Day 3 10:10-10:30

Good Review Practice – Communication

Experiences Sharing on Interagency Communication

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Disclaimer

This presentation was not officially cleared, and the views offered here do not necessarily represent the official positions at MOHW, including TFDA.

Outline

- History of CDE & Building Up of Review Capacity
- Cooperation and communication between CDE and Taiwan FDA

History of CDE & Building Up of Review Capacity

Agencies for Drug Regulation in Taiwan

- **Taiwan Food and Drug Administration (TFDA)**
  - Formerly **Bureau of Pharmaceutical Affairs (BPA)**
  - Subordinate to Ministry of Health & Welfare (MoHW)
  - Official regulatory authority for licensing new drugs
  - Review the administrative documents
- **Taiwan Center for Drug Evaluation (CDE)**
  - A non-governmental organization (NGO)
  - Responsible for review of technical documents

CDE

- An NGO established and founded by Ministry of Health (MoH) in 1998
- Objective:
  (1) to establish in-house review capacity
  (2) to facilitate domestic pharmaceutical development
  (3) international cooperation
- Vision: Regulatory Science, Service for Life
- Major tasks
  Conducted scientific review of cases delegated by BPA

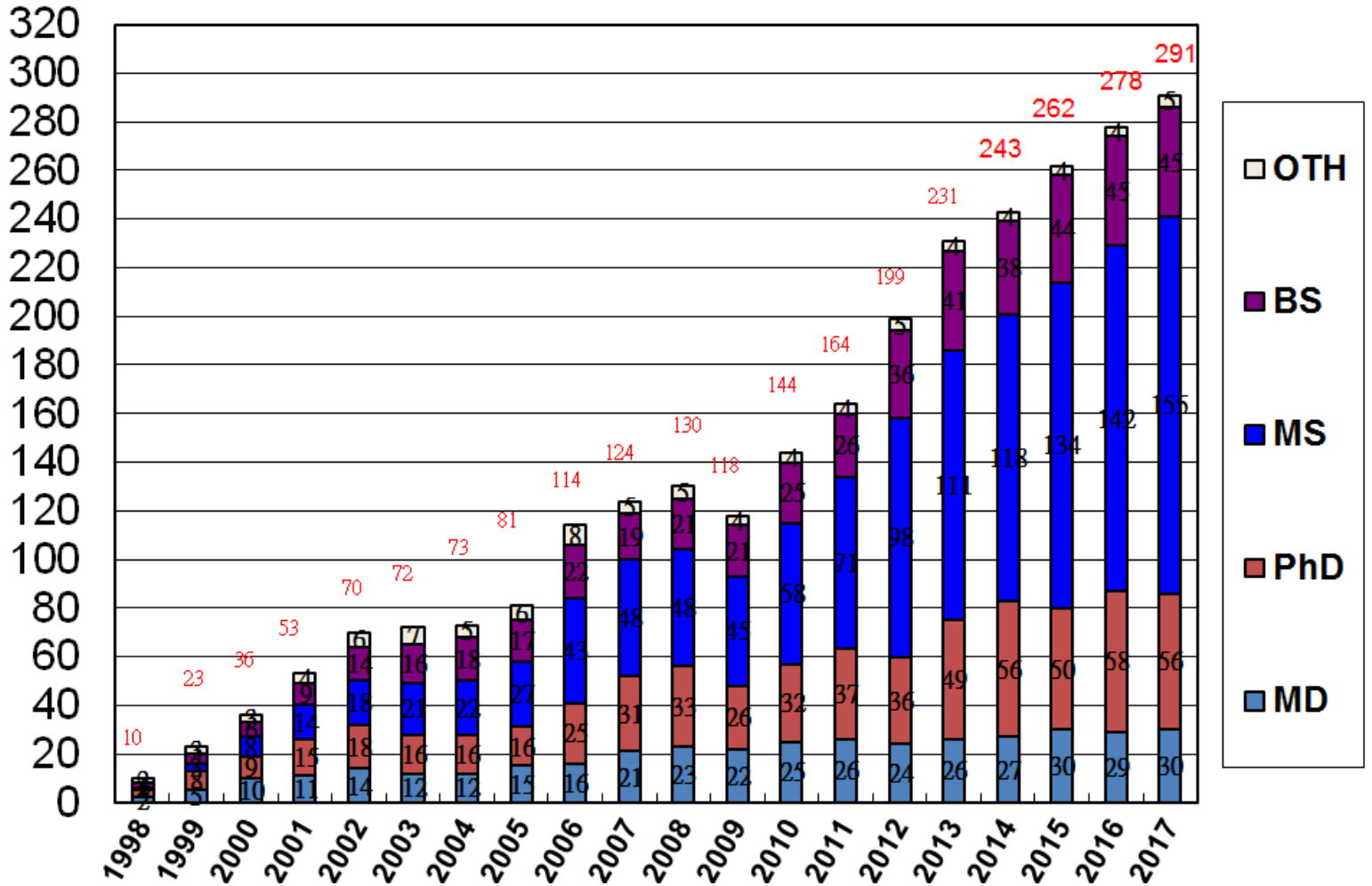
Learning Curve for Drug Review (Categories of NDA increased gradually)

