Global Development of Drugs and Co-operation among Asian Economies

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Introduction

The Main Objective of the Pharmaceutical Regulatory Authorities and Good Review Practice is to Protect Public Health.
Why Safety is a Prominent Issue in New Drug Development

- Media’s major interest in accident & risk
  → General public’s demand for absolutely safe drugs.

- Political Environment
  → Opposition party’s competition on pleasing media and the general public.

- Liability
  → Large amount of compensation.
The Consequences of an Absolute Safety Drug

- Increase the request for enormous amount of safety data.
- Increase the cost/time for R&D.
- Increase the time lag for new drug approval.
- Decrease the accessibility of new drugs to patients.
Missions of the Pharmaceutical Regulatory Authorities

- Balance between
  - Public health protection
  - Health industry promotion
- To approve new drugs as soon as possible, without jeopardizing drug safety.
Roles of the Pharmaceutical Regulatory Authorities

Balance between Public Health Protection & Promotion

- **Gate-keeper**
  - Prudent evaluation based on Good Review Practice
  - Drug quality, safety and efficacy

- **Health-promoter**
  - Consultation and “Critical Path Program”
  - Efficient and transparent review process
  - International harmonization
Pharmaceutical Regulatory Scheme

New Drug Review Board

Cosmetics Review Board

Orphan Drug Review Board

BFDA PMF Review

3rd Parties Medical Device GMP Review

TPQRI Oversea Inspection

TDR Drug Injury Relief

BPA Bureau of Pharmaceutical Affairs

CDE IND/NDA/BSE /Medical Device/ Consultation

PDC OTC Review

Drug Injury Relief Review Board

Bulk Pharmaceutical Review Board

OTC (I, II) Review Board
Drugs Innovation Lag

- Retrospective study (1996~2002, n=347)
- Marketing lag after first country approval
  - USA 5.6 months
  - Europe 8.2 months
  - Canada 18.0 months
  - Chinese Taipei 30.5 months
- Drug withdrawals from market
  - US FDA 7 Drugs (1993~1999)
  - Chinese Taipei BPA 1 Drug (1993~1999)
New Drug Marketing Lag

- **Drug Lag Index**
  - from 0 (no drug lag) to 1 (serious drug lag)
  - 0.14 in USA
  - 0.21 in Europe
  - 0.45 in Canada
  - 0.76 in Chinese Taipei
Impetuses for Drug Regulatory System Reform

- Development of pharmaceutical and biotech industry.
- Public health demands for efficient pharmaceutical review and approval.
- Compliance with international norms.
Critical Path

FDA Critical Path Initiatives (since 2004)

Research Support for Product Development

- Basic Research
- Prototype Design or Discovery
- Preclinical Development
- Clinical Development
- FDA Filing/Approval & Launch Preparation

Translational Research

CDE’s Critical Path Project
Increase interactions of new drug development and regulatory agencies

Cf. Critical Path Initiative of FDA

Basic Research → Prototype Design or Discovery → Preclinical Development → Clinical Development

Phase 1 → Phase 2 → Phase 3 → FDA Filing / Approval & Launch Preparation

Candidate to Market

Industry-FDA Interactions During Development

Not fully completed in Chinese Taipei due to budget and regulation limitations

Pre-IND Meeting → Initial IND Submissions → Pre-BLA or NDA Meeting

End of Phase 2 Meeting → End of Phase 2a Meeting → Ongoing Submission

Safety Update → Market Application Submission

IND Review Phase → Application Review Phase
Timeline of the New NDA Process

- **NDA Day 0**
- **Filing Day 20**
- **Review Meeting Day 80**
- **Draft Report Day 100**
- **AC meeting Day 130**
- **Final Report Day 140**
- **BoPA Decision making**

Roles:
- **Sponsor**
- **Advisor**
- **AC+ / AC++ meeting Day 130**
- **Final Report Day 150**
The New NDA Process

- Solved the inconsistency between CDE and AC.
- NDA review is transparency and publicity.
  - Sponsor can online check the review status/progress.
  - Sponsor meeting can be arranged, if needed.
  - Inform sponsor with written letter when reject or more information is required.
  - Finish minutes of AC meeting in 2 working days.
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<th>Paradigm Shift in New Drug Evaluation</th>
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Objectives of Harmonization

- Avoid redundant R&D studies
- More efficient utilization of resources
  - R&D
  - Formats of technical documentation
  - Sharing review reports
  - Sharing ADR information
  - Sharing review experience
- Prompt access of new drugs with guaranteed safety and efficacy.
Regional Harmonization

- APEC (Asia-Pacific Economic Cooperation)
- Japan-Chinese Taipei Joint Seminar, 2005 and 2006
- Asean (Association of South-East Asian Nations)
- GCC (Gulf Cooperation Council)
- PANDRH (PAHO) (Pan America Network of Drug Regulatory Harmonization)
- SADC (Southern African Development Community)
The ICH Approach
since 1990

