Regulation of Boundary Products in Taiwan

Shirley Pan

Section of Generic Drugs
Division of Medicinal Products
Taiwan Profile

- Population: 23.4 million
- Area: about 36,000 sq.km. (14,400 sq. m.)
- Capital: Taipei City
- 99.8% citizen covered by NHI
  - A single payer national health insurance system
- Pharmaceutical market:
  - US$ 5.6 billion in 2016
  - Aging population
Nonprescription Products are Tools

Modified from WSMI publication
Better regulation of nonprescription medicines
Ministry of Health and Welfare (MOHW)
Organization Chart

Headquarter

Department of Planning
- Department of Social Insurance
- Department of Social Assistance and Social Work
- Department of Protective Services
- Department of Nursing and Health Care
- Department of Medical Affairs
- Department of Mental and Oral Health
- Department of Chinese Medicine and Pharmacy

Department of Secretarial Affairs
- Department of Personnel
- Department of Civil Service Ethics
- Department of Accounting
- Department of Statistics
- Department of Information Management

Legal Affairs Committee
- Hospital and Social Welfare Organizations Administration Commission
- National Health Insurance Committee
- National Health Insurance Dispute Mediation Committee
- Health & Welfare Workers Training Center
- Office of International Cooperation
- National Pension Supervisory Committee

Organization
- Social and Family Affairs Administration
- Centers for Disease Control
- Food and Drug Administration
- Health Promotion Administration
- National Health Insurance Administration

Institution
- affiliated Hospitals
- Social welfare Institution
- National Research Institute of Chinese Medicine
Life Cycle Management of Medicinal Products

New Drug Discovery
- Consultation

Preclinical Testing
- GLP/GTP

IND
- GCP
- IRB
- SUSAR Reporting
- Insurance
- GRevP

NDA

Pre-Market Approvals

Marketing
- ADR Reporting
  - GPvP
  - GDP
  - GPP
  - Drug Injure Relief

Post-Market Management

ICH – Based Regulations

PIC/S GMP

REMS/RMP
Classification and Retail Distribution

Factory

Wholesaler or Distributor

OTC

Pharmacy

Retail outlet

Consumers or Patients

"FDA"
Distribution Chart of Drug Licenses

The total number of drug licenses (including the API) ~25,000

- Prescription Drugs 67%
- General Sale Drugs 1%
- Pharmacy Drugs 32%

Total number of foods in tablet or capsule form (including vitamin products) ~10,000
Classification of Capsule and Tablet Products

- Considerations
  - Ingredients and Contents
  - Dosage and Usage
  - Intended use

Listed in Pharmacopoeia or the official National Formularies?

- N
  - Can affect the body structure and physiological functions?
    - N
      - Food
    - Y
      - Drug

- Y
  - Drug
### Determination Criteria for Vitamins in Tablet or Capsule Form

<table>
<thead>
<tr>
<th>items</th>
<th>Upper limit in daily dosage</th>
<th>Dietary Reference Intake 150%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vit. A</td>
<td>10000 I.U. (3000 μg)</td>
<td>1050 μg</td>
</tr>
<tr>
<td>Vit. B&lt;sub&gt;1&lt;/sub&gt;</td>
<td>50 mg</td>
<td>1.95 mg</td>
</tr>
<tr>
<td>Vit. B&lt;sub&gt;2&lt;/sub&gt;</td>
<td>100 mg</td>
<td>2.25 mg</td>
</tr>
<tr>
<td>Vit. B&lt;sub&gt;6&lt;/sub&gt;</td>
<td>80 mg</td>
<td>2.1 mg</td>
</tr>
<tr>
<td>Vit. B&lt;sub&gt;12&lt;/sub&gt;</td>
<td>1000 μg</td>
<td>3.6 μg</td>
</tr>
<tr>
<td>Vit. C</td>
<td>1000 mg</td>
<td>150 mg</td>
</tr>
<tr>
<td>Vit. D</td>
<td>800 I.U. (20 μg)</td>
<td>15 μg</td>
</tr>
<tr>
<td>Vit. E</td>
<td>400 I.U. (268 mg)</td>
<td>18 mg</td>
</tr>
<tr>
<td>Vit. K</td>
<td>500 μg</td>
<td>140 μg</td>
</tr>
<tr>
<td>Nicotinic Acid</td>
<td>100 mg</td>
<td>25.5 mg</td>
</tr>
<tr>
<td>Folate</td>
<td>800 μg</td>
<td>600 μg</td>
</tr>
</tbody>
</table>
### Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>Pharmaceutical Affair Act</td>
</tr>
<tr>
<td>1973</td>
<td>Pharmaceutical Affair Act Enforcement Rules</td>
</tr>
<tr>
<td>1975</td>
<td>Regulations for Registration of Medicinal Products</td>
</tr>
<tr>
<td>1995</td>
<td>OTC program working group</td>
</tr>
<tr>
<td>1996</td>
<td>OTC monograph</td>
</tr>
<tr>
<td>1999</td>
<td>OTC Expert advisory committee</td>
</tr>
</tbody>
</table>