1998	Since ～ 2001	Since ～ 2007	Since ～ 2012
New chemical entity (NCE)	NCE New combination New indication New route of administration	NCE New combination New indication New route of administration New formulation New strength OTC Labelling change	NCE New combination New indication New route of administration New formulation New strength OTC Labelling change ANDA (generic drug) DMF API

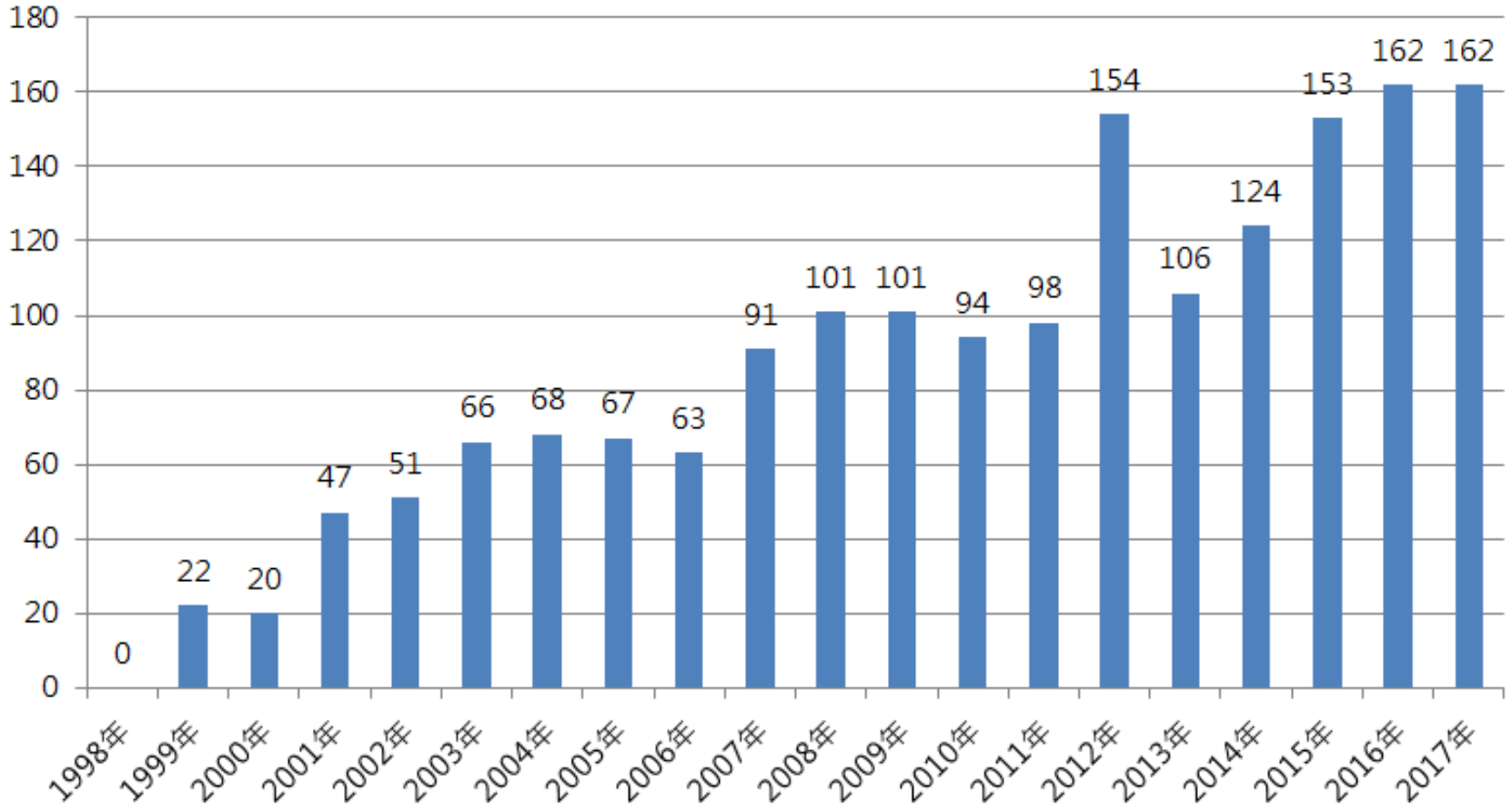
Learning Curve for Drug Review (Reviewers training)

