

Asia Regulatory Conference 2013

Day 3: Wednesday, January 30th

Update of New Drug Regulatory Convergence in Taiwan



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FDA Taiwan Profile

- ❖ **Area:** 36,188 Km²
- ❖ **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)





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

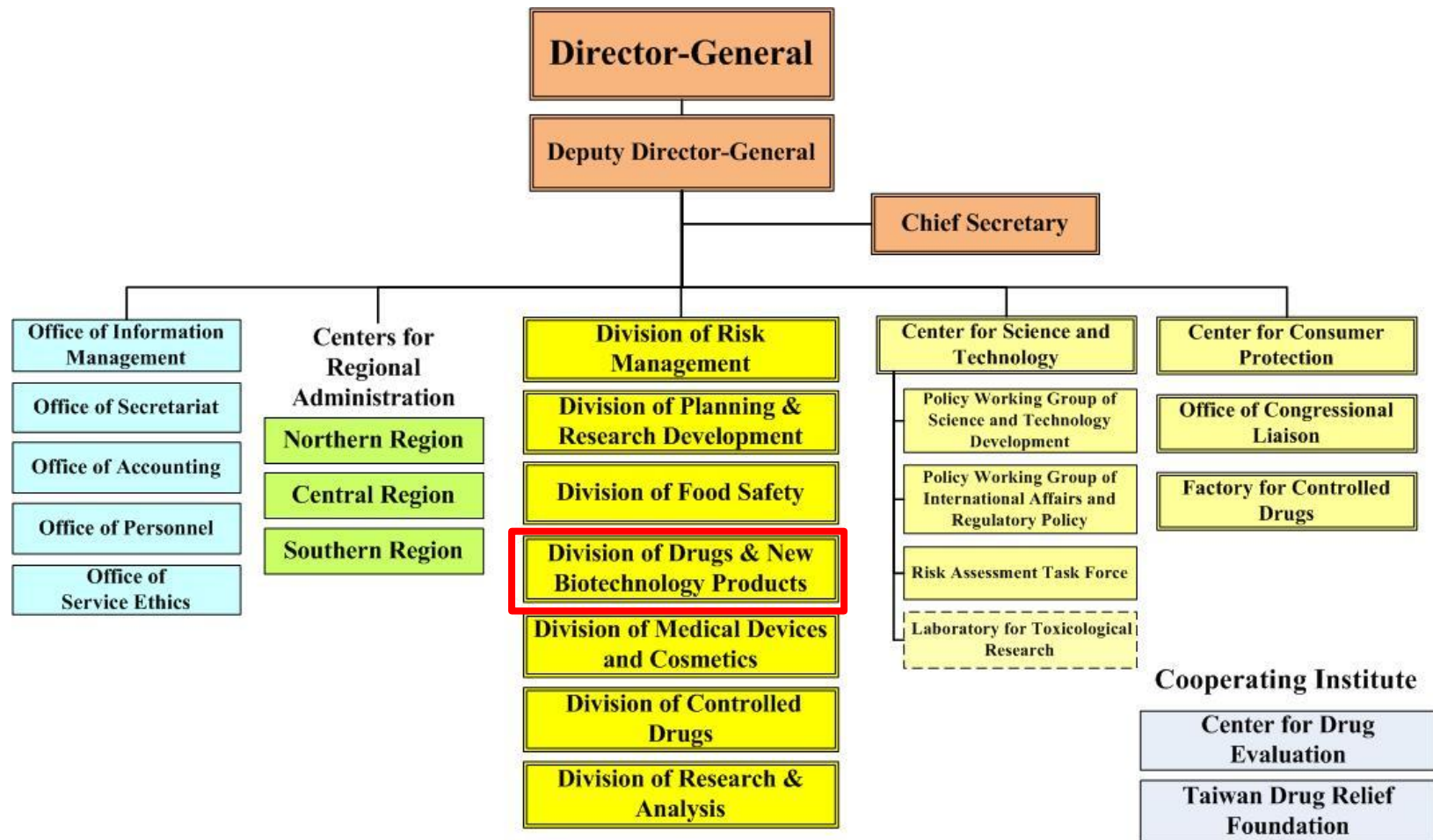
Taiwan FDA (TFDA) was inaugurated on Jan. 1, 2010

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



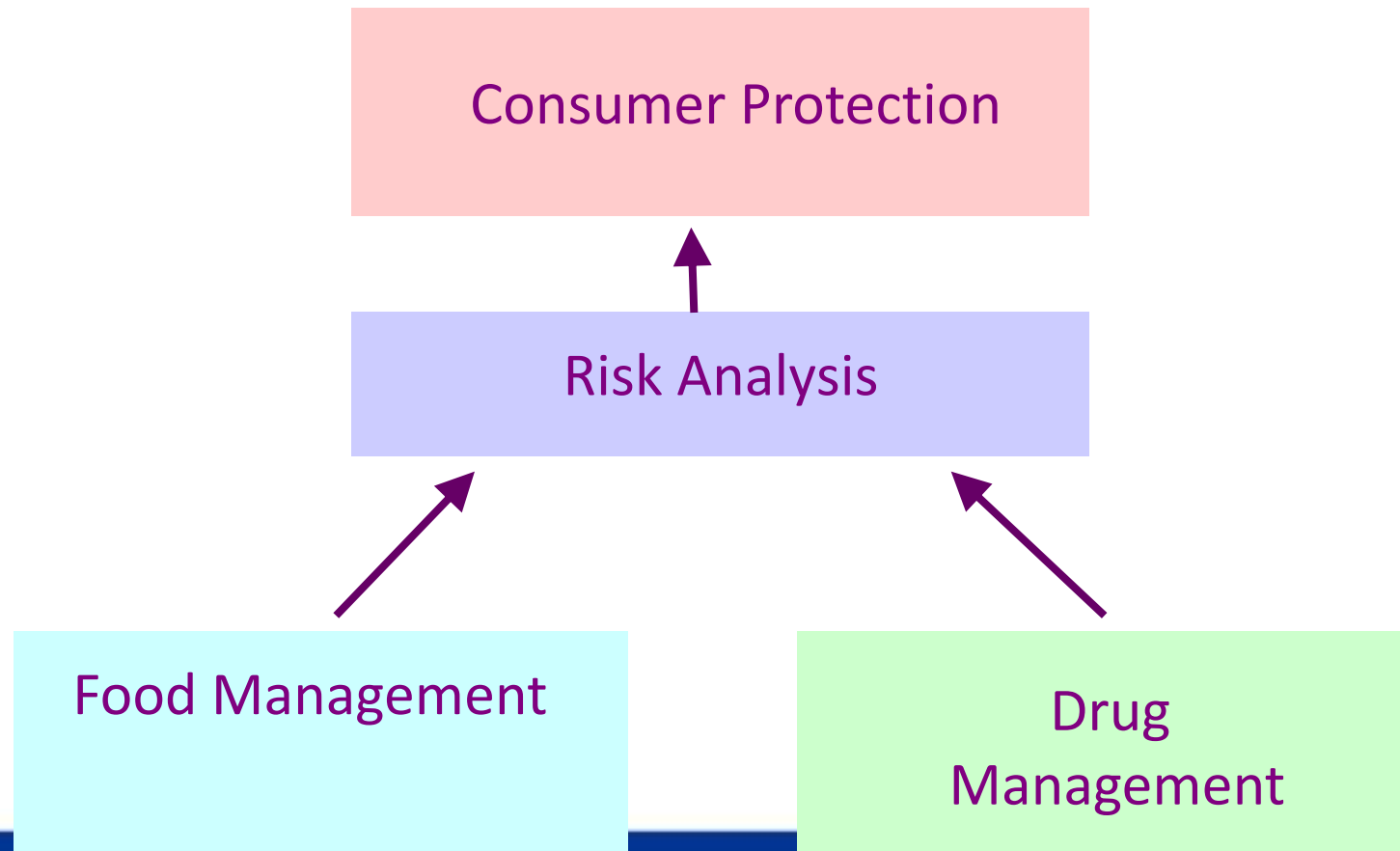
Food and Drug Administration Department of Health, Taiwan





