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Good Review Practice – Communications

- Fundamentals of Communication for Regulatory Authorities and Experience Sharing on Interagency communication

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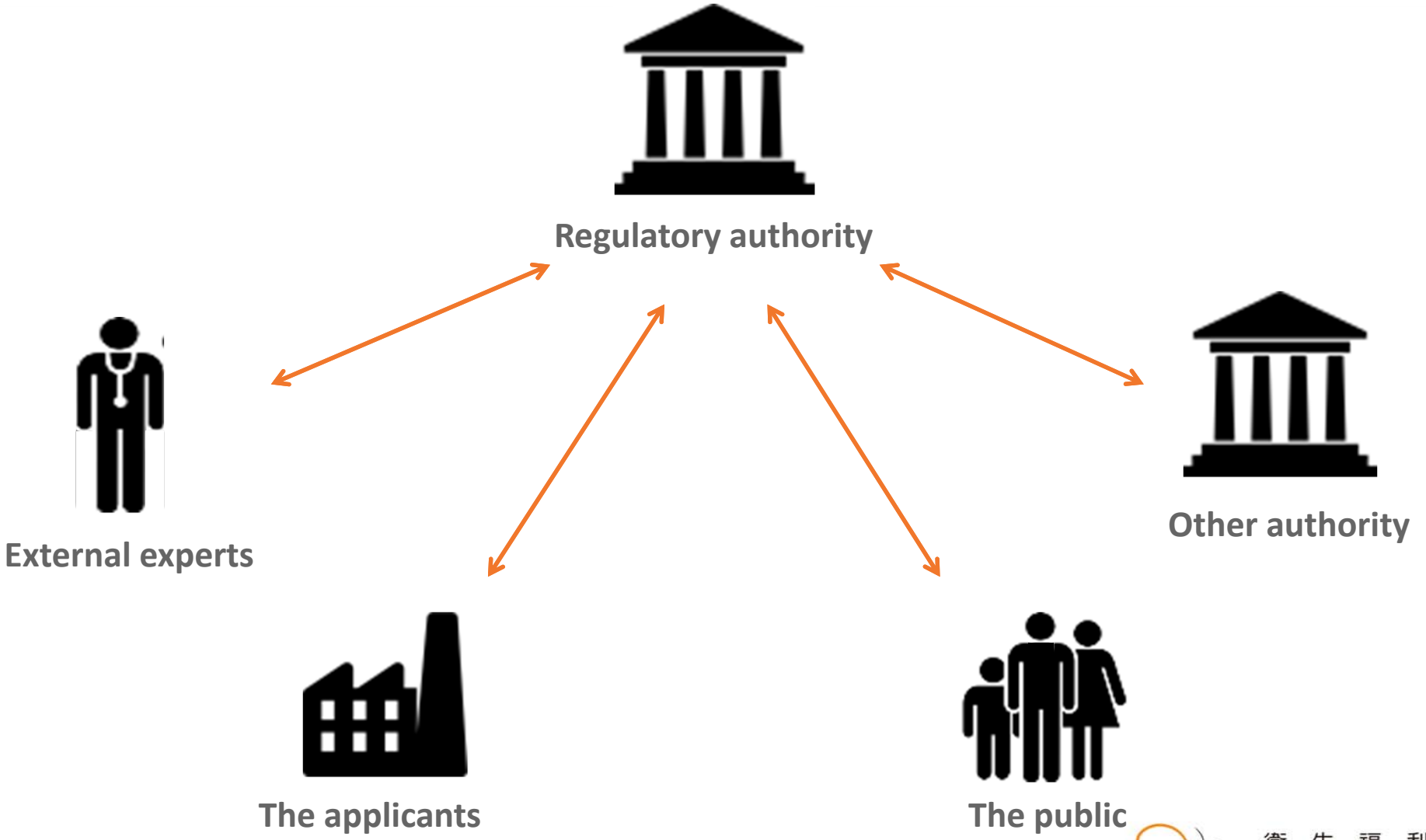
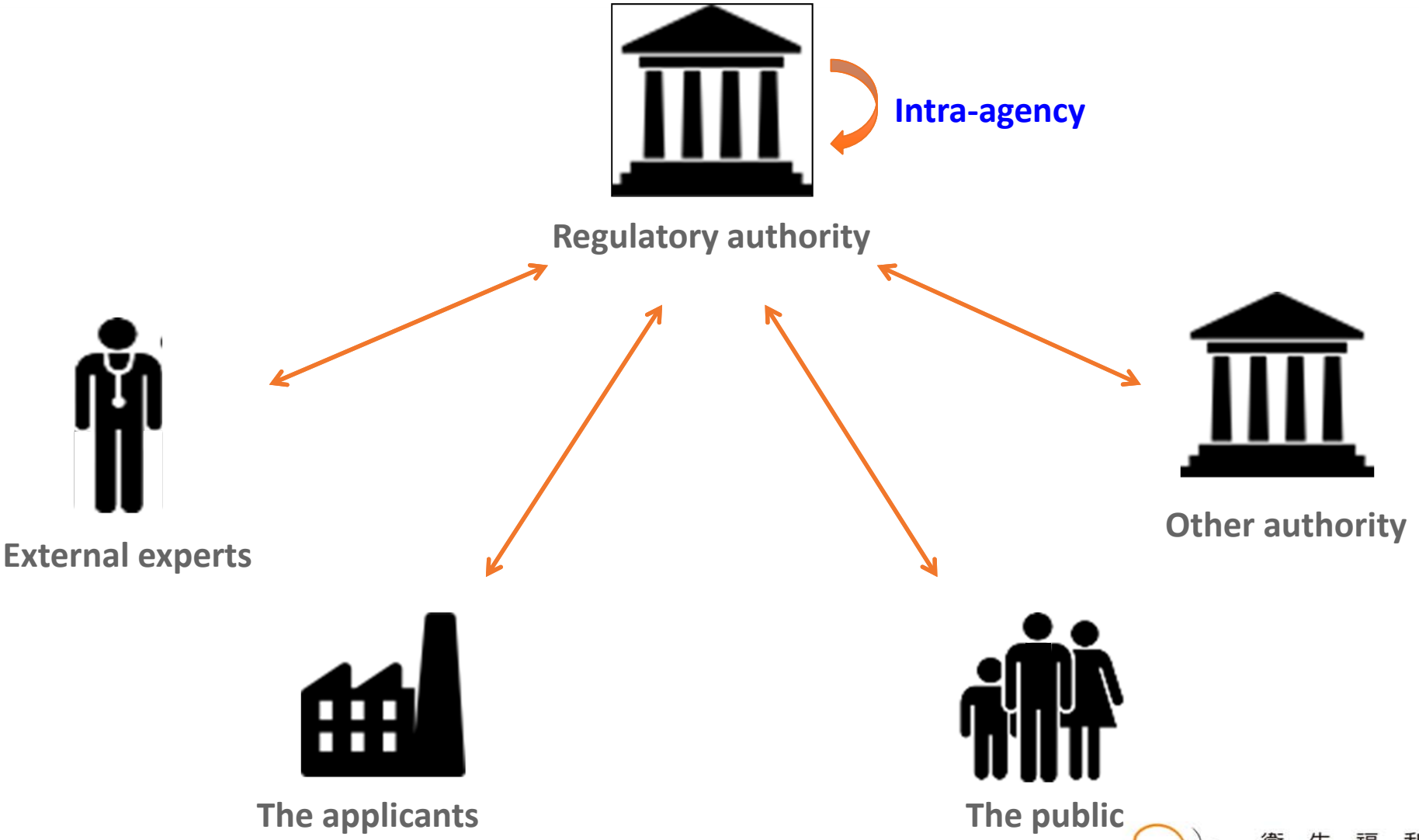
Food and Drug Administration

