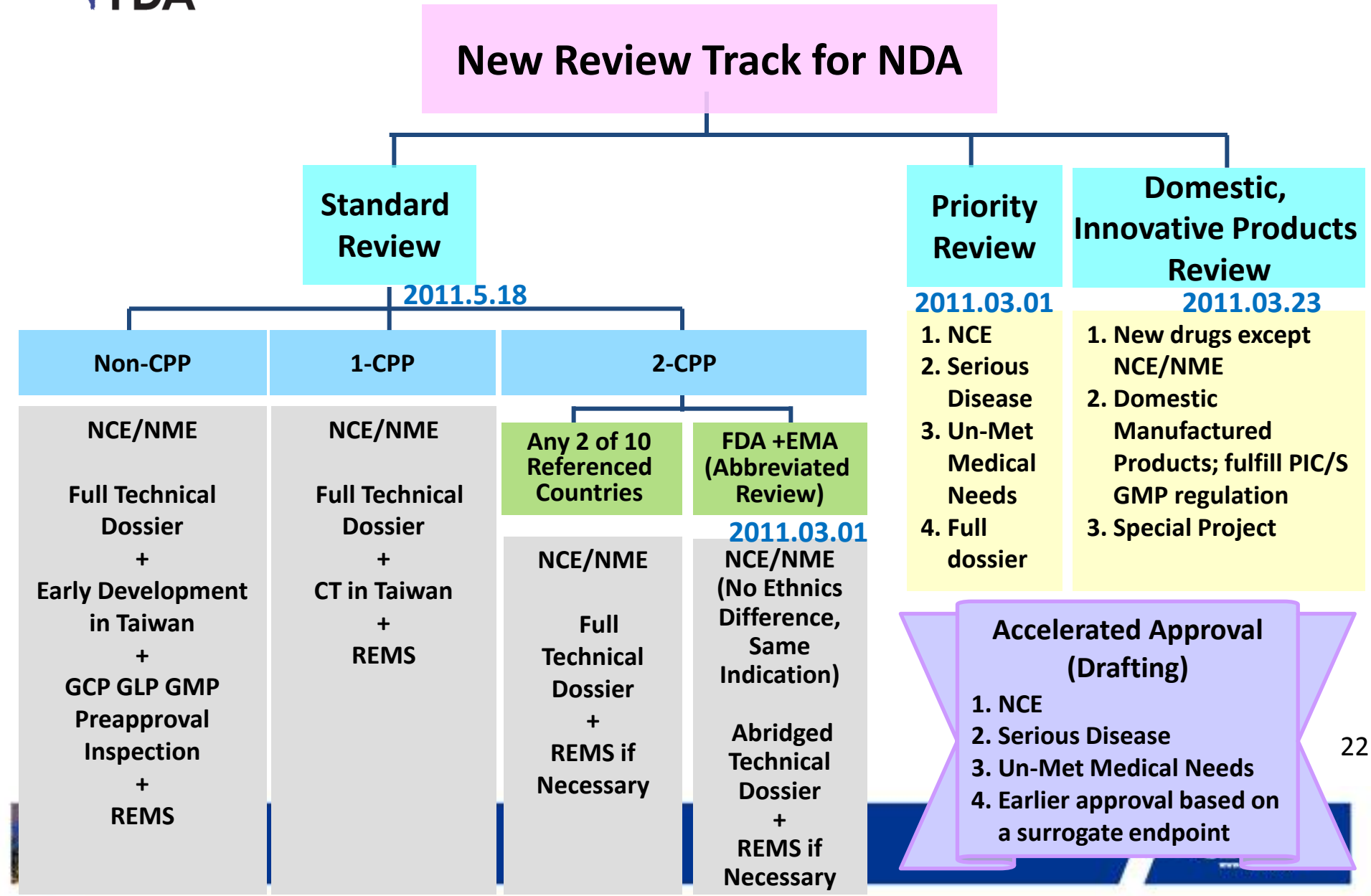
Laws and Regulations

- Laws:
  - Pharmaceutical Affairs Act and Enforcement Rules(1970, 1973)
- Regulations:
  - Guideline of Good Manufacturing Practice (1982)
  - Guideline of Bioequivalence and Bioavailability (1983)
  - Guideline of Good Laboratory Practice (1998)
  - Guideline of Good Pharmacovigilance Practice (2004)
  - Guideline of Drug Review and Approval (2005)

