Over-the-Counter Drugs Monograph in Korea

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MINISTRY OF
FOOD AND DRUG SAFETY

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Classification

- **Pharmaceutical Drugs**
  - Prescription drugs
  - Over-the-counter(OTC) drugs
    - ✓ Pharmacy only medicines(P)
    - ✓ General sales list medicines(GLS)
- **Quasi-Drugs**
- **Medical Devices**
- **Health Functional Food**

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Over-the-Counter Drugs(1)

- Used by the public as self-medication
- Properly decided by **the public on selection of indication, dose, compliance with dose, prevention of side effects, or treatment**
  - Dosage forms that have high possibility of misuse and abuse, or of less or no safety and efficacy unless medical experts use are not acknowledge as OTC drugs.
- When applying for approval of OTC products, **some of safety and efficacy supporting data are exempted**
- **Selling the drugs at pharmacy is possible without doctor's prescription**.
  - Doctors can prescribe not only prescription drugs, but also OTC products.

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Over-the-Counter Drugs(2)

- New chemical entities are classified as prescription drugs, but they are always open to possibility of being **re-classified as OTC products**.
- Korea adopted pharmaceutical drug classification system in 1985 for the first time. In 1988, names of classification group were changed to prescription drugs and OTC drugs.
- **General sales list medicines were added to the classification in 2012**.
- In 2011, MFDS initiated evaluation **on reclassification of all drugs** that were domestically approved.

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General Sales List (GSL)

- As one of OTC products, they are **urgently used for light symptoms and patients can decide whether to use the medicine or not.**
- This is the medicine of at most 20 items, determined and notified by MHW, considering substance, adverse effects, content, dosage form, level of recognition, convenience of purchase, etc.
- Until now there are **13 items** such as Children`s Tylenol® TAB 80mg (10 tab), Tylenol® TAB 160mg (8 tab), Tylenol® TAB 500mg (8 tab), Children`s Tylenol® SUSP (100㎖) in GSL

OTC Drugs Monograph

- **In 1994**, OTC Drugs Monograph was established to facilitate efficiency of management of approval and notification for pharmaceuticals
- The monograph demonstrates standardized guidelines for **ingredients' type, specification, strength, and combination (compounding) of ingredients** such as vitamins and minerals in each therapeutic category
- Similar to OTC monograph in USA and Japans system
- Not require safety and efficacy review but **require review GMP and inspection**
- **14 therapeutic categories** are listed in the OTC drugs monograph and the quasi-drugs monograph, respectively

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OTC Drugs Monograph

Chapter 1. Multi-Vitamins / Mineral Supplements
Chapter 2. Antipyretic-Analgesics
Chapter 3. Cold Drug Products
Chapter 4. Antacids, Stomachics, Digestants, Intestinal Drugs, Antidiarrheals and Analgesic-Antispasmodics
Chapter 5. Antiemetics
Chapter 6. Laxatives
Chapter 7. Antitussive-Mucoactive Agents
Chapter 8. Ophthalmic Drug Products
Chapter 9. Rhinitis Drug Products (Oral)
Chapter 10. Rhinitis Drug Products (Spray)
Chapter 11. Hemorrhoid Drug Products (External Use)
Chpater 12. Athlete's Foot and Tinea Drug Products
Chapter 13. External Analgesics
Chapter 14. External Antipruritics

Quasi-drugs Monograph

Chapter 1. Hair dyes
Chapter 2. Toothpaste
Chapter 3. Bath preparations
Chapter 4. External pain relieving spray
Chapter 5. Low-dose vitamins and minerals
Chapter 6. Nutrients, tonics and alternatives
Chapter 7 Depilatory
Chapter 8. Stomachics and digestives
Chapter 9. Intestinal drugs
Chapter 10. Cataplasma
Chapter 11. Epidermal ointments
Chapter 12. Contact lens cleaning solutions
Chapter 13. Mosquito repellent
Chapter 14. External sanitizer

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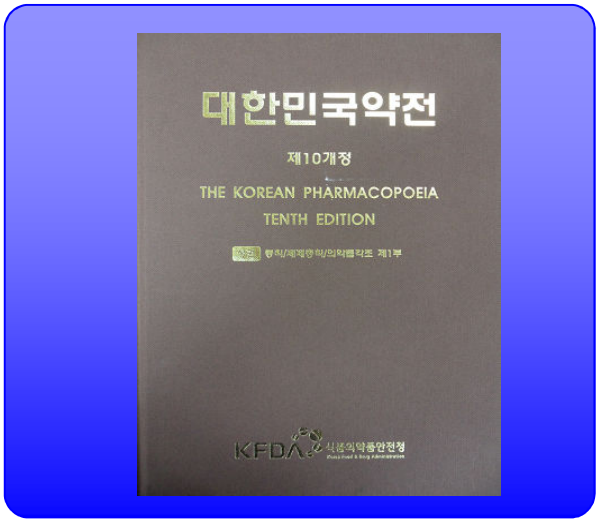
OTC Drugs Monograph