http://www.fda.gov.tw/

Communications



Communications



Intra-agency communications

- **Improving efficiency by:**
  - Collaboration among scientific reviewers
  - Defining roles and responsibilities
    - Review team members
    - Leadership
  - Transparency
  - Equal voices
- **Open, clear, constructive and timely communications in:**
  - Progress of review, sharing review findings, differing data interpretations, resolution mechanisms, decision makings on actions
- **Establishing format and process of communications**
  - Within agency
  - With external stakeholders (experts, public, RA, applicants, etc.)

Evidence-based review and decision making are critical for accountability !

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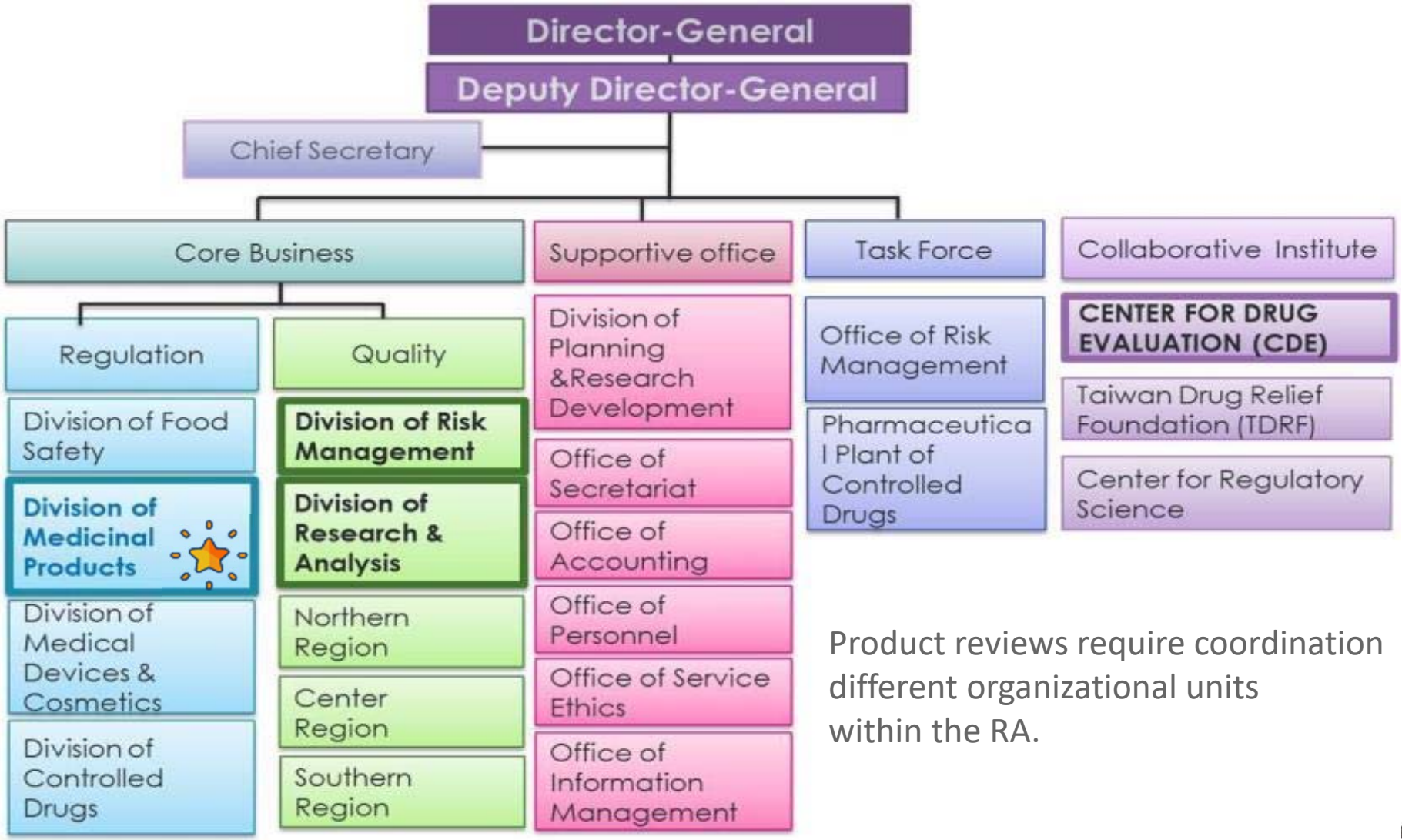
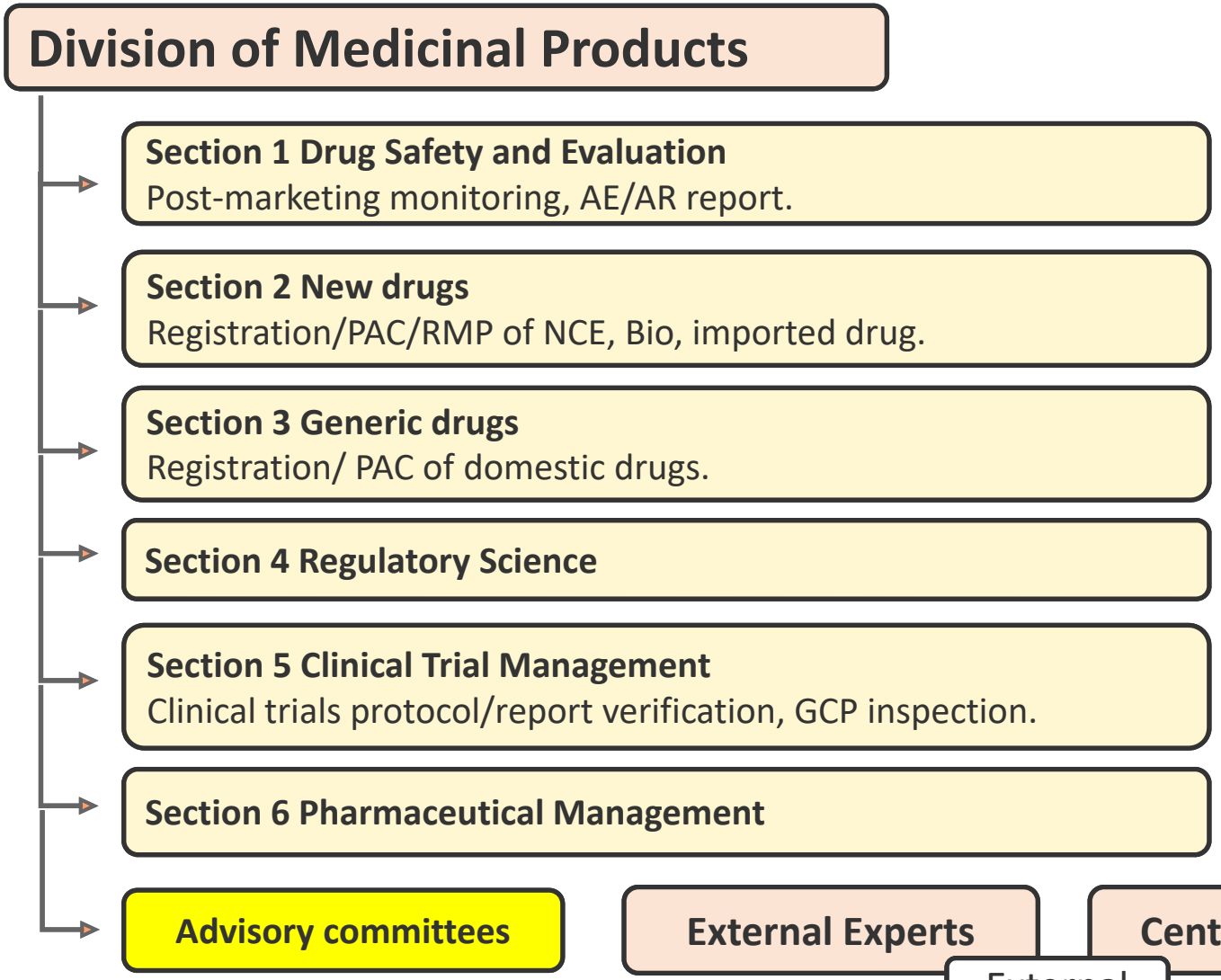
TFDA Organization Chart



