Regulatory Updates for Medical Products in Taiwan

藥求安全　食在安心

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

Outline

- Mission, Vision and Core value
- Life cycle management of medical products
- Regulatory updates of medical products in Taiwan
  - Enhancing accessibility of medical products
  - Enhancing supply chain integrity of medical products
  - Creating a friendly and informative environment
- Future

Mission, Vision and Core Value

Quality and Safety of Food and Medical products
(藥求安全 食在安心)

Safe Food

Safe medical products

To safeguard national health
To lead the nation to a new era
of food and drug management

- **Profession (專業)**
- **Service (服務)**
- **Quality (品質)**
- **Innovation (創新)**

Life Cycle Management of Medical Products

Pre-Market Approval/ Control

- Product Designation
- GLP/GTP
- GCP
- Registration (Approval/ Listing)
- General/Case Consultation
- IRB
- SUSAR Reporting
- Insurance
- ICH –Based Regulations
- MD Advisory Committee

Post-Market Management / Control

- ADR & Product Defect Reporting
- GPvP/ GVP
- GDP
- GPP
- Drug injury relief

- Manufacturer's Quality System Audit (GMP)-MD
- PICS/GMP-Drugs
- RMP

MDs ：Medical Devices
GLP ：Good Laboratory Practice
GTP ：Good Tissue Practice
GCP：Good Clinical Practice
IRB： Institutional Review Board
GMP：Good Manufacturing Practice
ADR：Adverse Drug/Device Reaction
GVP：Good Vigilance Practice
SUSAR: Suspected Unexpected Serious Adverse Reactions
GRevP: Good Review Practice
GPvP：Good Pharmacovigilance Practices
GPP：Good Pharmacy Practice
RMP: Risk management plan

Regulatory Updates of Medical Products in Taiwan

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Whole life cycle Management

Post-Market Management

Enhancing Accessibility of Medical Products

- Enhancing review efficiency
- Announcing guidance/ standards
- Ensuring sufficiency in medicinal products

Enhancing Supply Chain Integrity of Medical Products

- Increasing traceability
- Implementing Good Distribution practice (GDP)

Creating a friendly and informative environment

- Labeling and revision for OTC drugs

Enhancing Accessibility of Medical Products

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Enhancing review efficiency

Announcing guideline/guidance/ standards

Ensuring sufficiency in medicinal products

Enhancing review efficiency

Pre-clinical → clinical → Marketing approval

Consultation and Rolling Review

- Revising “Review process and Timeline” 【10/27】
- Amending “Review time for non-NCE NDA“
- Announcing “Refuse-to–File” (new) 【10/27】
- Trying-out “Pre-NDA meeting”
- Drafting “Checkpoints for all types of NDAs”
- Applying “On-line approval application for Class 1 MD”
- Simplifying application mechanism for certain announced MDs
- Announcing “application of Class III MDs should follow EP/STED format”
- Revising “MD classification”

Quality、Efficiency、Consistency、Transparency、Clarity、Predictability

Announcing guideline/guidance/ standards

- **Guidance**【2016】
  - OTC drugs 【10/26】
  - Stability test【 3/11】
  - Combination product 【 1/21】
- **Rules** 【2016】
  - Abridged review mechanism (revision) 【 08/18】
  - Format for labeling and package of OTC drugs 【 3/8】
  - Checklist for the application of ICF amendment 【 5/11】
  - Checklist of technical document for approval application of generic drugs 【 4/13】
  - Process and review timeline for medical products 【 10/27】
- **Law** 【2016】
  - Data exclusivity and patent linkage in PAA (draft 8/4)

- **Pre-clinical Testing Guidance**
  - **Medical devices with drug (Hyaluronic Acid Dermal Implant, coronary angioplasty balloon catheters, Wound Dressing) 【1/18】**
  - **Electrosurgical Devices for General Surgery 【2/3】**
- **Clinical Trial**
  - Medical Device Good Clinical Practice"(GCP)【2015/10/16】
- **Guidance**
  - **16 technical guidances for IVDs (since 2015) , such as**
    - Human leukocyte antigen molecular typing system 【5/13】
    - Herpes simplex virus serological reagents 【 5/13】
    - Household glucose test system 【 5/13】
  - Good Submission Practice (GSP)
  - Medical Software Classification
  - Nano-Medical Devices Identification
- **Principles for Household Medical Devices Compiling Chinese Instructions【 6/24】**
- **Postmarket management**
  - **Unique Device Identification (UDI) System Practice", with Annex I & Annex II【2015/10/30】**
  - **Selling MDs via internet 【2016】**
  - Regulations for Medicament Recall【2015/8/5】
  - Medical Device Good Distribution Practice" (GDP) 【2015/6/18】
  - **Pilot Program for Medical Institutions on the Medical Device Adverse Event Reporting and Evaluation by volunteered hospitals**