- External expert consultation
- Advisory Committee (AC)
  - Before 2011 each case reviewed by CDE be discussed in AC
- International conferences (to name but a few)
  (1) DIA annual meeting (US, Europe)
  (2) Safety Pharmacology Society Annual Meeting
  (3) International society for cellular therapy annual meeting
  (4) American Society of Clinical Pharmacology & Therapeutics
  (5) The ASA Regulatory-Industry Statistics Workshop
  (6) American Association of Pharmaceutical Scientists Annual meeting

Manpower Increasing



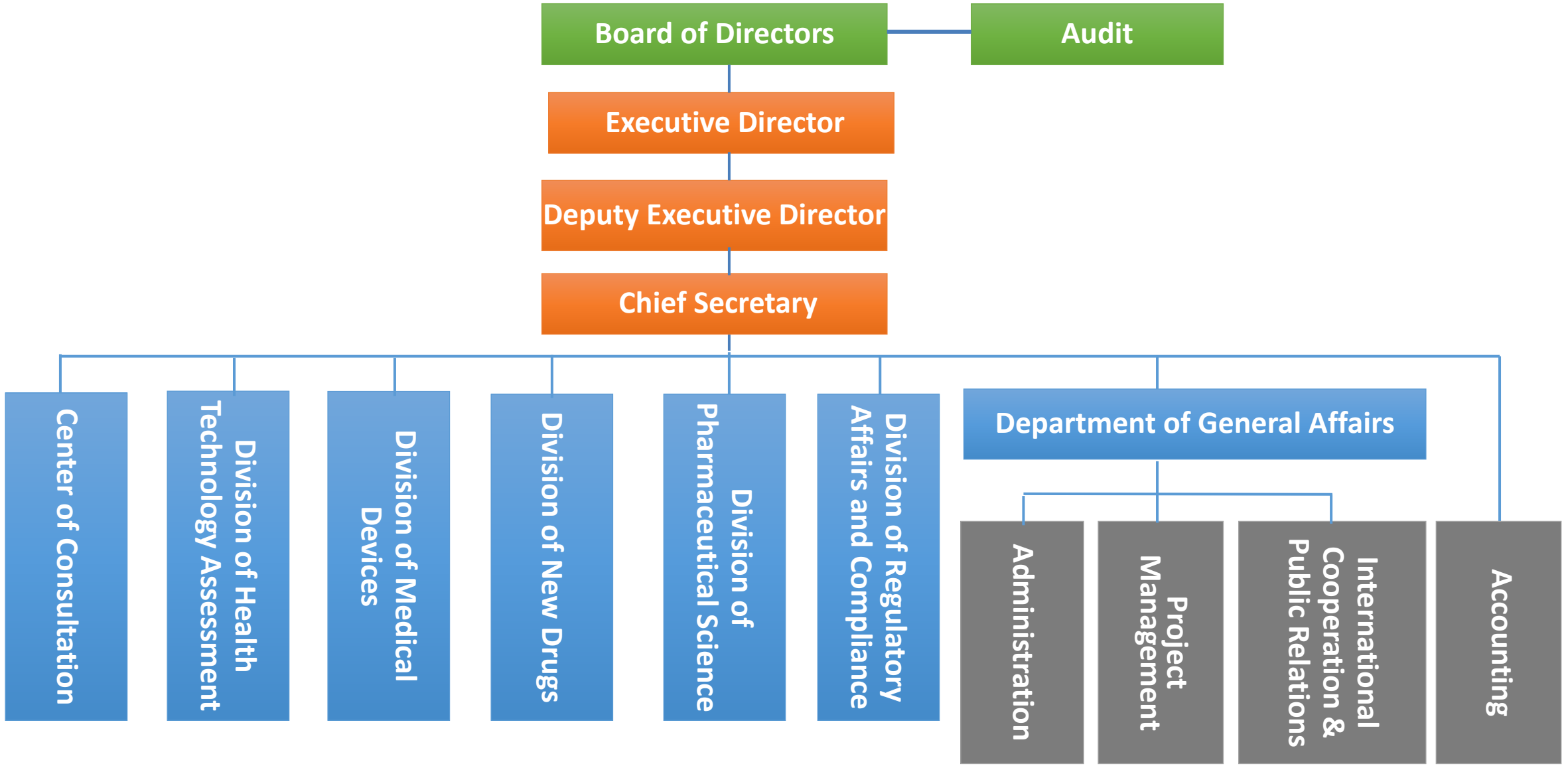
NDA Case Number



International Activities (to name but a few)

- ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)
  (1) Join several Expert Working Group as observers since 2011
  (2) Taiwan became ICH member this year.
- IDGRP (International Generic Drug Regulators Program), now merged to IPRP(International Pharmaceutical Regulatory Program)
- International Workshop on Drug Delivery Systems for Liposome Drug Products (Hold by CDE in 2016, Taipei)
- International Conference on Early Phase Clinical Trial (Hold by CDE in 2016, Taipei)

Center for Drug Evaluation (CDE), Taiwan



Major Tasks of CDE

Drugs	Medical device	Health technology assessment (HTA)	Consultation
NDA BSE (bridging study evaluation) IND (investigatory new drug) ANDA DMF API RMP (risk management plan) OTC	IDE (investigational device exemption) PMA (pre-marketing approval)	HTA cases - served for National Health Insurance Administration (NHIA) HTA projects	General consultation Pay consultation IDX (index case) Guidelines/regulations drafting

