Good Review Practice

Experience Sharing on Communications –Reviewer Specific

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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

- Communication with Applicants
- Communication with External Experts
- Communication with the Public

Communication with Applicants

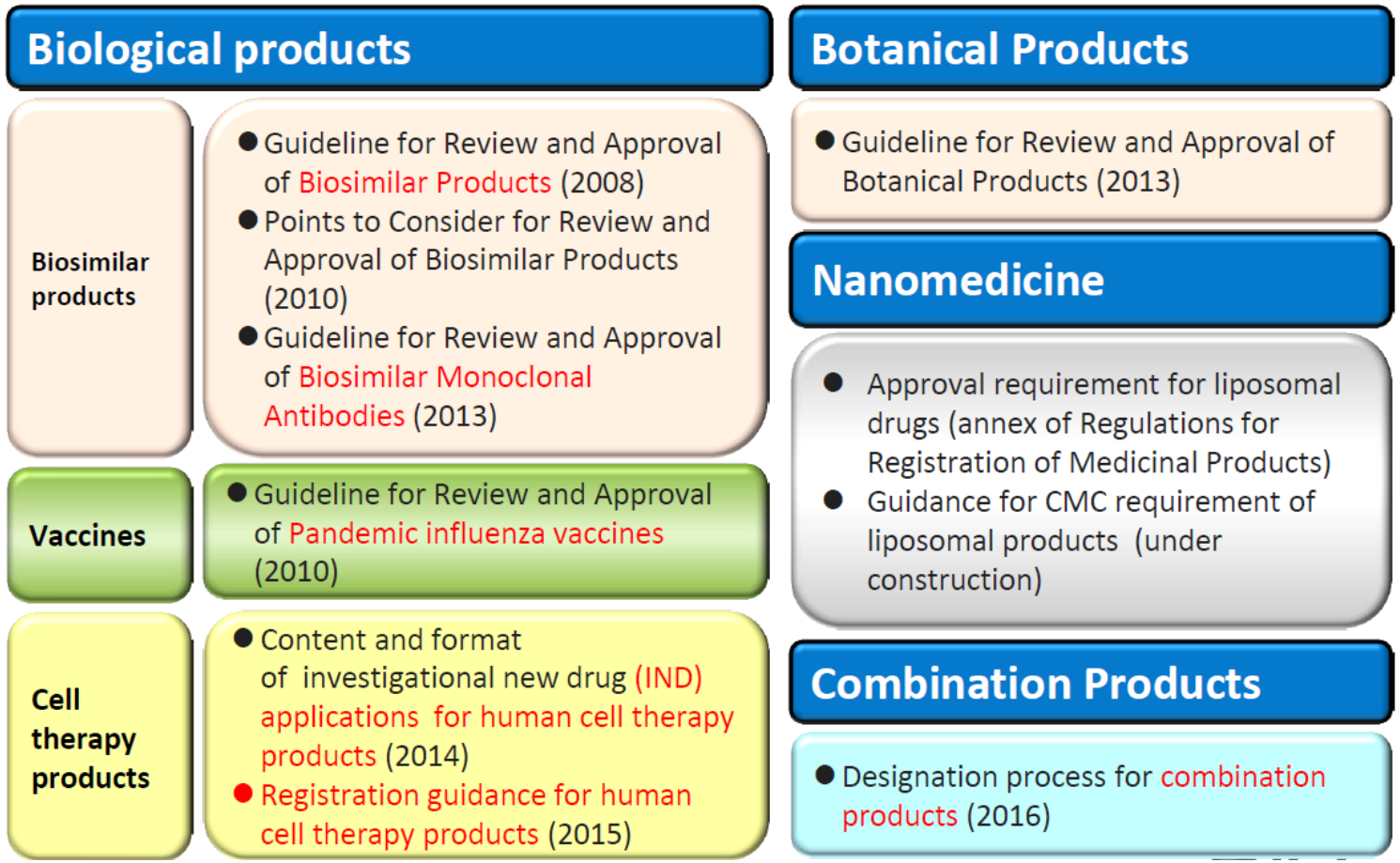
Legislations & Regulations

Law	**Pharmaceutical Affairs Act** Medical Care Act
Regulation	**Regulation for Registration of Medicinal Products** Regulations on Human Trials Regulation on Good Clinical Practice (GCP) Regulation on Good Manufacture Practice (GMP)