Establishing the Act for the Management of Medical Devices

Establishing the Act for the Management of Medical Devices with international harmonization and of domestic needs

2016

Promoting the legislative process of the Act for the Management of Medical Devices

Proposing policy statement and communicating with The Legislative Yuan and the industry to reduce the impact of legislation

2015

Drafting the Act for the Management of Medical Devices

Completing the draft of the Act for the Management of Medical Devices and the supporting measures.

16 policy meetings, 2 expert meetings and 4 public explanation sessions were held to achieve consensus.

2014

Setting the framework of the Act for the Management of Medical Devices

Analyzing the international legislation regarding the management for medical devices.

Evaluating the impact to the industry

5 public explanation sessions and 6 expert meetings were held.

Drug shortage events are increasing

Potential causes of drug-shortage

- Marketing reason (NHI pricing、pricing of API and materials)
- GMP regulation (global issues)

Recent cases of drug-shortage (2016)
Oxytocin Injection
Calcium gluconate Injection
Potassium phosphate Injection
Quinax Eye Drops
Prednisolone Ophthalmic Solution

Shortage on cataract eye drops?!

2016/09/19 14:49 黃益源 報導 / 台北市

市面上有不少眼藥水可延緩白內障惡化，其中以「快納史」眼藥水市佔率7～9成最進口該藥的廠商接獲原廠通知，上周開始，國內已暫停供藥且將停產。醫師憂心，

Ensuring sufficiency in medicinal products

☐product with license ~ essential drugs

prevention

Pharmaceutical Affairs Act (PAA) §27-2【 new-2015】

- List of essential drugs in accordance with PAA §27-2【 draft-8/24】

Reporting and evaluation

- Event reporting
- Evaluation for possible substitution

action

- Dispatching
- Special permit in manufacturing and importation for essential drugs

Pharmaceutical Affairs Act (PAA) §27-2 (new)

- **Government:**
  - ✓ establishing on-line reporting platform.
  - ✓ Announcing essential drug list and regulations.
- **Stakeholders:**
  - ✓ For announced **essential drugs**, stakeholders should notify the authority **6 months ahead** for possible supply inadequacy due to manufacturing, importation or others issues.

Ensuring sufficiency in medicinal products

☐products without licenses ~ under special circumstances

Pharmaceutical Affairs Act (PAA) §48-2 (new)	Pharmaceutical Affairs Act (PAA) §55	Rare Disease Control and Orphan Drug Act §19, §22
● Specified Products, for : ✓ life-threatening diseases or major disability ✓ emergent public health events (Emergency Use Authorization)	● Samples and Gifts of Medicaments, for : (2003)(1973) ✓ For research and technical improvement ✓ For clinical trial ✓ For patient use ✓ For exhibition and education ✓ for public health	● Un-licensed products, when: ✓ License holders are not able to provide the drug ✓ The price is obviously unreasonable
HOW: Guidance		
➢ Regulation of manufacturing and importing on specified medical products 【09/08】	➢ Regulations Governing Management of Samples and Gifts of Medicaments 【 2003 】 【 1973 】	➢ Regulation of manufacturing and importing on orphan drugs 【2000-08-09 】

Enhancing Drug supply chain integrity

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Increasing traceability

Implementing Good Distribution practice (GDP)

Increasing traceability is the public demand

Pharmaceutical Affairs Act (PAA) §6-1 (new)

- **Government:**
  - ✓ **Announcing drug items to be traced and reported**
  - ✓ **establishing e-reporting system**
- **Stakeholders: establishing traceability system and e-reporting**

flow information, from manufacturing, importing, and exporting

Dealers and license holders

Drug information (name, lot, shelf life….)