- The specification of active ingredients should be referred to **the Korean Pharmacopoeia(KP), Korean Herbal Pharmacopoeia (KHP) and the other *Pharmacopoeias acknowledged by the MFDS****
  - *USP, NF, JP, BP, EP, DAB, PF*

- The specification of active ingredients used for Quasi-Drugs listed should be referred to **the Korean Pharmacopoeia(KP), Korean Quasi-drugs Codex(KQC)**

The Korean Pharmacopoeia (KP)

- KP has been **served as characteristics of an official standard for description and quality of drugs** which are generally recognized to be safe and efficacious in treatment and prevention of diseases.



- Its role should **specify the standards of drugs on preparation, identification, efficacy, quality, and storage**.
  - ✓ established by Korean government
  - ✓ first established on October 10, 1958

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Drug approval process

Application	Pre-review	Review / Inspection	Approval
Applicant	NIFDS 6 Regional FDA	NIFDS (Drug Evaluation Department) MFDS Regional FDA	NIFDS Regional FDA
• Research and development of drug • Preparation of dossier for drug approval	• Composition of preliminary report - Examination of submitted application	• Report Review • Efficacy, Safety • Quality Evaluation • DMF • GMP Assessment • GMP inspection - Foreign Manufacturing sites (MFDS) - Domestic Manufacturing sites (Regional FDA)	•Issuing certificate of approval •Disclosure of Review Result

Sponsors have submitted application as electronic documents through online system for Pharmaceutical application since Oct. 2nd, 2006

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Classification of Pharmaceutical Products

Approval Products	Notification Products
Items require safety efficacy review and management	Items do not require safety and efficacy review
New Drugs	Products listed in : ▪ Korea Pharmacopeia (KP) and other Pharmacopoeia acknowledged by the Minister of MFDS ** Except products never marketed in Korea* ▪ Korea Herbal Medicines Codex ▪ **OTC monograph**
Drugs Required of Evaluation of Safety & Efficacy	
Generic Drugs	
MFDS/NIFDS	**Regional FDA**

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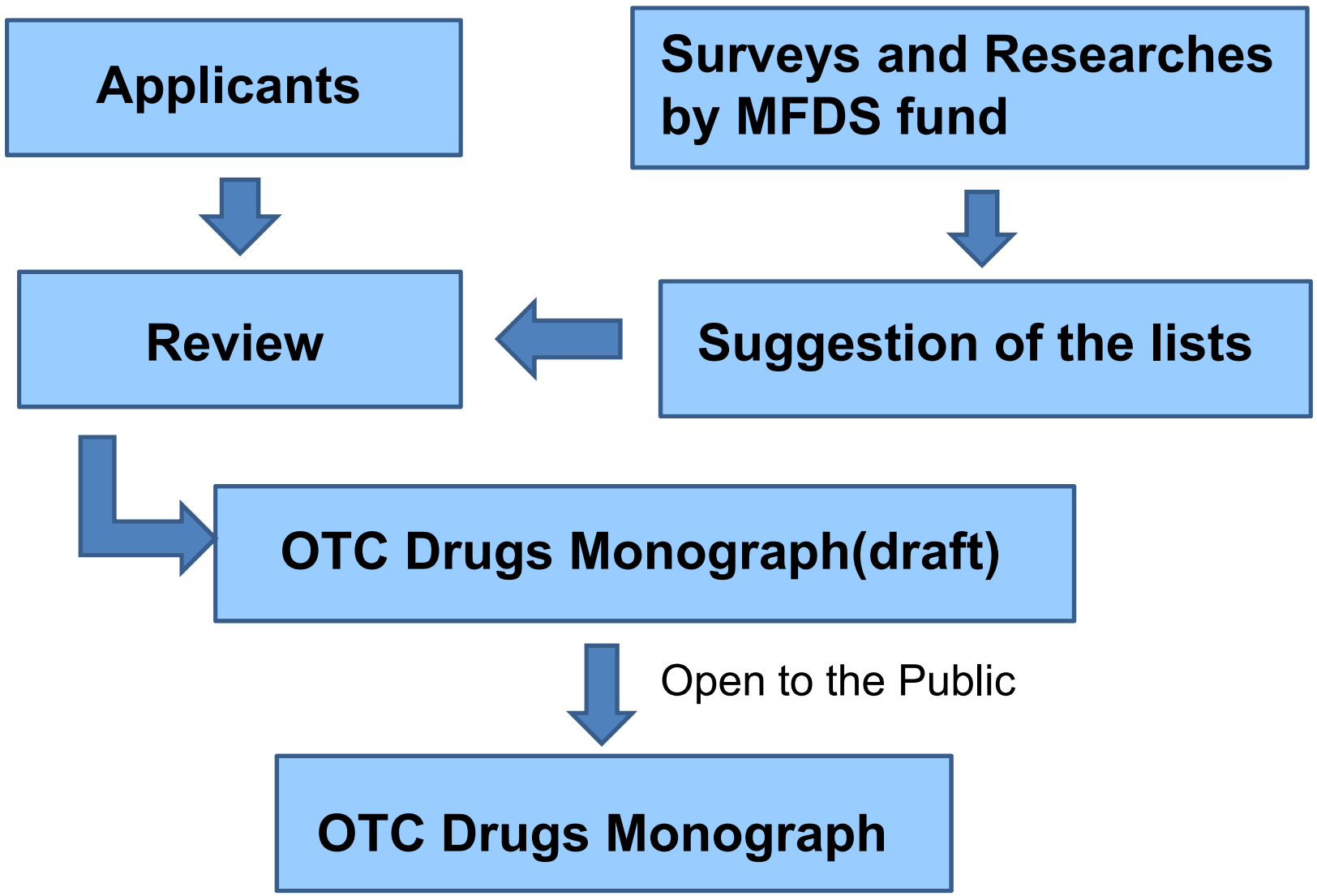
NDA and OTC Monograph Process