![Diagram showing various committees and their milestones](image-url)
For drugs commonly used to alleviate mild symptoms, monographs with active ingredients and dosage range were developed.

Manufacturers can design formulas within the scope of the monograph, and not be subject to the limitations of the reference drugs.

It’s easy to follow standard usage, precautions, warnings and labeling, to provide people with convenience and safety.
OTC Medicines Registration

Does it belong to any of the 10 categories in the OTC monographs?

- **YES**
  - Determine if it complies with the measures in the OTC monograph
- **NO**
  - Check if identical to any registered drug in ingredient/dosage form/indication/usage (Generics)

If identical, comply with:
1. Reference drug is not required
2. Quality portion evaluated by similar standard as generics
3. Labeling has to follow directions in the monograph

If not identical, comply with:
1. Reference drug is required
2. Quality part evaluated by the identical standard as generics
3. Indications has to be the same as registered products

New Drugs

Provide complete dossier for new drug registration

Expert committee if necessary
# Dossier Requirement

<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, PK/PD/BA/BE, Clinical trials</td>
<td>Bioequivalence (BE) as a surrogate to clinical trial</td>
<td>BE may be required in some cases</td>
</tr>
<tr>
<td>Quality</td>
<td>Chemistry, Manufacturing and Controls (CMC), PIC/S GMP, 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>
Labeling Revision

**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

**Directions**

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

**Package**

Consumer Language

- Begin with the **Must-Know Before-Use** information
- Follow with the **Direction**
- Follow with **What-to-Do** when uncomfortable symptoms occur after taking the medicine
Package Revision

~QR Code

Easy to read by using a smart phone scanning

Name of the product, use (indications), usage & dosage, dosage form and shape, consultation phone
# Regulations for Different Categories

<table>
<thead>
<tr>
<th></th>
<th>Prescription Drugs</th>
<th>Pharmacy Drugs</th>
<th>General Sale Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>License required</strong></td>
<td>v</td>
<td>v</td>
<td>v</td>
</tr>
<tr>
<td>Pre-approval</td>
<td>v</td>
<td>v</td>
<td>v</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital/Clinical</td>
<td>v</td>
<td>v</td>
<td>v</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>v</td>
<td>v</td>
<td>v</td>
</tr>
<tr>
<td>General distribution</td>
<td>x</td>
<td>x</td>
<td>v</td>
</tr>
<tr>
<td>Internet</td>
<td>x</td>
<td>x</td>
<td>v</td>
</tr>
<tr>
<td><strong>Advertisement</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-approval</td>
<td>v</td>
<td>v</td>
<td>v</td>
</tr>
<tr>
<td>Mass media</td>
<td>x</td>
<td>v</td>
<td>v</td>
</tr>
</tbody>
</table>
Perspectives

Health Authority

1. recognize the positive role in self-medications
2. encourage competition between companies

Industry

1. develop and invest in self-medication products
2. support public health objectives

Healthcare Provider

1. provide high quality service to the public
2. encourage the responsible self-care & self-medication
The 4th Self-CARER Annual Meeting

Date: March 20 – 22, 2018
Venue: National Taiwan University Hospital (NTUH) International Convention Center, Taipei (to be confirmed)

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Thank You for Your Attention!

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