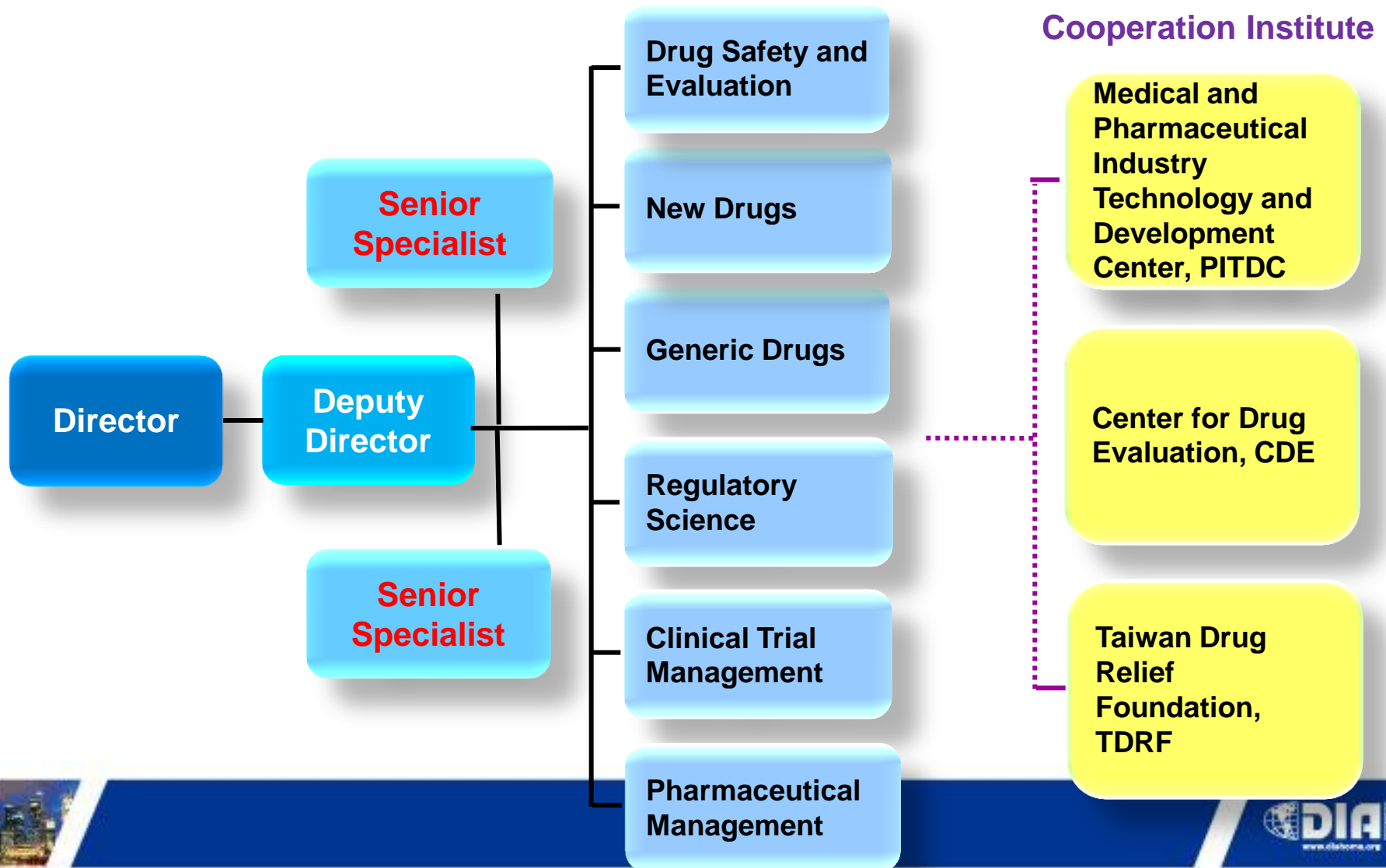
Core Value of TFDA

from **Product** Center to **Consumer** Center

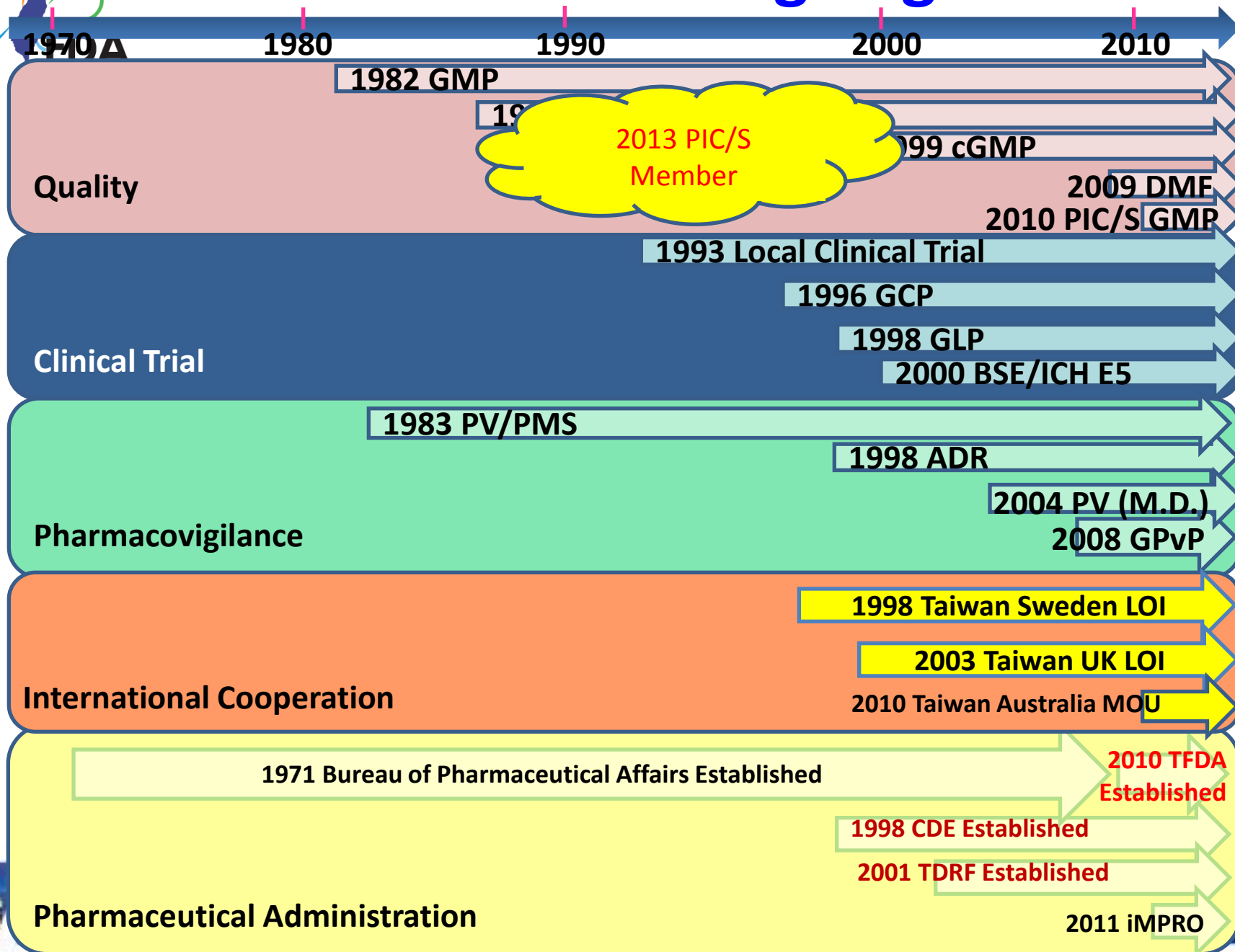




Division of Drugs and New Biotechnology Products