Scientific Guidelines (1)

Guidance of Stability Testing of Biological Products
Guidance of Comparability of Biological Products
Guidance for Registration of Vaccines
Guidance for Registration of Pandemic Influenza Vaccines
Guidance for Registration of Blood-related Products
Guidance for Registration of Allergenic Products

Scientific Guidelines (2)



Communication with Applicant for Guidelines

- Conferences (biosimilar, botanic drugs, GCP inspection……etc.)
- Training courses (need to pay)
  (1) Training course of ANDA report writing (CMC/administrative)
  (2) Training course of DMF report writing
  (3) Training course of report writing for dissolution test
  (4) Training course for study design of phase I clinical trial (statistical part)

Good Submission Workshop

- Category:
  NDA, ANDA, GCP inspection, refuse-to file, DMF, API, OTC, generic drug
- A face-to-face workshop between regulators and sponsors
- One category for each workshop
- List major deficiencies regulators experienced
- Measures to improve submission quality

Stakeholders Meetings

- Periodic meetings, 6 times/year
- Participants
  (1) TFDA officers
  (2) Regulators from CDE
  (3) Representatives of industry associations
  (4) Related academia or organizations
- Topics: Recent Announcements and related Q/A
- Topics of recent Stakeholders Meeting (May 23, 2018)
  (1) Breakthrough therapies designation
  (2) Revision of orphan drugs designation
  (3) Risk communication for certain approved drugs