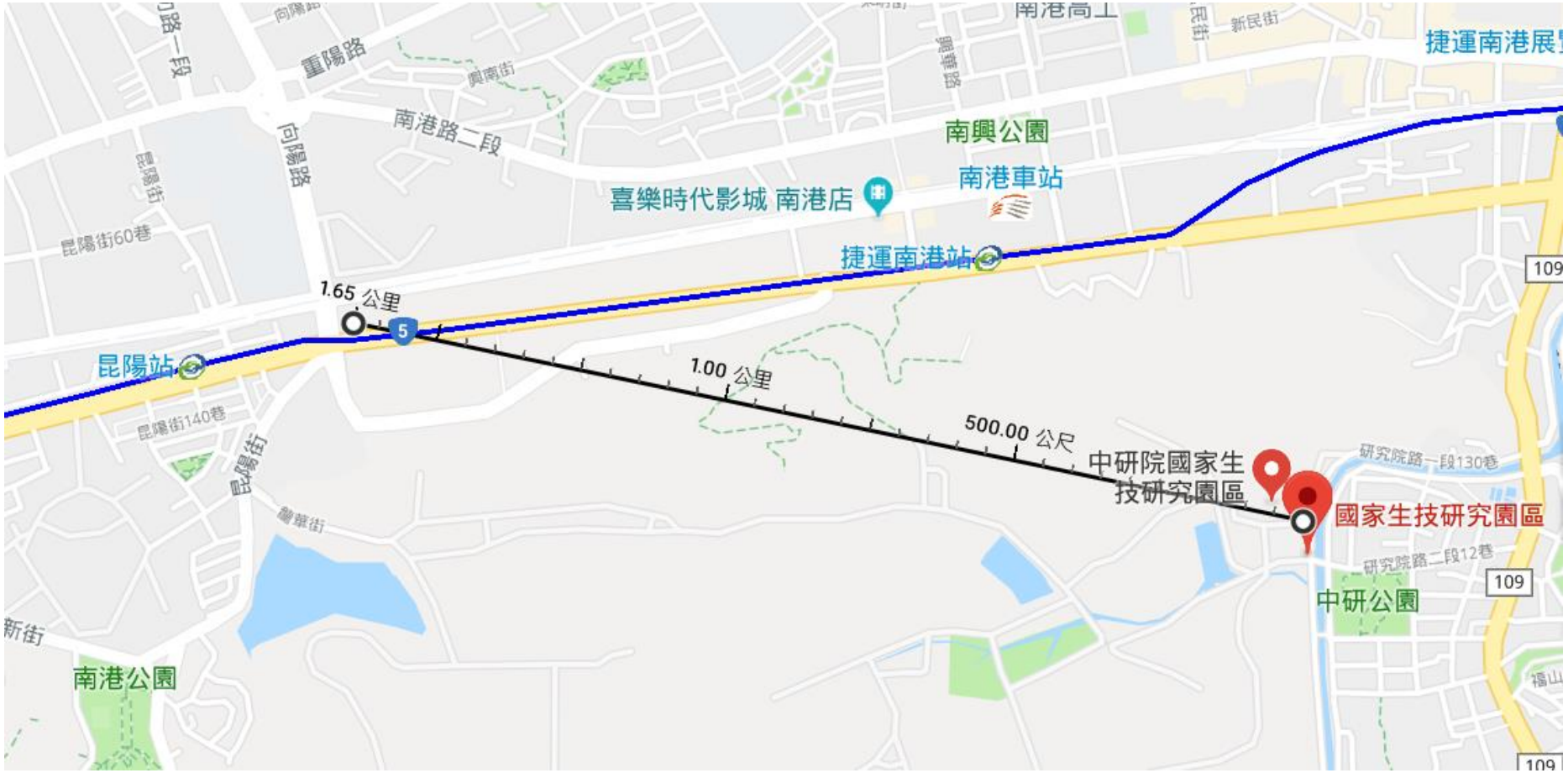
Milestones of New Drug Review in Taiwan

- Before 1998
  External experts and Advisory Committee (AC) → BPA
- 1998 - 2011
  (1) CDE → AC → BPA
  (2) External experts and (AC) → BPA
- After 2011
  (1) CDE → BPA
  (2) CDE → AC → BPA (for complicated cases)