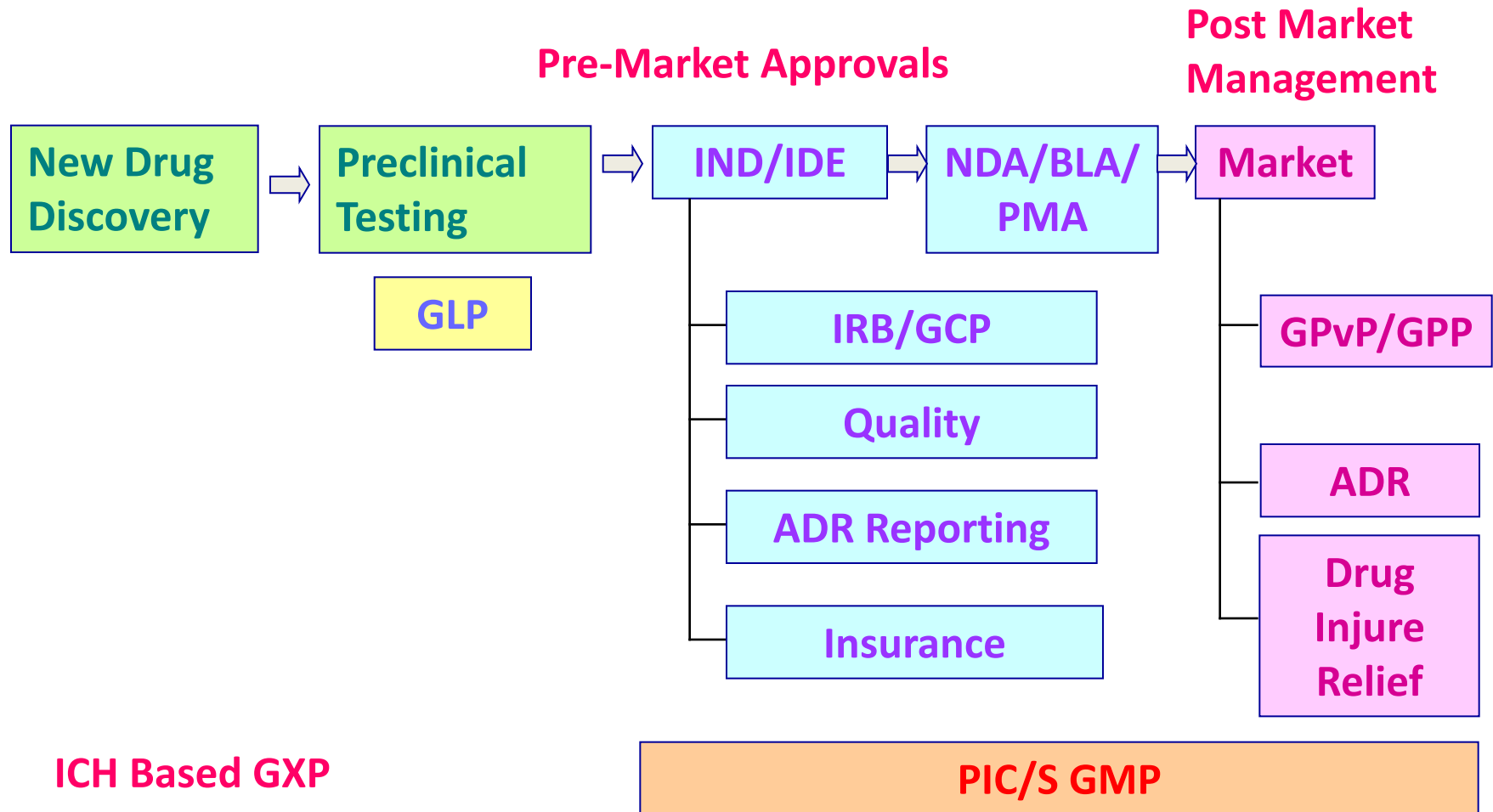


Milestone of Drug Regulation



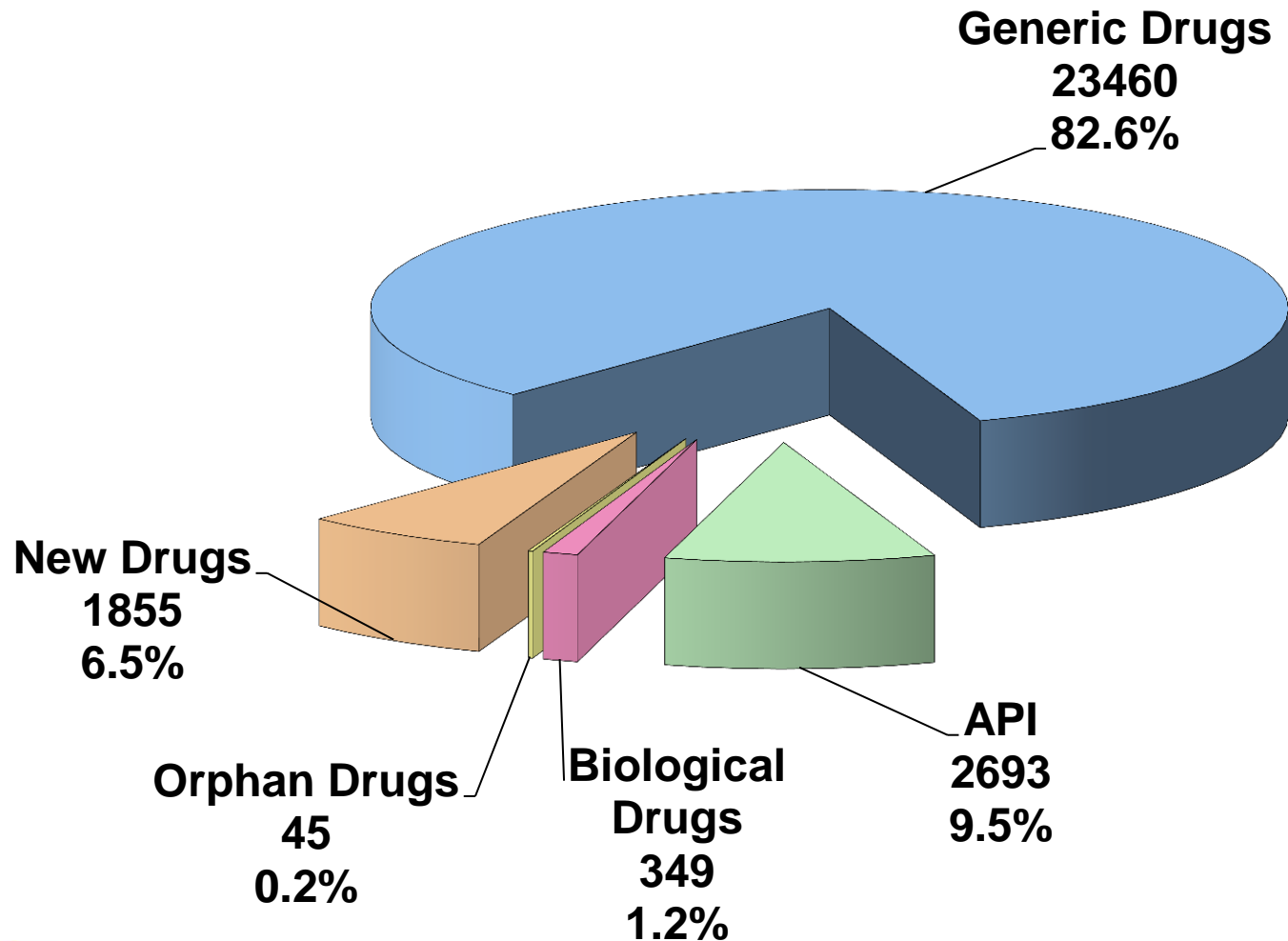


Pharmaceutical Regulation





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 Pls
- **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