Consultation

- General consultation
- Pay (charged) consultation

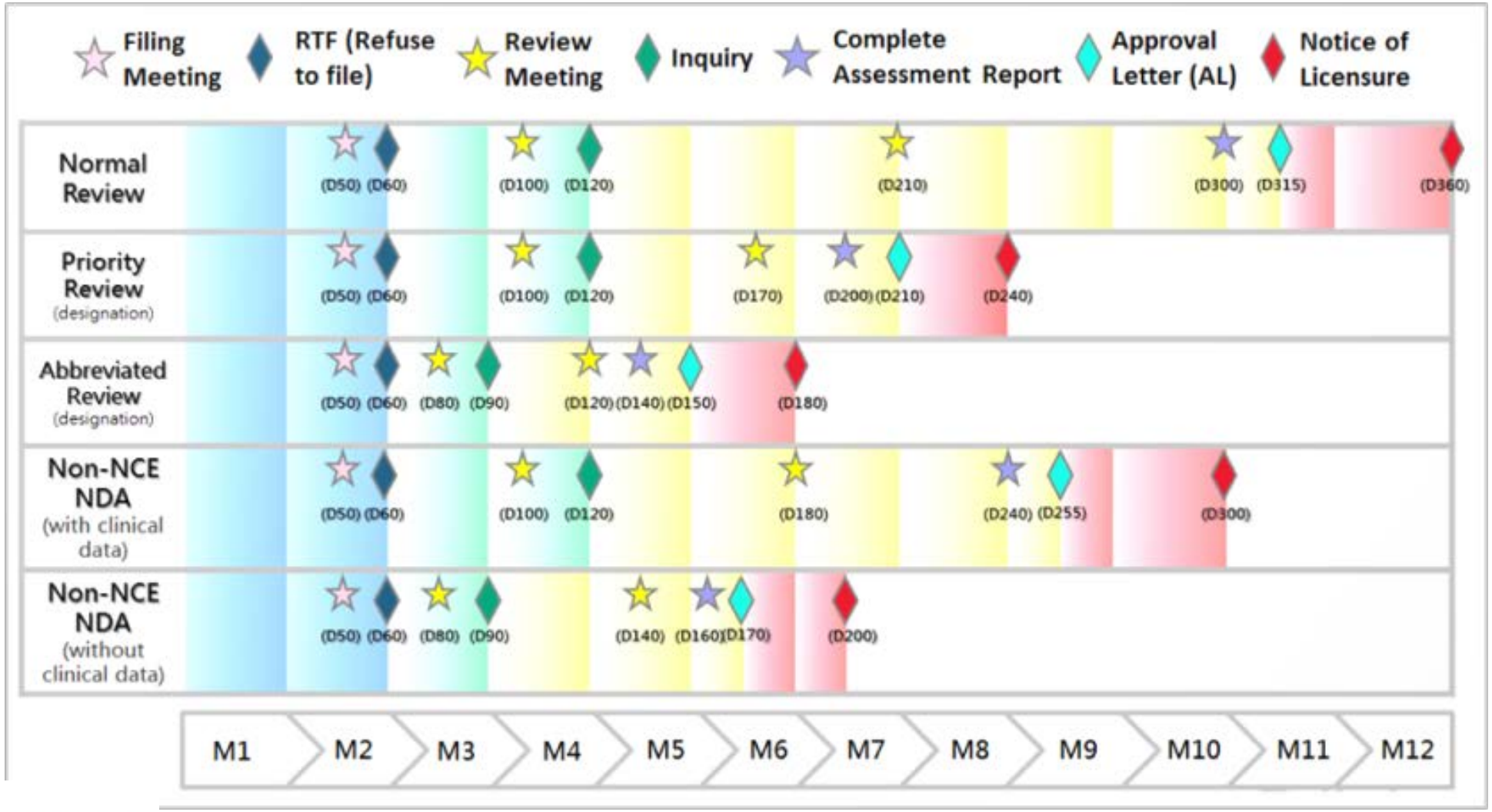
General Consultation

- Consultation for deficiency letter
- Free charge
- Detailed explanation of the deficiencies listed
- Face-to-face meeting as necessary
- Discussion of strategy for appeal/supplementary submission

Pay Consultation

- Consultation before IND submission
  (1) Biologics
  (2) Non-biologics
- Consultation for design of clinical trial
  Phase I, II and III
- Consultation for strategy of submission
  (1) NDA
  (2) BSE (bridging study evaluation)
  (3) BA/BE/dissolution protocol/stability protocol
  (4) Others, e.g. animal rules

Transparency: Status of Case Review



Transparency: Status of Case Review

Communication with Applicants
Refuse-to File (RTF) Procedure as an Example

- Before Announcement:
  Stakeholder meeting on Oct. 6, 2016:
  (1) introduction of the RTF Procedure
  (2) Dossier of NDA submission should be arranged according to CTD format
- Announcement of RTF Procedure on Oct 27, 2016
- After Announcement:
  Another stakeholder meeting on Nov. 16, 2016: discussion/communication for the RTF Procedure
- RTF Procedure effective since Jan. 1, 2017
- After Jan. 1, 2017
  Several stakeholder meetings to discuss/communicate the implementation of RTF Procedure

Communication with External Experts and Public

Consultation to External Experts

- The reviewers may consult external experts as needed, case by case.
- External experts join the review meeting/sponsor meeting for certain cases
- Case discussion with external expert (one-on-one teaching)

Advisory Committee (AC)

- Three major ACs in TFDA
  (1) AC for New drugs
  (2) AC for cell/gene therapy
  (3) AC for OTC drugs
- Conflict of interest will be declared by AC members
- Special (controversial) cases might be discussed in AC
- The sponsor my attend the AC

Communication to Public

- Summary of assessment reports are posted in TFDA website.
- Publications: Regulatory Science Today（當代醫藥法規月刊）
  (1) Monthly journal issued by CDE
  (2) New information/announcements/policies of regulatory sciences
- Annual Report of CDE

Thanks for Your Attention