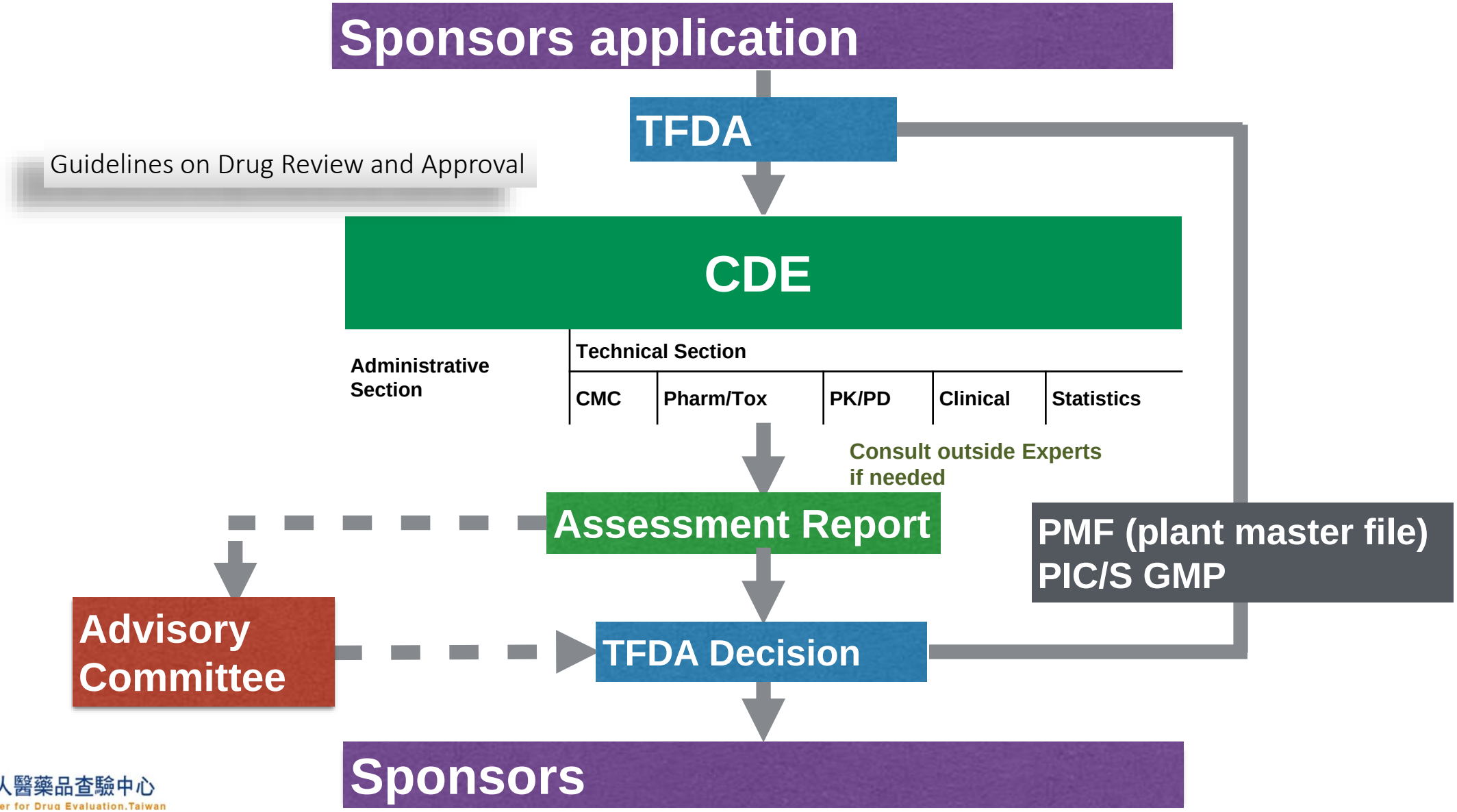
- Due to building up of review capacity and manpower, CDE became a competent regulatory agency. TFDA delegate most of the scientific review tasks to CDE and cooperate with CDE in international activities.

Communication between CDE and Taiwan FDA

Locations of TFDA and CDE



NDA Process


Sponsors application
TFDA
Guidelines on Drug Review and Approval
CDE
Administrative Section
Technical Section
CMC
Pharm/Tox
PK/PD
Clinical
Statistics
Consult outside Experts if needed
Assessment Report
PMF (plant master file)
PIC/S GMP
Advisory Committee
TFDA Decision
Sponsors

How to Communicate Each Other between TFDA & CDE ?

- By telephone ?
- By email ?
- By Fax ?
- By traditional letters ?
- Through teleconference ?
- Through LINE ?
- Through Facebook ?