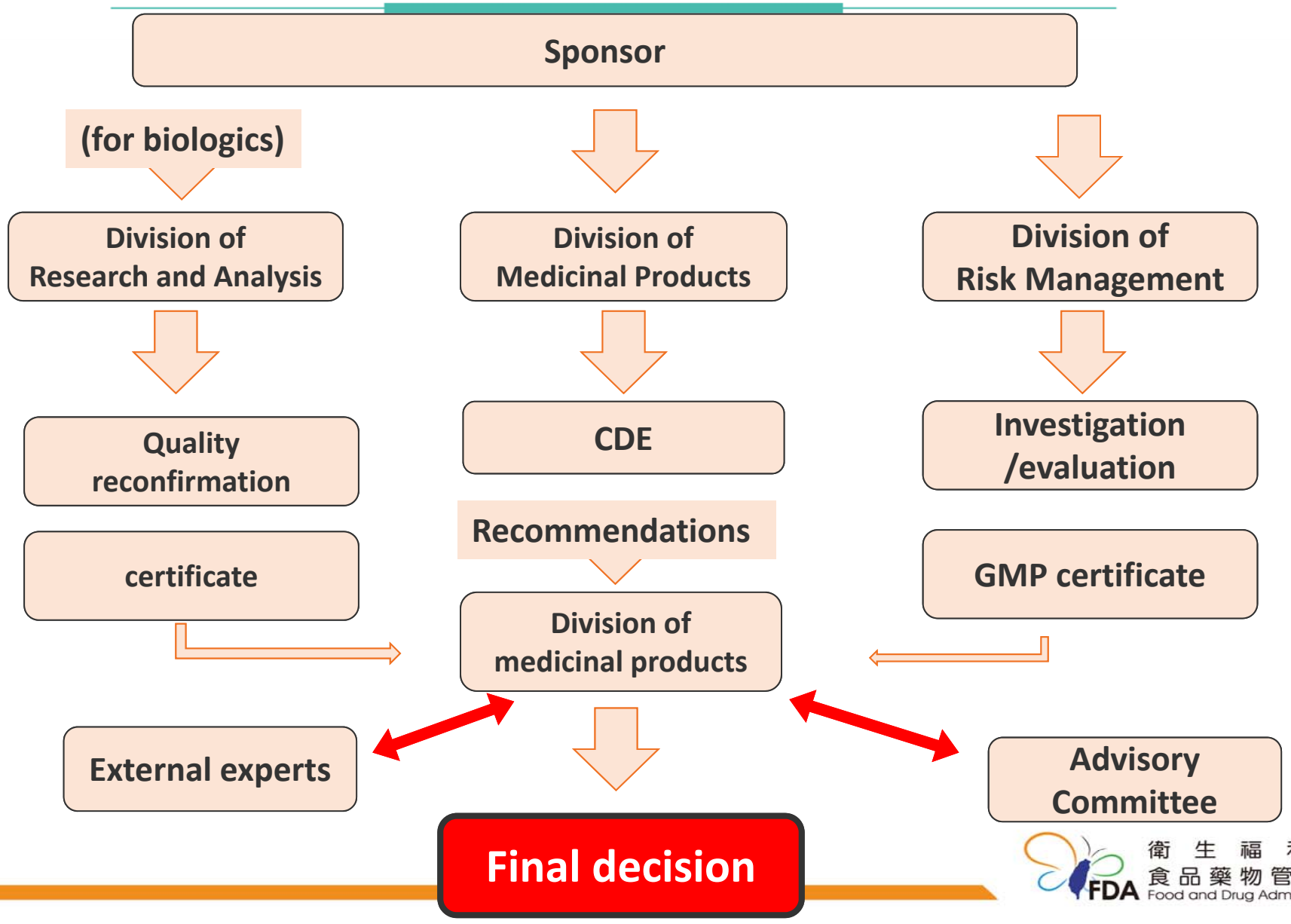
Product reviews require coordination different organizational units within the RA.

Division of Medicinal Products Organization Chart



Product reviews require expertise from different organizational units Within the RA.

TFDA Review Process and Intra-agency Communications



Communications

Regulatory authority

Inter-agency

External experts

Other authority

The applicants

The public

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Inter-agency communication

- Can increase the efficiency and quality of medical product development and review process
- Usually needs an inter-agency agreement in a form of MOU (Memorandum of Understanding), confidentiality arrangements, and consent from the applicants
- Types of communications-
  - Published guidelines, application decisions, available review reports to effectively facilitate the review and decision making
  - Actively pursuing reviews during review, e.g., non-clinical, clinical and inspection findings
  - Joint nation review of applications if possible
- Establishing format and process of communications to comply with nation's laws and inter-agency agreement

Application decision is still up to the Nation

Examples of Interagency Communication with TFDA

Sharing and awareness of information:

- Participation of international or regional harmonization initiatives, such as membership in APEC, ICH, IPRP and PIC/S
- Hosting APEC GRM CoE training events
- Information exchanges with other regulatory authorities
  - Annual joint conference of Taiwan and Japan on Medical Products Regulations
  - Collaboration document over Pharmaceutical regulations with NPRA
  - Workshops featuring experts from other authorities
- Posting regulatory actions
  - Assessment reports for approved NCE
  - Information of domestic and international manufacturers conferred with GMP certificates by Taiwan regulatory authorities

Consideration of review findings:

- New drugs review scheme pilot with PMDA

Communications

Regulatory authority

External experts

With the applicants

Other authority

The applicants

The public

Communication with applicants

- Before and after submissions, and during regulatory review
- Published available guidelines provide insights into RA's current thinking and expectations for better quality submissions and compliance
- Important timelines
  - Product development or pre-IND and IND stage (getting more important)
  - Pre-NDA
  - During NDA reviews
  - Postmarketing requirements
- Establishing format and process of communications
  - Formal meetings, submissions, e.g., face-to-face meeting, teleconference, or written response only (WRO)
  - Preliminary comments, final meeting minutes, and responses
  - Including feedback mechanisms

Nothing is final until all available information has been reviewed

Consultation system in Taiwan

Consultation System

- **Online Information**
- **Consultation by Request**
- **Active Consultation**
  - **Domestic Innovative Consultation** (Early Harvest Lists)
  - **National Research Program for Biopharmaceuticals (NRPB)**
- **Industrial Communication Platform**

Transparency

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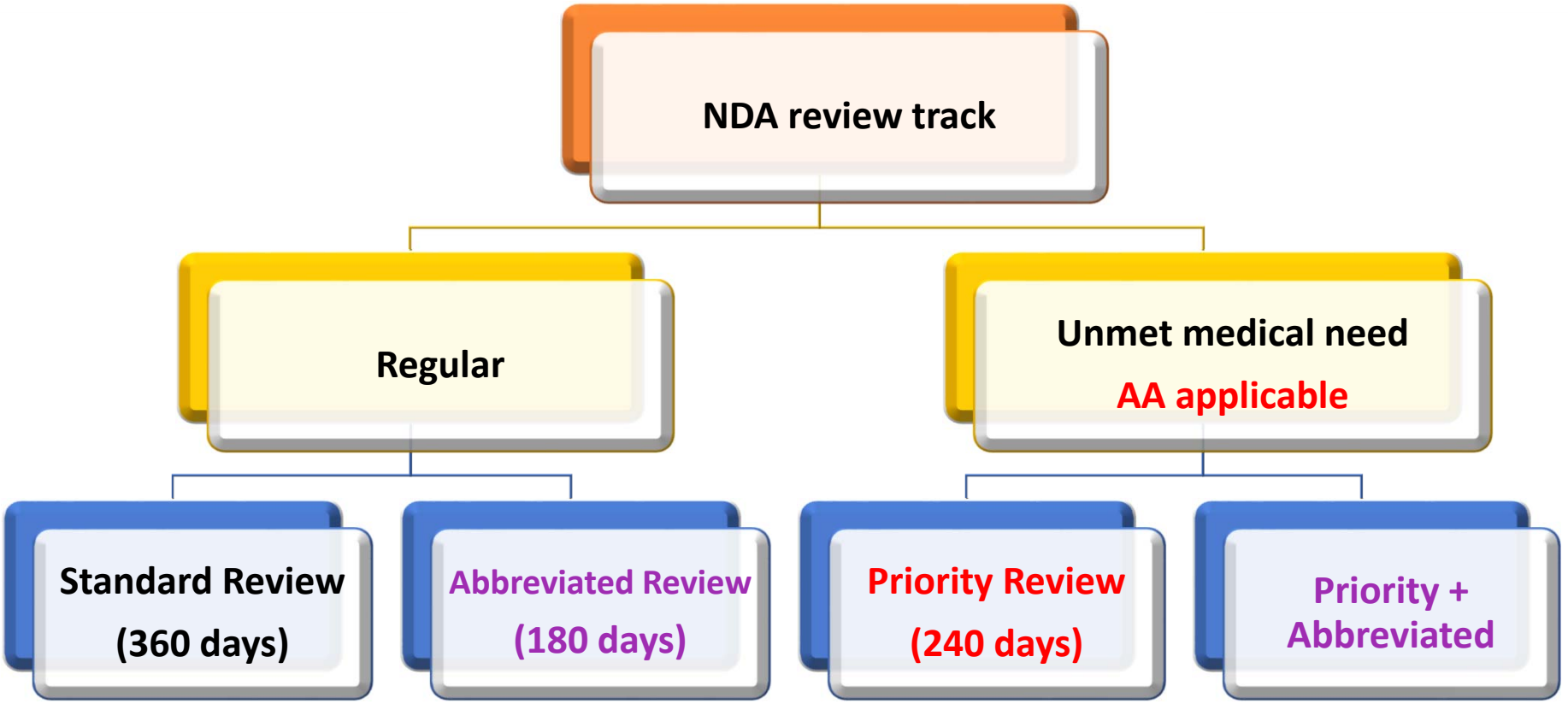
Expedited Programs for NDA



*Abbreviated Review：NCE + US FDA, EMA, MHLW approved (2 in 3)
*AA: Accelerated approval (AA): Surrogate endpoint CT accepted