➢ **Regulations for establishing traceability 【 9/6】**

Documentation Retention period (5yrs)

inspection

➢ **Items to be traced and reported in accordance with PAA §6-1 【draft, 10/28】**

- **Plasma derivatives**
- **Vaccines**
- **Botox**

Implementing Good Distribution Practice (GDP)

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Manufacture

- **GMP**
  Good Manufacturing Practices

Storage、Transportation

- **GDP**
  Good Distribution Practices

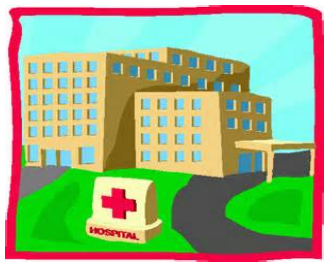
Hospital、Pharmacy to Patients

- **GDP**
  Good Dispensing Practices

Ensuring the quality and package integrity during the manufacturing, storage and transportation.





Quality Assurance

Implementation Schedule of GDP in Taiwan

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Announcement of " Guide to Good Distribution Practice for Medicinal Products" 【2015-7-16】

Wholesale Distribution

Drug Manufacturer

From July 1, 2016, all new manufacturers, logistics companies and product license applicators shall comply

Drug Dealers

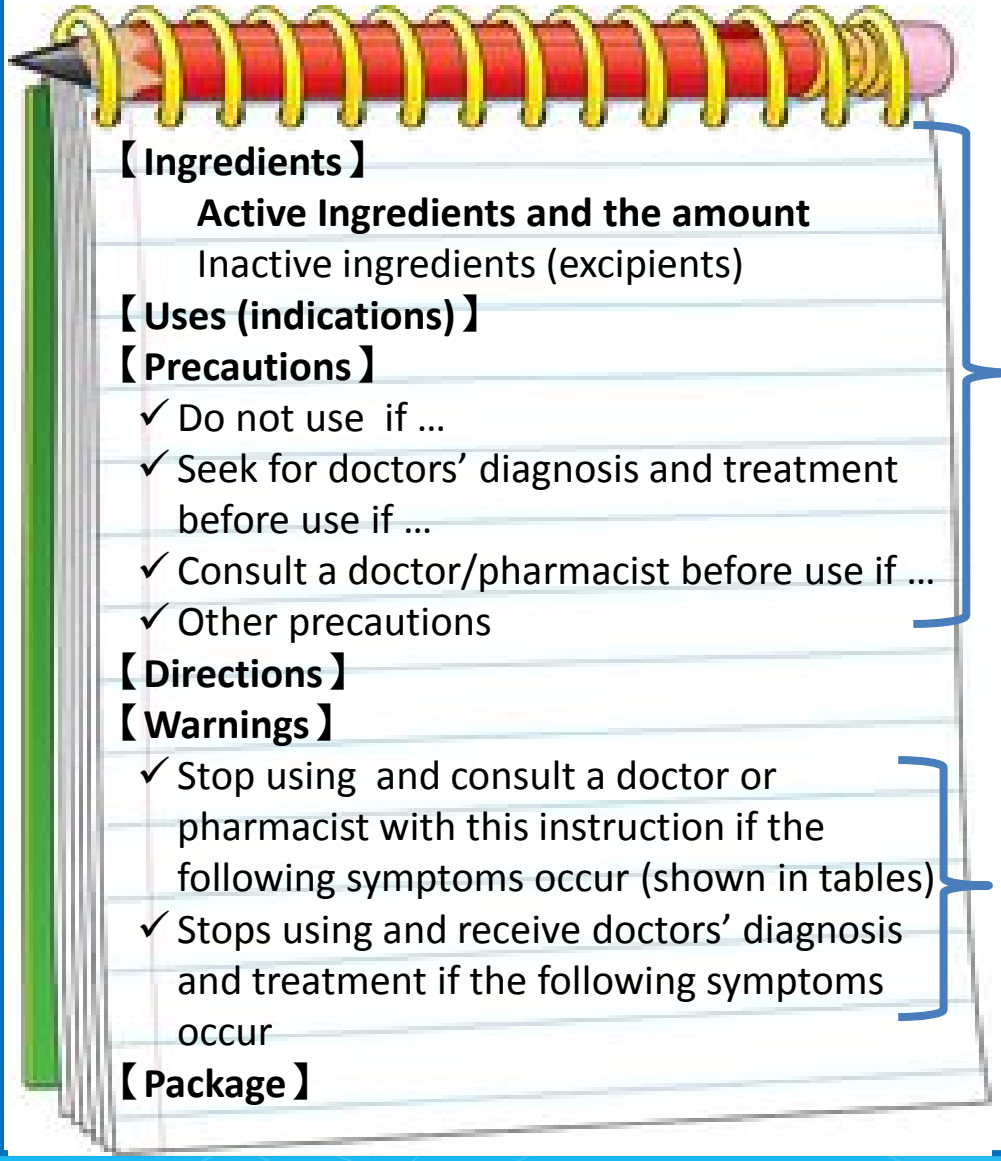
By January 1, 2019, the existed manufacturers, logistics companies and product license holder shall comply