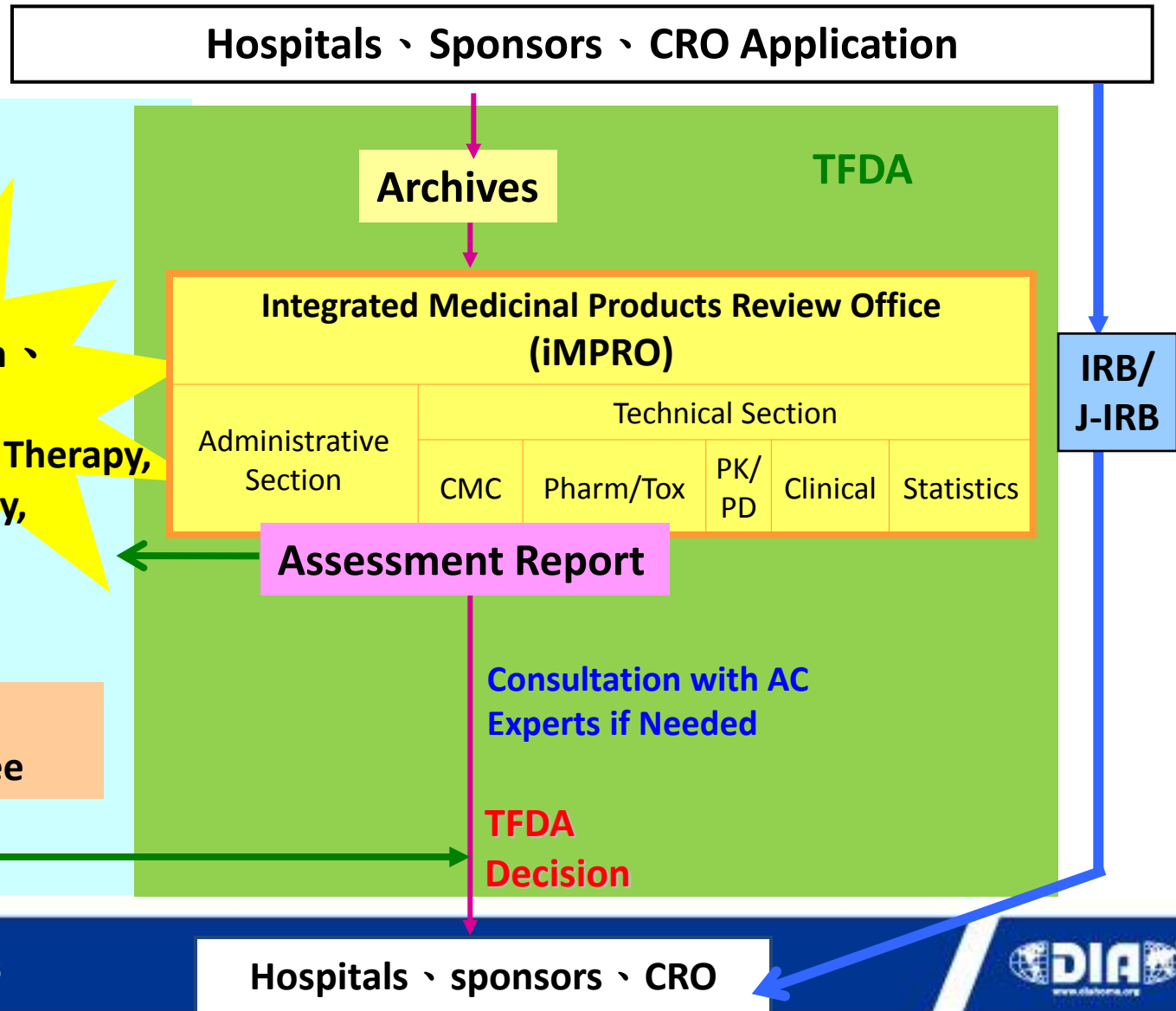
- Declaration of Helsinki and ICH-GCP
- SIDCER / FERCAP Recognition Program
 - Establish a Forum for Regional Network
 - Promote Protection for Human Subjects