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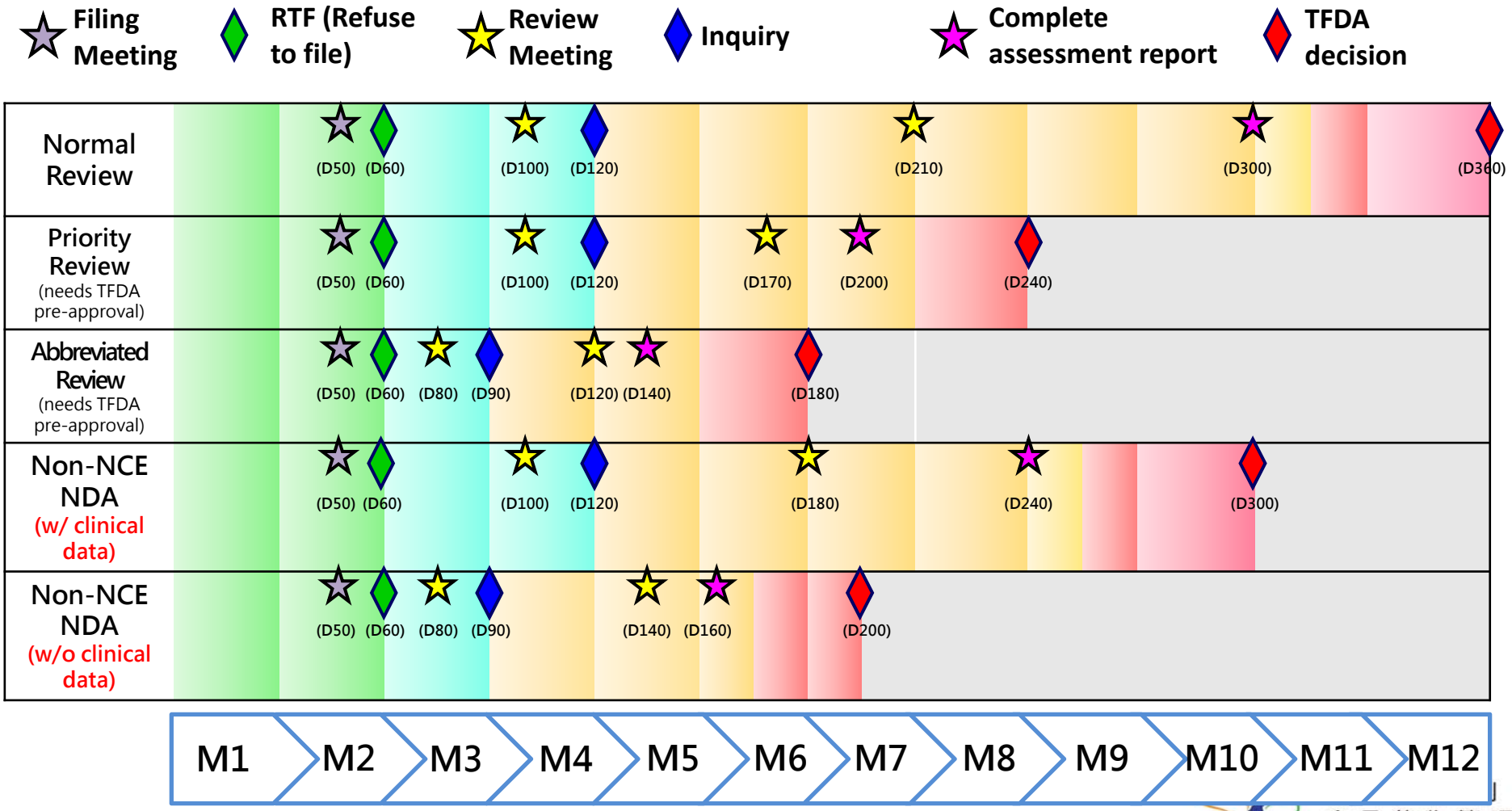
Review Timeline Management

Predictability



Communication between reviewers and sponsors

- Formal pre-submission consultation
- Consultation on development of new drugs (domestic companies only)
- Letters of inquiry
- Sponsor requested meeting
- Over-the-phone information (informal)
- Over-phone discussions (for applications of post-approval variation only)
- Appeals against final decision

Types of Advice- Examples

- Critical advice
  - trial design, dose selection, nonclinical study, manufacturing and facility issues
- Regulatory plans for submission
- Clinical/statistical outcomes and endpoints, trial size, enrichment designs, Pediatrics
- Safety, the overall safety database, concerns related to particular populations, post-approval pharmacovigilance plans, risk evaluation and mitigation strategies, plans for human factors studies, issues related to evaluation of abuse potential
- Clinical pharmacology and pharmacokinetics
- Nonclinical pharmacology, pharmacokinetics, and toxicology
- Product quality, e.g., proposed shelf life and stability studies, delivery systems, GMP

Communications

Regulatory authority

With external experts

External experts

Other authority

The applicants

The public

Communications with external experts

- Academics, patient and medical organizations
- Enhancing the available information for better decision making process
- Timely planning the pursuit of applicable experts
- Establishing format-
  - Advisory panels for public opinions
  - Individual invitation for specific issues
  - Maintaining confidentiality and conflict of interest

