Update of New Drug Regulatory Convergence in Taiwan

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Taiwan
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
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

Director-General

Deputy Director-General

Chief Secretary

Centers for Regional Administration
- Northern Region
- Central Region
- Southern Region

Division of Risk Management
Division of Planning & Research Development
Division of Food Safety
Division of Drugs & New Biotechnology Products
Division of Medical Devices and Cosmetics
Division of Controlled Drugs
Division of Research & Analysis

Center for Science and Technology
- Policy Working Group of Science and Technology Development
- Policy Working Group of International Affairs and Regulatory Policy
- Risk Assessment Task Force
- Laboratory for Toxicological Research

Center for Consumer Protection
- Office of Congressional Liaison
- Factory for Controlled Drugs

Cooperating Institute
- Center for Drug Evaluation
- Taiwan Drug Relief Foundation
Core Value of TFDA

from Product Center to Consumer Center

- Consumer Protection
- Risk Analysis
- Food Management
- Drug Management
Division of Drugs and New Biotechnology Products

Director

Deputy Director

Senior Specialist

Senior Specialist

Drug Safety and Evaluation

New Drugs

Generic Drugs

Regulatory Science

Clinical Trial Management

Pharmaceutical Management

Cooperation Institute

Medical and Pharmaceutical Industry Technology and Development Center, PITDC

Center for Drug Evaluation, CDE

Taiwan Drug Relief Foundation, TDRF

- **Generic Drugs**: 23,460 (82.6%)
- **New Drugs**: 1,855 (6.5%)
- **Orphan Drugs**: 45 (0.2%)
- **Biological Drugs**: 349 (1.2%)
- **API**: 2,693 (9.5%)
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:
  – 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)

<table>
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<th>Year</th>
<th>Taiwan</th>
<th>South Korea</th>
<th>China</th>
<th>Thailand</th>
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Standard Review Process for IND

Hospitals, Sponsors, CRO Application

Archives

Integrated Medicinal Products Review Office (iIMPRO)

Administrative Section
- CMC
- Pharm/Tox
- PK/PD

Technical Section
- Clinical
- Statistics

Advisory Committee

Consultation with AC Experts if Needed

TFDA Decision

TFDA

IRB/J-IRB

First-in Human, Ethnic and Ethical Concern, Cell Therapy, Gene Therapy, etc.
New Review Track for IND

Standard Review

- IND with The Same U.S. FDA-Approved IND Number (2004.7.2)

Fast Track

- Multi-National IND Approved by Advanced Referenced Countries (2010.8.8) (With The Same IND Number, Local Medical Centers Joined)
Clinical Trials Network in Taiwan
Regulation in NDA
Laws and Regulations

• Laws:

• Regulations:
  – Guideline of Bioequivalence and Bioavailability (1983)
  – Guideline of Good Laboratory Practice (1998)
NDA Standard Review Process

Sponsors Application

Integrated Medicinal Products Review Office (iIMPRO)

- Administrative Section
  - CMC
  - Pharm/Tox
- Technical Section
  - PK/PD
  - Clinical
  - Statistics

Advisory Committee

Assessment Report

Special Concern consult with AC experts

TFDA Decision

Sponsors

TFDA

PMF/PIC/S GMP

Global New  
NCE/Biological product 
(except USFDA & EMA approved) 
Botanical product  
Biosimilar  
etc.

TFDA
New Review Track for NDA

Non-CPP
- NCE/NME
  - Full Technical Dossier
  - Early Development in Taiwan
  - GCP GLP GMP Preapproval Inspection
  + REMS

1-CPP
- NCE/NME
  - Full Technical Dossier
  - CT in Taiwan
  + REMS

2-CPP
- NCE/NME
  - Any 2 of 10 Referenced Countries

Priority Review
- 2011.03.01
  1. NCE
  2. Serious Disease
  3. Un-Met Medical Needs
  4. Full dossier

Domestic, Innovative Products Review
- 2011.03.23
  1. New drugs except NCE/NME
  2. Domestic Manufactured Products; fulfill PIC/S GMP regulation
  3. Special Project

Accelerated Approval (Drafting)
- 2011.03.01
  1. NCE
  2. Serious Disease
  3. Un-Met Medical Needs
  4. Earlier approval based on a surrogate endpoint

Standard Review
- 2011.5.18
- 2011.03.01
- 2011.03.18
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 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

- Online Information
- Consultation by Request
  - Taiwan Special Protocol Assessment (T-SPA) 2012.10.12 (Draft)
  - Domestic Innovative Consultation (Early Harvest Lists) 2011.8.2
- Active Consultation
- Industrial Communication Platform
  - Critical Path
  - National Research Program for Biopharmaceuticals (NRPB)

1. Domestic R&D
2. Innovative Invention
3. Major Public Health Contribution
Domestic Innovation Consultation Mechanism: Evaluation Process

- **Contents:**
  1. Product information
  2. Clinical uses

- **Application (Applicants):**
  - **Evaluation (TFDA):**
    - Acceptance criteria:
      - Innovation
      - Contribution
      - Progression
      - Satisfaction to the regulation

- **Is the applicant willing to apply to Critical Path Consultation Program (IDX) in CDE?**

- **Willing to join IDX?**

- **Accepted**

- **Enrolled in Consultation Project**
  - Yes
Future Prospects
Future Prospects

Ensure Drug Quality, Safety and Efficacy

International Harmonization on Medicinal Products Regulations

Promote Taiwanese Brands Globally

Consumer

Government
Thank You for Your Attention

For more information

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