Inspection: with GMP，or application before 2017-12-31，whichever comes first

Creating a friendly and informative environment

Labeling and packaging revision for OTC drugs

Labeling Revision~ 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

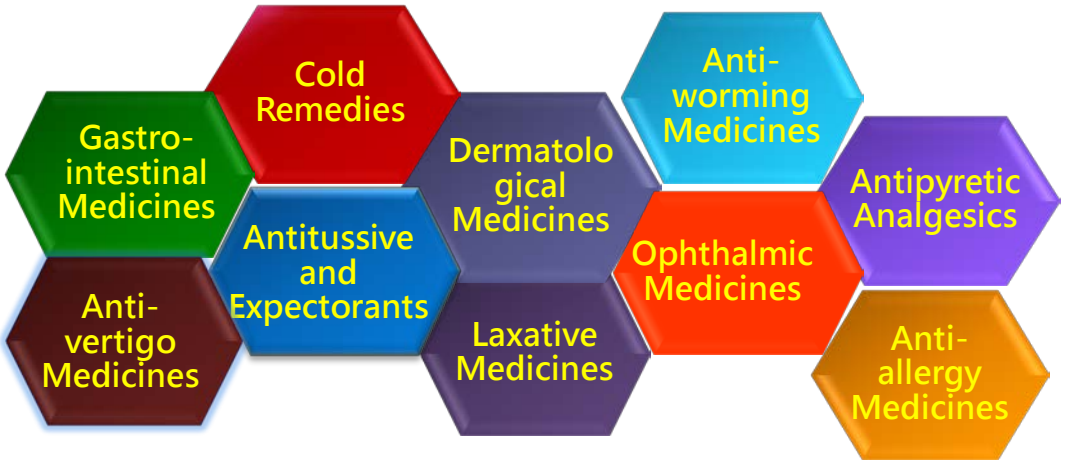
Labeling information of OTC

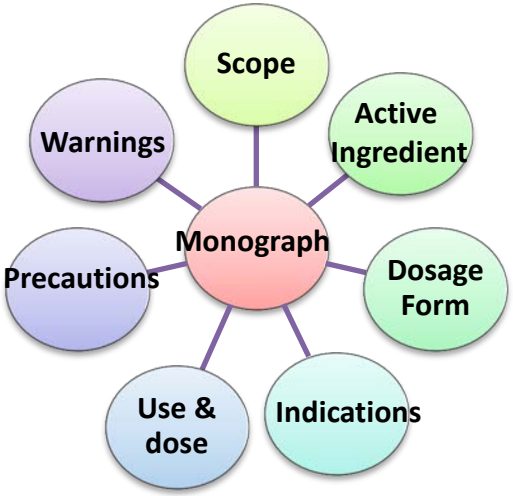
- Labeling, package and package insert of nonprescription (OTC) drugs should be clearly marked in order to improve information accessibility and strengthen drug safety use for consumers

Format for labeling and package of OTC drugs 【3/8】

OTC Monograph【10/27】

Format for labeling and package of OTC drugs - Implementation Timeline 【11/16】





Package Revision ~QR code

Product name , Uses (Indications)、Directions、Dosage form and presentation 、contact information

Future Prospect

✓Creating Win-Win-Win Situation

Public: protection

Health authority: regulation

Manufacturer: promotion

- Thank you