Still, the Nation has the final decision based on all available information

Communications

Regulatory authority

External experts

With the public

Other authority

The applicants

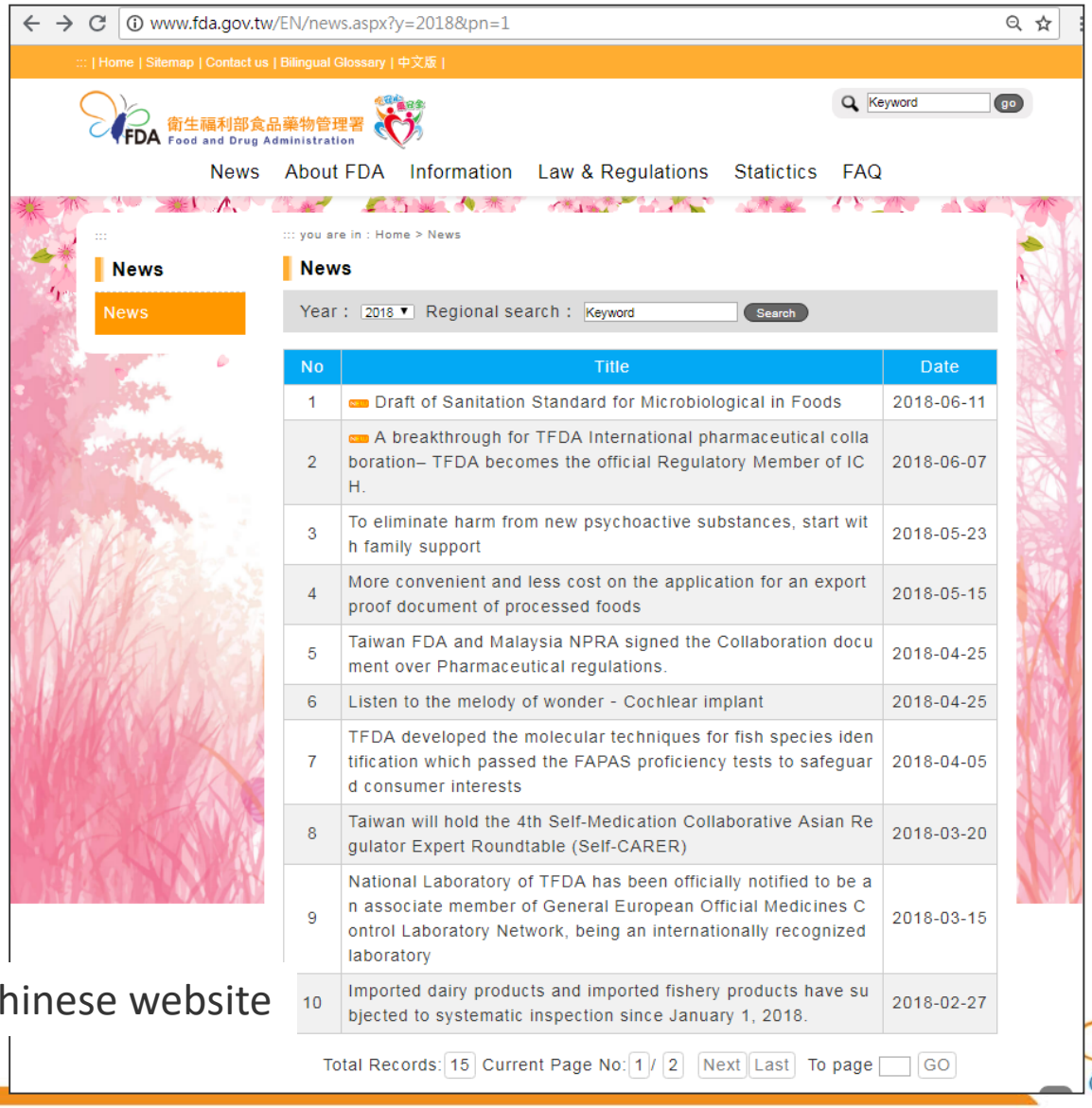
The public

Communications with the public

- Policies and procedures for guidelines, decision-makings, reviews, and accomplishments for public access
- Mechanisms for public input
  - Website postings requesting for input, surveys, public meetings, workshops, advisory boards, medical organizations, etc.
  - For product development, regulatory review, and postmarketing risk management strategies
- Clear messages avoiding public panicking

Many factors affecting RA's ability to develop, disseminate, and oversee effective product communications in an evidence-based manner

Information for the public in Taiwan



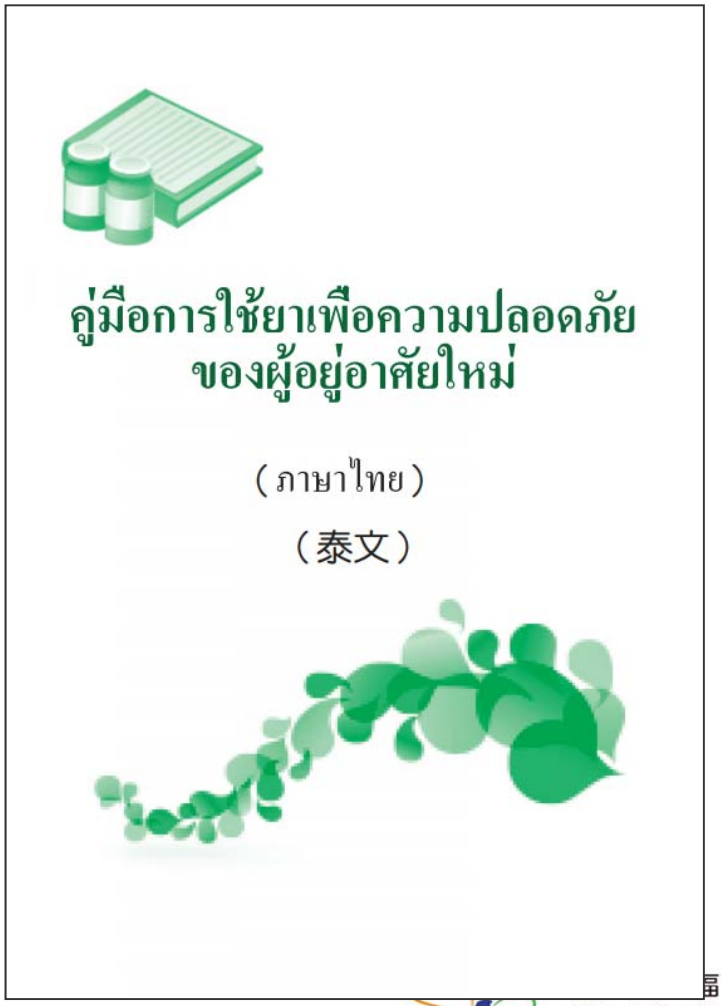
More information in Chinese website

Publications for the public in Taiwan

Food & Drug Consumer Newsletter (weekly)