NDA Standard Review Process



New Review Track for NDA



New Regulation Policy for NDA

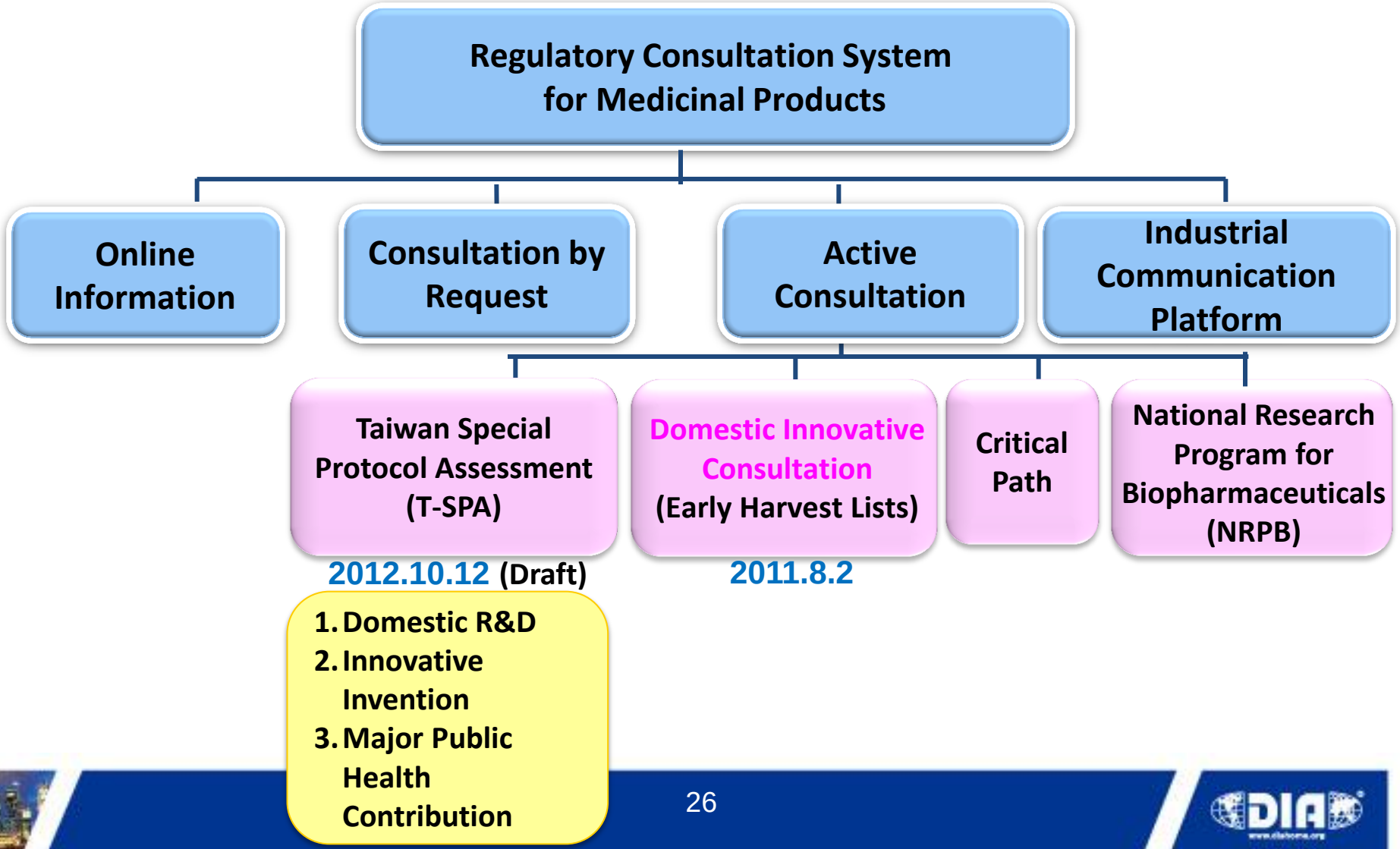
- **Publish Assessment Report for NCE** (Since 2010.8.10, 7 cases)
- **Points to Consider for Review and Approval of NCE** (2012.01.19)
- **Risk Evaluation and Mitigation Strategy (REMS) or Risk Management Plan (RMP)** (2012.04.05)
- **CPP Relaxation** (2012.05.08)
- **Implementation of Common Technical Document (CTD) Format** (2012.11.1)
- **Implementation of electronic CTD (eCTD)** (2012.10.15)
- **Amendment of Definition of New Drug** (2012.12.7)
- **NCE-2** (to be announced soon)