- To maintain a constructive forum between regulatory authorities and the pharmaceutical industry on technical requirements for product registration in the EU, USA and Japan.
- To monitor and update harmonized technical requirements leading to a greater mutual acceptance of R&D data.
- To facilitate the dissemination and communication of information on harmonized guidelines and their use.
- To ensure a more timely introduction of new medicinal products, and their availability to patients.
The ICH Achievements

- ICH technical guidelines, Q&A and concept papers.
- Global Cooperation Group (GCG): promote mutual understanding, ICH guidelines harmonisation and capacity building.
- The Common Technical Document (CTD): divided into Organization/General; Quality; Safety; Efficacy; Electronic Sections.
- ICH Conferences
The APEC Approach

What is APEC?

- Asia-Pacific Economic Cooperation (APEC), is the premier forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region.
- APEC has 21 member economies.
- APEC accounts for approximately:
  - 40% of the world's population,
  - 56% of world GDP,
  - 48% of world trade.
The APEC Network on Pharmaceutical Regulatory Science Project

(Objectives)

Establish an APEC network for solving common problems and for better mutual understanding on drug regulatory issues.
The APEC Project

History

Chinese Taipei initiated the APEC Project in the 16th APEC ISTWG in March, 1999. The APEC Project was approved in the 17th APEC ISTWG in August, 1999, under the support of Australia, Mexico, Philippines and Singapore.

ISTWG: Industrial Science and Technology Working Group
Hosted an expert working group workshop in 2000.
Hosted a symposium on bridging study joint research project in 2001.
Japan hosted a symposium on bridging study joint research project in 2002.
Hosted a bridging study conference in 2003.
Organized and sponsored the 2005 APEC symposium.
Date: November 14-15, 2005
Venue: Taipei International Convention Center, Taipei, Chinese Taipei
Themes of the APEC 2005 Symposium

- Sharing Review Experience
- Extrinsic Factors of Bridging Study
- Anti-Counterfeiting Drug and Rational Drug Use
- Pharmacovigilance Plan
- Good Review of Combinational Products
Outcomes of the APEC 2005 Symposium

- Thirty-three speakers from ten different countries presented their remarkable opinions.
- There were almost 450 participants from 16 different countries attending this symposium.
- A regulatory meeting, including government officials from Australia, Japan, Korea, Malaysia, Singapore, Chinese Taipei, and USA, is open to all attendee to discuss current regulatory issues.
Chinese Taipei will host the APEC 2007 Symposium in Taipei!
Japan-Taiwan Joint Seminar

- Started in 2005
  - Held in Tokyo
  - Hosted by Japan
- 2nd Joint Seminar in 2006
  - Held in Taipei
  - Hosted by Chinese Taipei
Recent Development of Japan-Chinese Taipei Joint Seminar

- Exchange Reviewers between CDE, Chinese Taipei and PMDA, Japan.
- Relationship between Chinese Taipei’s CDE and Japan’s PMDA changes from recognizing to mutual trust each other.
Vision of Harmonization in the Asian Pacific Region

- A collective evaluate on bridging studies.
- Exchange of regulatory reviews.
- Collaborative on inspections.
- Share post-marketing surveillance.
- Joint reviews of drug applications (IND/NDA/IDE/BLA).
- Mutual recognition of licensing.
Future Perspectives on Pharmaceutical Regulatory Issues

- **Sharing review experience**
  - exchange review reports of IND/NDA/IDE/PMA/BLA
  - ethnic issue study by retrospective data surveillance
  - establish *bridging study* review consensus.
  - joint review for IND

- **Enhance pharmaceutical regulatory networking**
  - joint training program
  - communication and information sharing, e.g. ADR report
  - mutual recognition

- **Establish reviewer exchange program**
Pharmaceutical Evaluation Scheme (PER)

- A mechanism for mutual recognition of partial assessment reports
- Continuous effort through APCE Networking
- Set up GRMPs standards for members
- Exchange assessment reports, CMC/CTD
- Reviewer Exchange Program
- Training program on regulatory issues
Reviewers: qualified teams with good training programs.

Review: pre-specified guidances, regulatory sciences, evidence based, risk/benefit evaluation, review template, consistence and quality control.

Process: transparent, predictable, timely, communicable with meeting minutes and SOPs.
Core Values of the Pharmaceutical Regulatory Authorities

- Safety
- Efficiency
- Quality
- Risk Management
- Health Promotion
- Globalization
MORE International Cooperation
Projects are Welcome!

Welcome to Taipei for the “2007 Symposium on APEC Network of Pharmaceutical Regulatory Science”!
Thank You for Your Attention