SIDCER Recognition Program (Recognized IRBs/ECs)

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

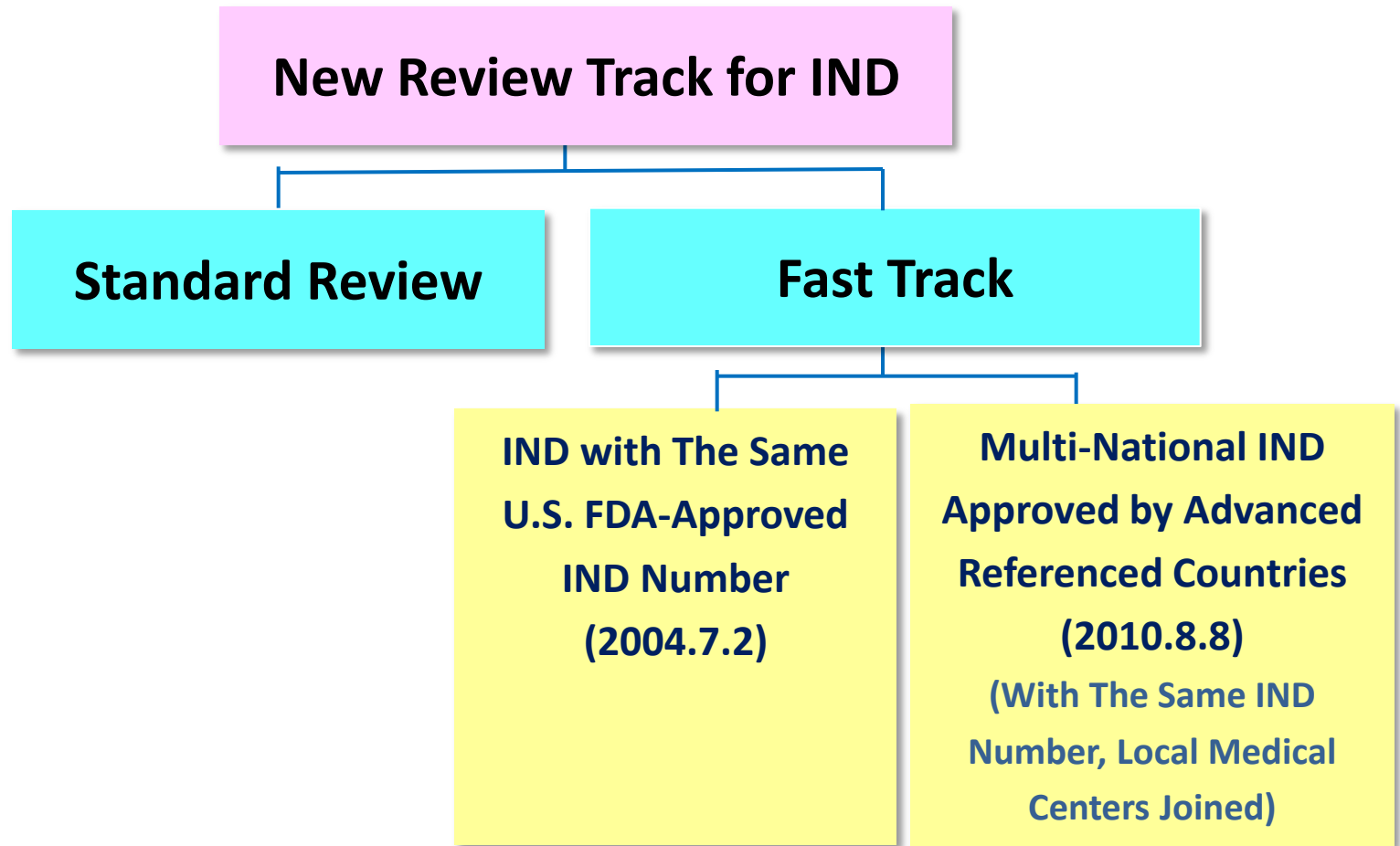


Standard Review Process for IND





New Review Track for IND



Clinical Trials Network in Taiwan

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



The screenshot shows the website of the Clinical Trials Network in Taiwan, accessed via Microsoft Internet Explorer. The browser's address bar displays the URL http://www.cde.org.tw/ct_taiwan/index.htm. The website's header features the title "台灣藥品臨床試驗資訊網" (Clinical Trials Network in Taiwan) and a navigation menu with links: "成立宗旨" (Establishment Purpose), "資料查詢" (Data Query), "名詞解釋" (Terminology Explanation), "責任聲明" (Statement of Responsibility), "意見反應" (Opinion Response), and "相關連結" (Related Links). The main content area is titled "成立宗旨" and contains a paragraph explaining the network's purpose: to ensure the safety and effectiveness of marketed drugs, protect public health, and promote the development of new drugs and the pharmaceutical industry. Below this, a section titled "臨床試驗公開項目涵括:" (Clinical Trial Public Disclosure Items Include:) lists five items: 1. 試驗委託/贊助單位名稱 (Sponsor/Investigator Name), 2. 試驗藥品名稱/成分/劑量/劑型 (Drug Name/Ingredients/Dose/Formulation), 3. 試驗計畫編號 (Trial Number), 4. 試驗計畫標題(名稱) (Trial Title/Name), and 5. 試驗目的 (Trial Purpose). The website also features a sidebar with links to "關於臨床試驗" (About Clinical Trials), "臨床試驗資訊" (Clinical Trial Information), and "行政院衛生署醫藥品查驗中心" (Ministry of Health Drug and Food Inspection Center).