New Regulation Policy for NDA: Special Categories of New Drugs

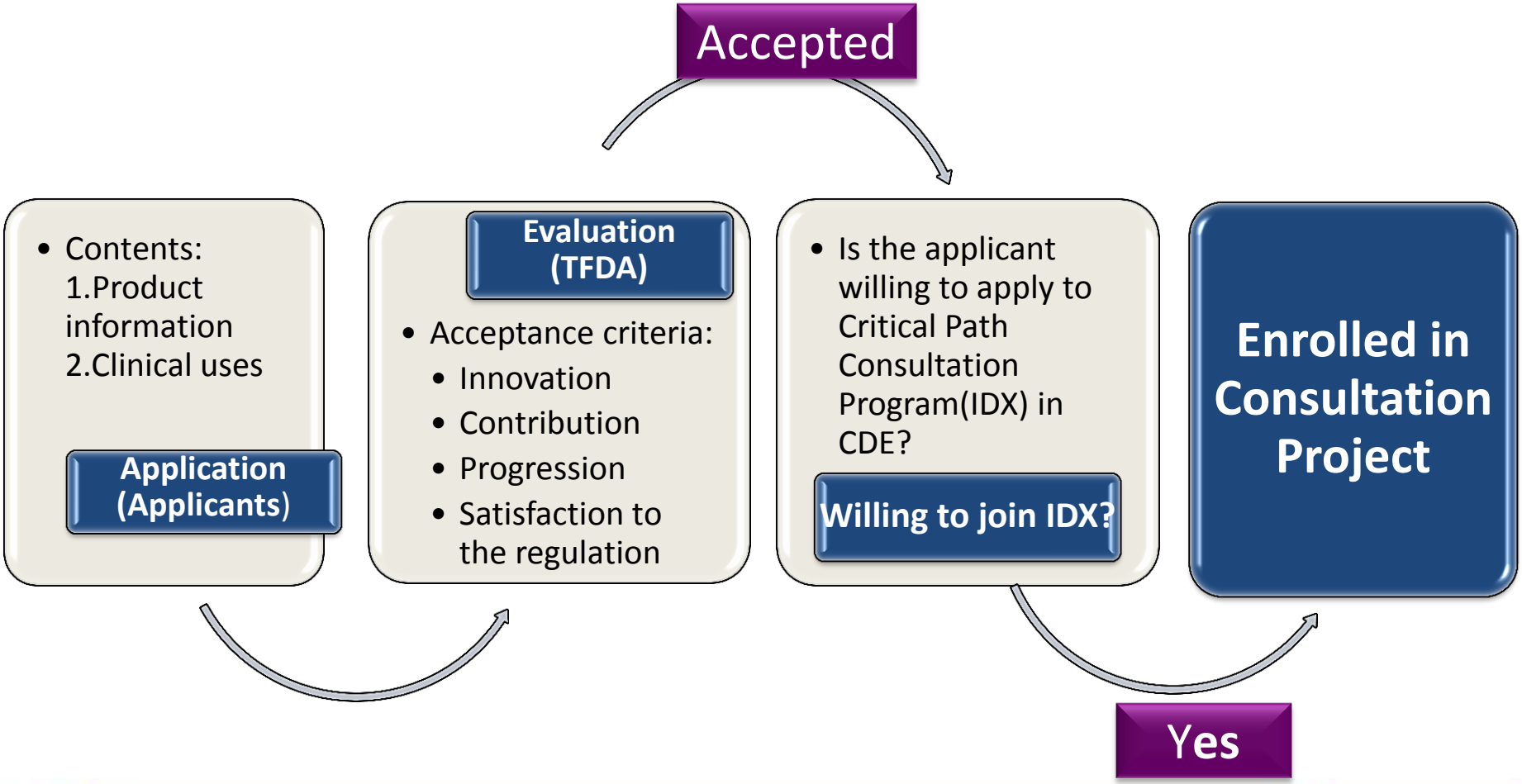
- **Botanical Product** (draft 2010.12.10)
- **Biologics:**
  - **Biosimilar** (2008.11.21)
    - Points to Consider for Common Technical Document (CTD) in Review and Approval of Biosimilar Products (2010.12.22)
  - **Vaccines** (2002.1.31)
    - Novel vaccines, e.g., EV71, OPT-822 (draft under discussion)
    - Pandemic influenza vaccines (2010.10.28)
  - **Cellular and gene therapy products** (draft 2011.2.22)

Regulatory Consultation System for Pharmaceutical Products

Regulatory Consultation System for Medicinal Products



Domestic Innovation Consultation Mechanism: Evaluation Process



Future Prospects

Future Prospects

Thank You for Your Attention

For more information

Website is at: http://www.fda.gov.tw

TAIWAN
Touch Your Heart