Regulatory Updates of OTC Drugs in Taiwan

Hui-Ping Chang
Section Chief
Section of Generic Drugs
Division of Medicinal Products
Outline

- Drug classification in Taiwan
- OTC expansion
  - Expansion of monograph
  - Rx switch to OTC
  - Co-existence of Rx and OTC
- OTC package labeling
  - Package format
  - QR code adoption
- Future perspectives
Drug Classification

Covered by NHI

OTC

General Sale

Factory

Wholesaler or Distributor

Pharmacy

Consumers or Patients

Retail Outlet

Self-Paid
Distribution Chart of Drug License by Category

- OTC Drugs: 29%
- General Sale Drugs: 2%
- Prescription Drugs: 69%

Total number of drug licenses (excluding the API) ~22,000

Not including Chinese Medicine, Foods in tablet or capsule form (e.g. vitamin products), Cosmetics
Milestones of Non-Prescription Regulation

- Pharmaceutical Affairs Act 1970
- Pharmaceutical Affairs Act Enforcement Rules 1975
- Regulations for Registration of Medicinal Products 1975
- OTC Monograph (10 groups) 1996
- Online sales for general sale drugs 2015
- Labeling Revision (Colloquial) 2016
- OTC Monograph (16 groups) 2018
- OTC Monograph (18 groups) 2019
Taiwan Non-Prescription Market

- Taiwan non-prescription market has turnover of around 443 million US dollars per year. Part of the non-prescription drugs were imported from Japan, Europe, US, and other developed countries. Some famous Japanese pharmacies like Tomod’s and Matsumoto Kiyoshi have entered the market since 2012 and 2019. Until Sep. 2019, there had been 46 stores in total.

- Some famous pharmacies in Taiwan are Watsons and Cosmed. Until Sep. 2019, there were 988 stores in total.
OTC Expansion
Expansion of Monograph: 18 Groups

(Announced in Aug. 2019)

Antipyretic and Analgesic
Cold Remedy
Antitussive and Expectorant
Ophthalmologic
Anti-allergy
Dermatological—others

Antibiotic and disinfectant
Antipruritic and anti-inflammatory
Anti-Acne
Diaper rash
Dry skin

Gastrointestinal
Motion sickness
Anthelmintic
Laxative
Anti-fungal

Topical hemorrhoids
Nasal drug
# Requirement of Registration

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>NDA</th>
<th>Generics</th>
<th>OTC Monograph Drug Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Drug</td>
<td>Not required</td>
<td>Required</td>
<td>Compiled with Monograph</td>
</tr>
<tr>
<td>Safety Efficacy</td>
<td>• Pharm/Tox</td>
<td>Bioequivalence (BE)</td>
<td>Not required</td>
</tr>
<tr>
<td></td>
<td>• PK/PD/BA/BE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality</td>
<td>• Chemistry, Manufacturing and Controls (CMC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PIC/S GMP</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• GLP, GCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>Labeling (direction of use)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DMF Exemption

(Announced on May 9, 2018)

• According to the Regulations for Registration of Medicinal Products, technical documents of active pharmaceutical ingredients (Drug Master File, DMF) are required.

• Announcement dated May 9, 2018:
  • OTC products which are not new ingredients or under pharmacovigilance
  • API source complied with GMP
  • DMF documents could be surrogated by an outline of synthesis route / manufacturing process, testing specifications, methods and results of active ingredients
Rx Switch to OTC

(Announced on Nov. 16, 2017)

• To encourage Rx switch to OTC, TFDA announced a checklist of Rx switch to OTC application

• Documents for submission:
  • Application form
  • Drug safety profile, clinical literature, or contents in pharmacopoeia of A10 countries
  • Draft of packaging inserts
  • Education plan for pharmacists

Please download from:
Review Process of Rx Switch to OTC

1. Sponsor's Application
2. Received by TFDA
3. TFDA Review Team
   - Administrative documents
   - Technical documents
4. Assessment Report
5. Final Decision in TFDA
6. Sponsor

Advisory Committee (AC)

Review time: 180 days (Not including 2-month inquiry)
Co-Existence of Rx and OTC
(Announced on Sep. 19, 2019)

PURPOSE: For encouraging manufacturers to develop new market, and further expanding the choices of OTC products.

- **BEFORE**
  - A license holder is not allowed to have drug licenses of same API with same dosage and same dosage form.

- **AFTER**
  - A license holder is allowed to have drug licenses of same API with same dosage form and same dosage but one in Rx and one in OTC category.
  - Licenses can be differentiated by name, indication, administration and packing amount.

---

Freepik from flaticon.com
OTC Package Labeling
Consumer Feedback on OTC Labeling

Before change

• Listening to the Patients
  – The need of clear instruction and warning

• Concerns
  – Comprehensibility: read & understand
  – Misuse

United Format of Package Labeling
(Announced on March 8, 2016)
4-Year Program of United OTC Labeling

- Aim to complete standardization within 4 years (2016~2019)
  - Advertisement products
  - Cold Remedy, Antitussive and Expectorant,
    Gastrointestinal products
  - Dermatological products
  - All the rest products unless specified

![4-year plan chart showing percentages for 2016, 2017, 2018, and 2019]
United Format of Package Insert

(Announced on March 8, 2016)

【Ingredients】
Active Ingredients and Contents
Inactive ingredients (excipients)

【Uses (Indications)】

【Precautions】
✓ Do not use if...
✓ Seek for doctor diagnosis and treatment before use if...
✓ Consult a doctor/pharmacist before use if...
✓ Other precautions

【Usage & Dosage】

【Warnings】
✓ Stop using and consult a doctor or pharmacist with this instruction if the following symptoms occur (shown in tables)
✓ Stop using and receive doctor diagnosis and treatment if the following symptoms occur

【Package】

Begin with the Must-Know Before-Use information

Directions of taking medicines

Follow with What-to-Do when uncomfortable symptoms occur after taking the medicine
United Format of Package

iOS: Voiceover
Android: Talkback

QR code
Easy to read by using a smart phone scanning

Key information:
Name of the product, use (indications), usage & dosage, dosage form and shape, consultation phone number
Communication with Stakeholders

- Communication with **visually impaired groups**
  - QR code instead of Braille
  - Pure text instead of website link
    - Scan anytime without internet

- Communication with **manufacturers and consumers**
  - Cities and rural areas
  - Senior people and caretakers
  - Surveys of before and after-changed
Co-Existence of multiple OTC Packages

(Announced on Sep. 11, 2019)

PURPOSE: Responding to and stimulating a volatile OTC market, under the premise of same drug quality.

- **BEFORE**
  - A product is allowed to have one kind of package in the market.

- **AFTER**
  - At most 5 kinds of packages (prior approval) in the market.
    - Approved version should be uploaded to TFDA website
    - Each flavor or color can also have 5 kinds of packages at most.
Future Perspectives:
Regulatory trend toward a more friendly environment for self-medication
Future Perspectives
(Quadruple-Win Scenario)

- Be responsible for self-care & self-medication
- Provide high quality service to the public
- Approve a wider range of safe and effective self-medication products
- Develop and invest in self-medication products