台灣藥品臨床試驗資訊網
Clinical Trials Network in Taiwan

成立宗旨
資料查詢
名詞解釋
責任聲明
意見反應
相關連結

● 成立宗旨

行政院衛生署為兼顧考量「確保上市藥品之安全性及有效性，以維護國民健康福祉」、「保護原開發廠之智慧財產權，以鼓勵研發新藥」及「扶植學名藥產業，以提供高品質價廉之藥品」等各種公益之衡平，以維護公益為目的，設立本網站，以定期更新公開經本署審查通過之臨床試驗。但如為非供查驗登記用之臨床試驗，雖仍經本署審查，廠商得自行決定公開與否。

● 臨床試驗公開項目涵括：

1. 試驗委託/贊助單位名稱
2. 試驗藥品名稱/成分/劑量/劑型
3. 試驗計畫編號
4. 試驗計畫標題(名稱)
5. 試驗目的

Regulation in NDA





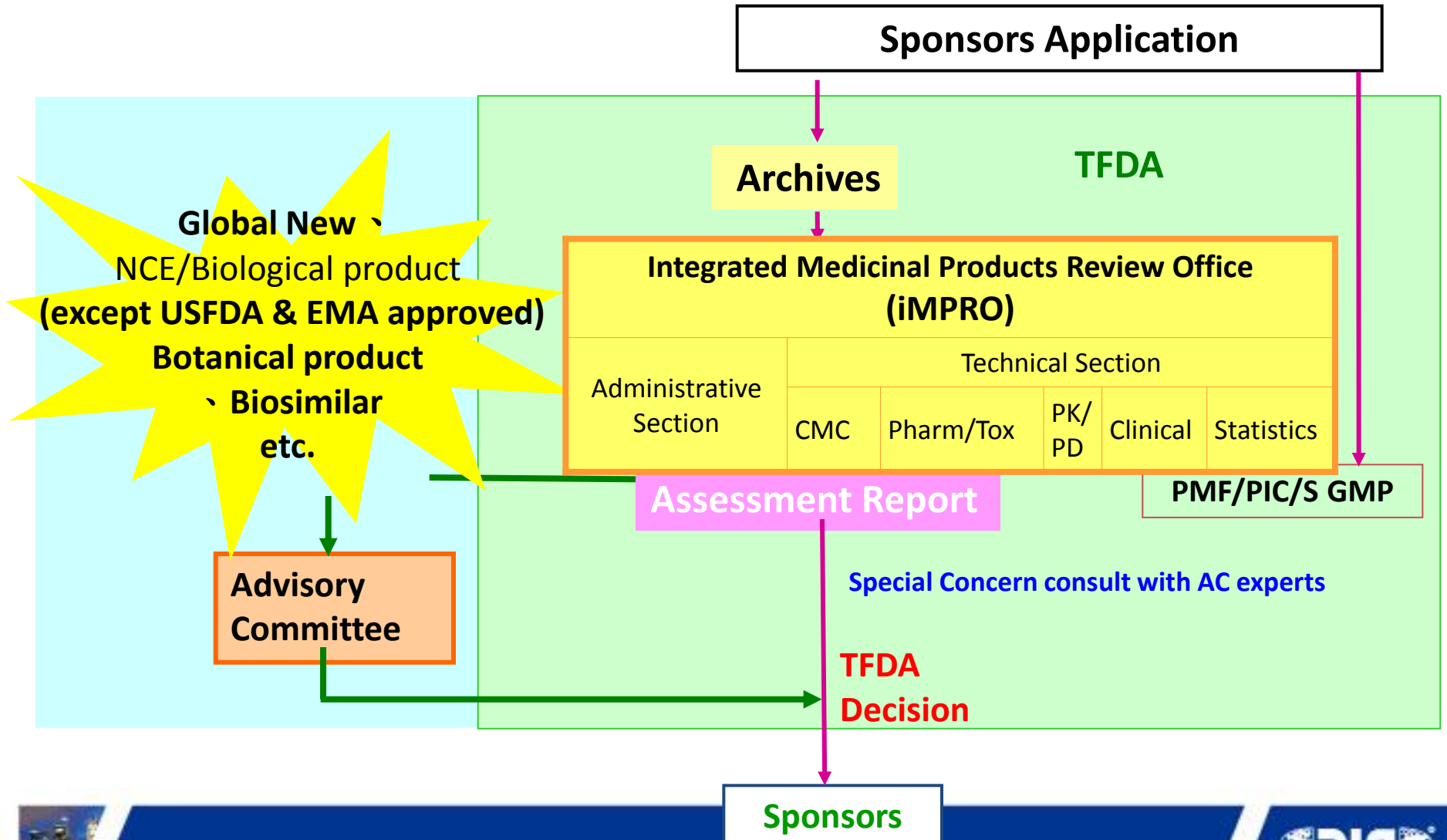
Laws and Regulations

- 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)