Medication Safety Handbook for New Immigrants

(with Thai, Cambodian, bahasa Indonesia, Vietnamese versions)



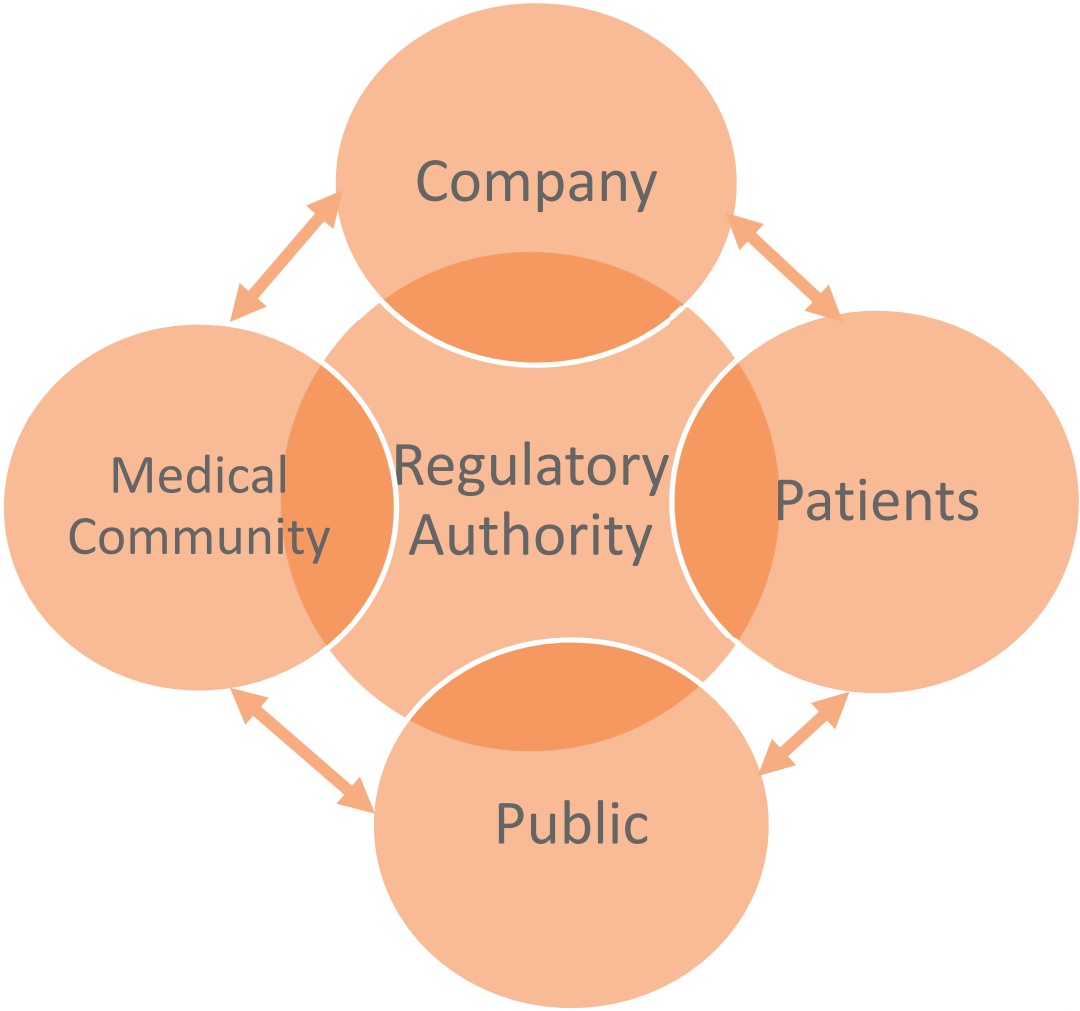
Considerations In Issuing a Communication to the Public

- When and what to issue the communication, including if the issue has been communicated before

– Strength of the evidence

- Issuing party
- Target audience(s)
- Key messages to communicate- quality, risk/potential risk, requesting input?
- Is the communication related to a regulatory action?
- *Are there communications to HCPs and patients that is consistent with medical practice without unintended or unanticipated consequences?*

Dynamics of Communication



Challenges in Communications

- The science and transparency of decision making process, especially when uncertainties of evidence occur
- How to manage communication in media channels?
- Nation's unique culture
- Moving forward- also need to seek ways to
  - measure the effectiveness
  - understand the audiences, e.g., nations, partner organizations, languages, and uncertainty in messages

More development on the best practice of communications may be needed

Potential Topics for Discussions

- What are the current communication practices in your institution?
- Have you reached the goal of good communication in your institution? What are the gaps?
- What is your planned solution to address the gaps in communication?
- How do you assess the impact of improved communication?

Thank you for your attention !

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