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The best way is face-to-face dialogue/meeting !

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Integrated Medicinal Product Review Office (iMPRO)

- Established in June 2011
- **A virtual office**
- Objectives: to improve the review efficiency
- Measures
  (1) Integration of manpower (TFDA and CDE)
  (2) Integration of review process (TFDA and CDE)
  (3) Reclassification of cases
- Project managers of CDE involve both technical (CDE) and part of administrative (TFDA) tasks → Simplify the process
- TFDA officers join the review meeting of CDE
- **Monthly QA/QC meeting**

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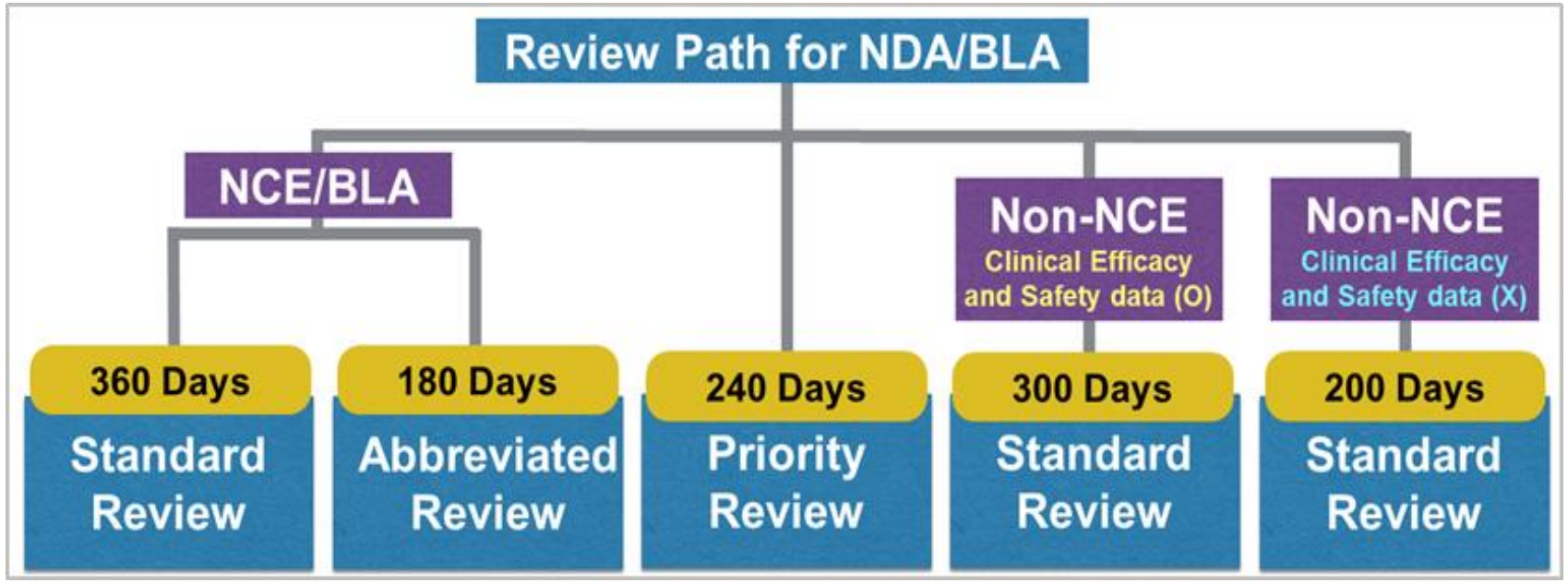
Monthly iMPRO QA/QC meeting

- Meeting members
  (1) TFDA officers of Division of Medicinal Products
  (2) Division directors of CDE
- Major tasks
  (1) **Time management of case review**
  (2) Policy implementation (e.g. RTF)
  (3) Discussion of special cases
  (4) Data analysis (prepared for new announcements)

Review Time Target for NDA (calendar time)



Accelerated approval pathway

Priority review designation

Abbreviated review designation

Thanks for Your Attention