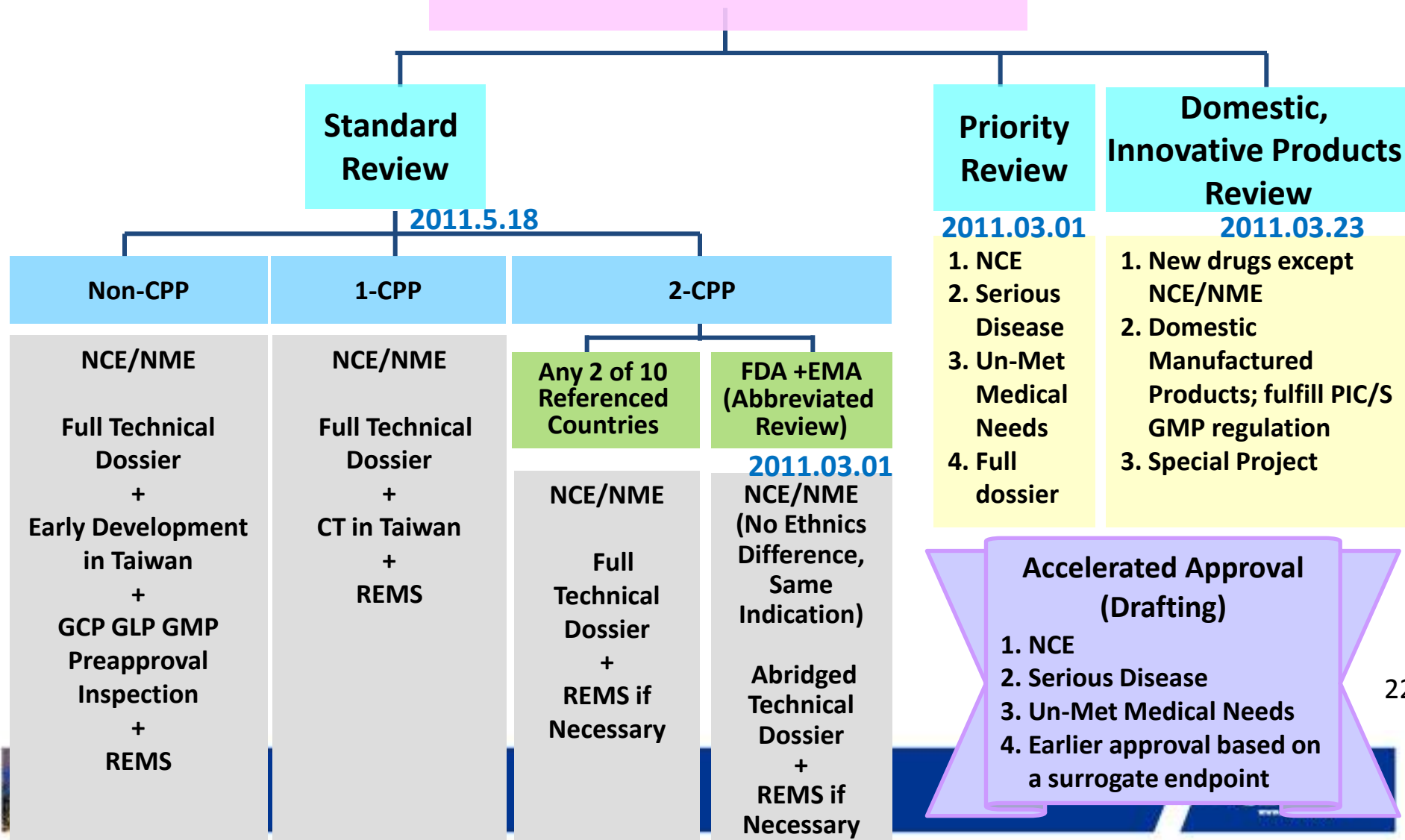
NDA Standard Review Process





New Review Track for NDA

New 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

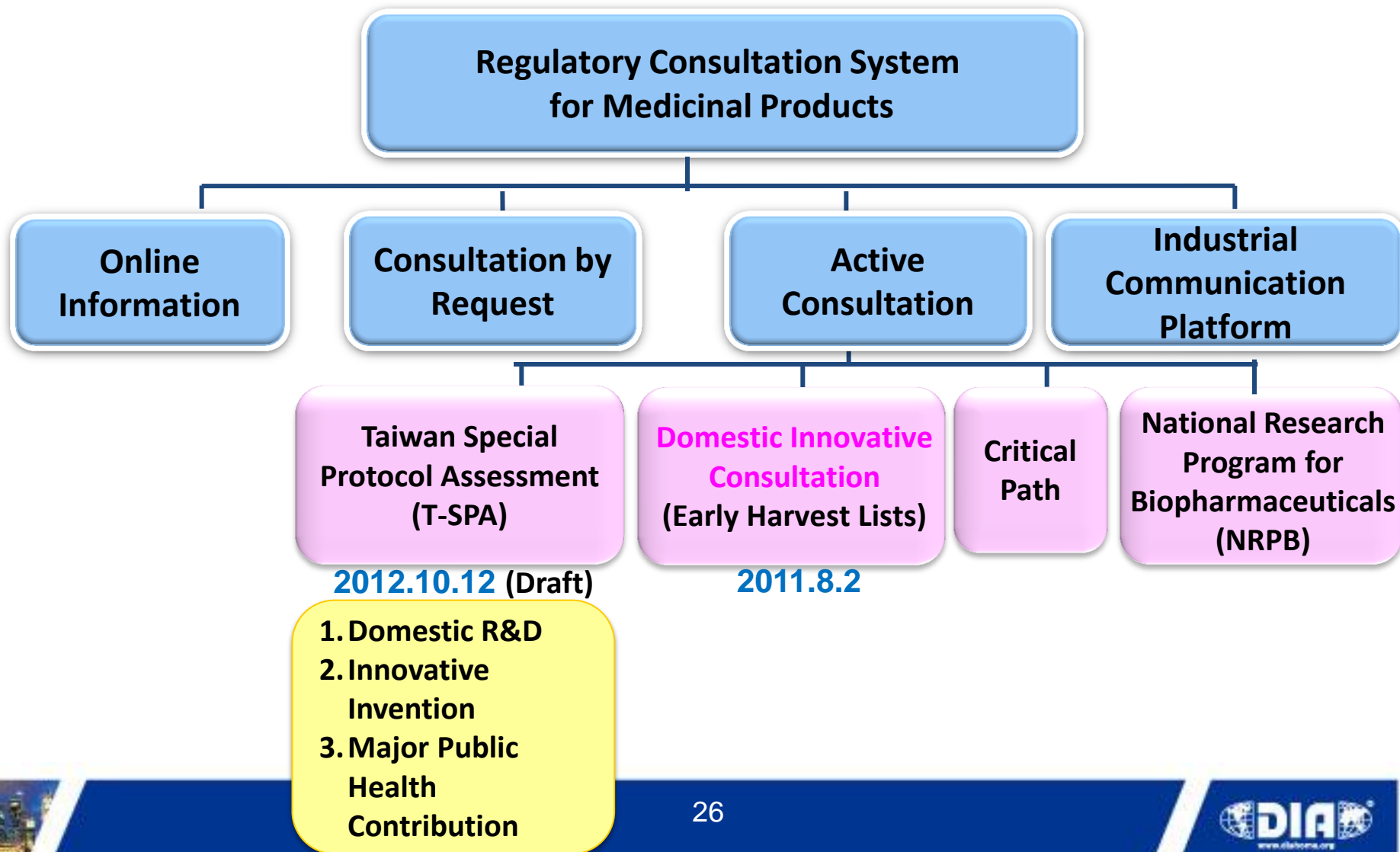
- **Botanical Product** (draft 2010.12.10)
- **Biologics:**
 - **Biosimilar** (2008.11.21)
 - Points to Consider for Common Technical Document (CTD) in Review and Approval of Biosimilar Products (2010.12.22)
 - **Vaccines** (2002.1.31)
 - Novel vaccines, e.g., EV71, OPT-822 (draft under discussion)
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



Regulatory Consultation System for Pharmaceutical Products

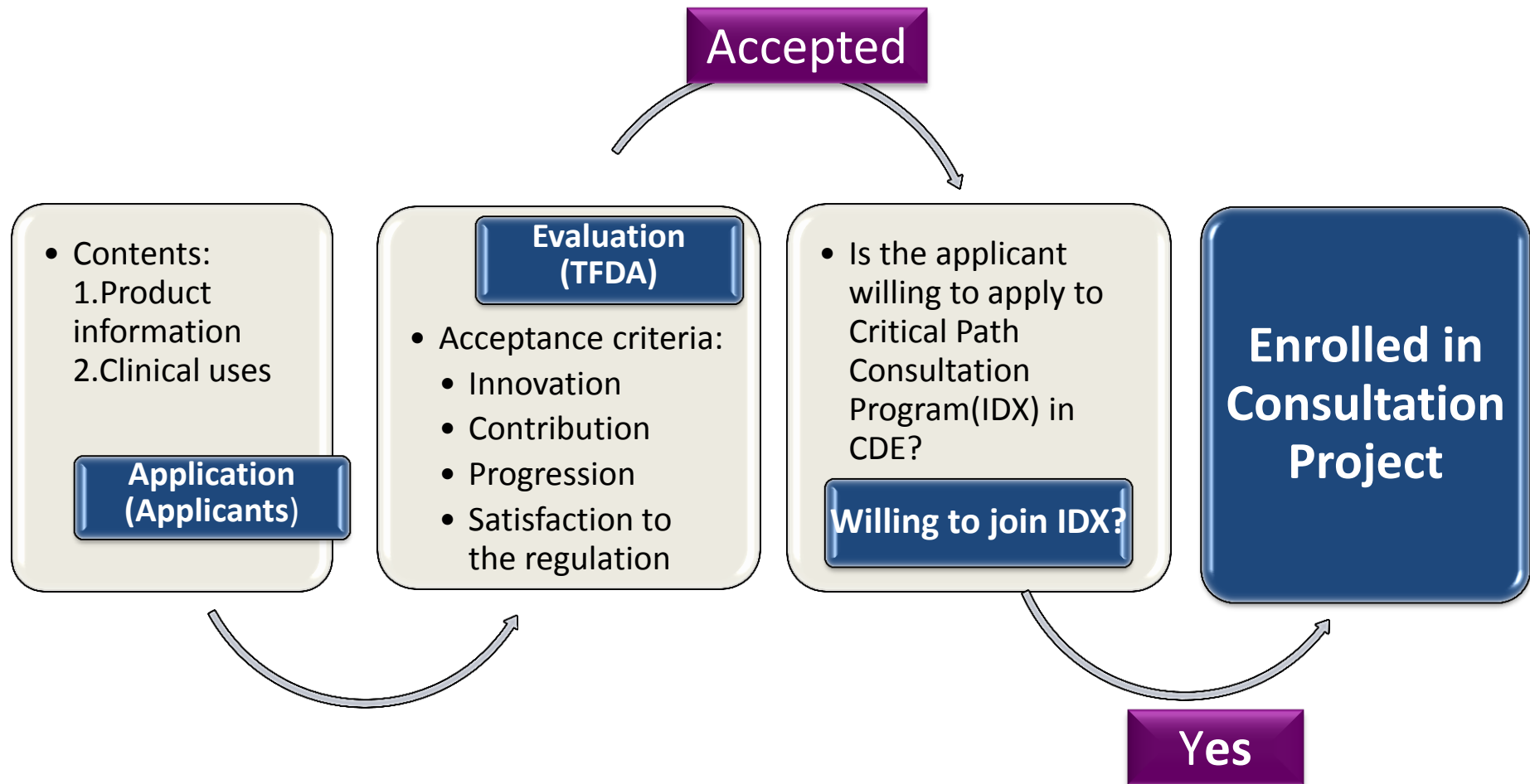


Regulatory Consultation System for Medicinal Products





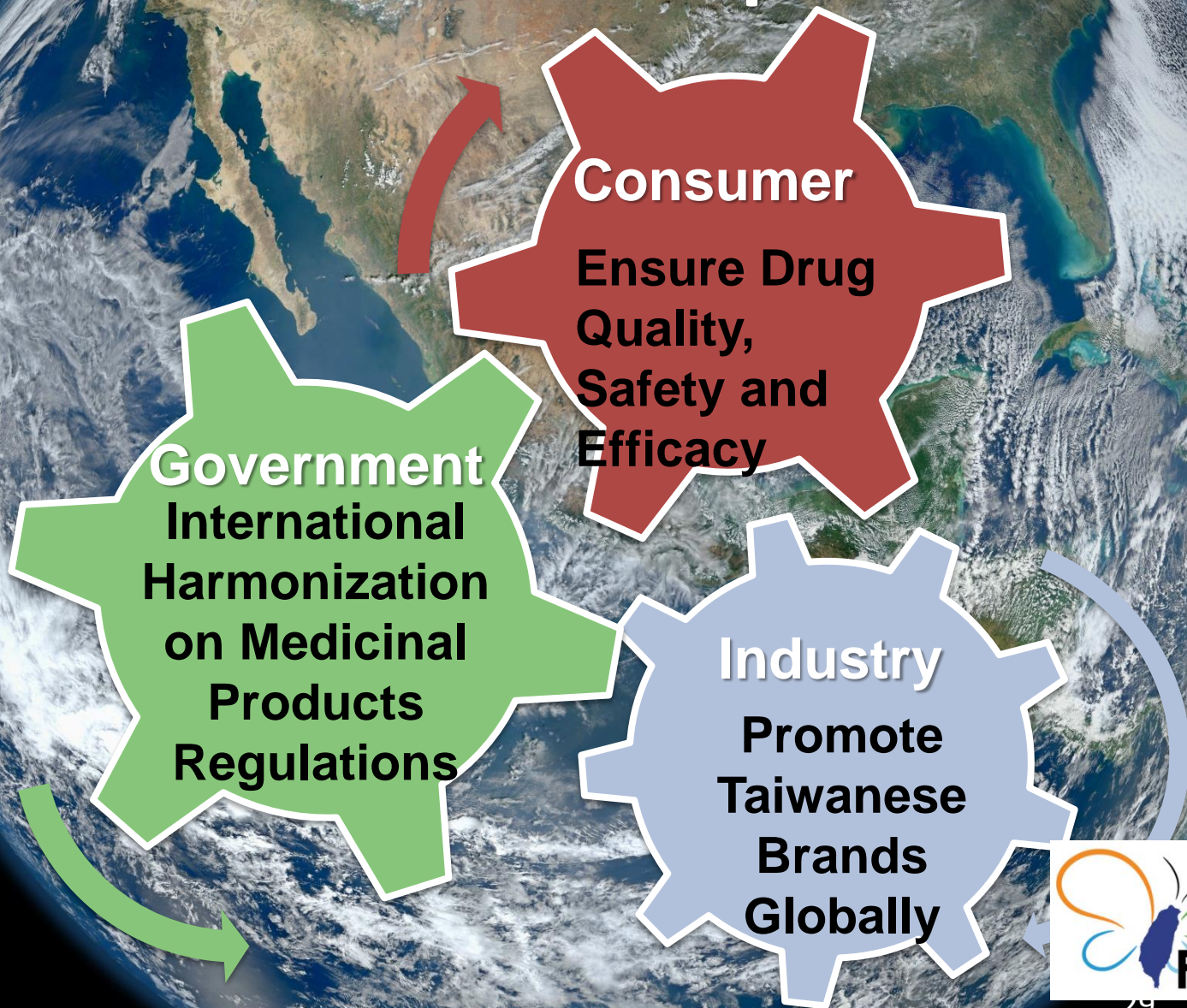
Domestic Innovation Consultation Mechanism: Evaluation Process



Future Prospects



Future Prospects



Thank You for Your Attention

For more information

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