NDA Approval process	OTC Monograph Notification Process
Pre-market approval – MFDS review and approves formulation and labeling prior to marketing	Pre-market approval – MFDS set forth specific conditions
Drug-product specific	Active ingredient-specific and evaluated by OTC drug category
Require a user fee	May require a user fee
Potential for marketing exclusivity	No marketing exclusivity
Full review timelines	Abbreviated review timelines
May require clinical studies, including studies on label comprehension and actual use	Not require clinical studies
Approved labeling is unique to the drug	Labeling is defined by the monograph. May be same labeling
Unique Approved labeling to the drug	Defined labeling by monograph
Trade name reviewed prior to marketing	Trade name reviewed prior to marketing

Process of Monograph List Revice



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Korean OTC Drug Monograph for Antipyretic Analgesics

- The Over-the-Counter(OTC) Drug Monograph was **established to facilitate efficiency of management of approval and notification for pharmaceuticals**.
- The monograph demonstrates standardized rules for **types and quantities of active ingredients, specification, dosage form, dosage and administrations, indications and combination of ingredients**.
- The monograph of antipyretic-analgesic **is intended for oral combination drugs to reduce fever and relieve pain**. Preparations only composed of herbal ingredients are out of this scope.

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Active ingredients listed in the Monograph (1)

Classification	Active Ingredient	Maximum single dose (mg)	Maximum daily dose (mg)
Group I	Sodium Salicylate	1000	3000
	Salicylamide	1000	3000
	Acetaminophen	500	1200
	Aspirin	750	1500
	Aspirin Aluminium	1000	2000
	Ethenzamide	500	1500
	Choline Salicylate	1100	3300
Group II	Ibuprofen	400	1200
Group III	Caffeine And Sodium Benzoate	100	300
	Caffeine Hydrate	50	150
	Anhydrous Caffeine	50	150
	Ammonium chloride	200	800
	Pamabrom	50	200

Active ingredients listed in the Monograph (2)

Classification	Active Ingredient	Maximum daily dose (mg)
Group IV	Vit B_1 and its derivatives and Salts	25(1)
	Vit B_2 and its derivatives and Salts	12(2)
	Vit C and its derivatives and Salts	500(50)
Group V	Dried Aluminum Hydroxide Gel	1000
	Magnesium Silicate	3000
	Magnesium Aluminometasilicate	1500
	Magnesium Oxide	500
	Magnesium hydroxide-aluminum potassium sulfate co-precipitate	1800
	Dried mixed aluminum hydroxide and magnesium carbonate gel	3000
	Aluminum hydroxide-sodium bicarbonate co-precipitate	900
	Aluminum hydroxide-calcium carbonate-magnesium carbonate co-precipitate	1500
	Aluminum hydroxide gel (as dried aluminum hydroxide gel)	1000

Active ingredients listed in the Monograph(3)

Classification	Active Ingredient	Maximum daily dose (mg)
Group V	Glycine	900
	Dihydroxyaluminum Aminoacetate Hydrate	1500
	Magenesium Carbonate	2000
	Synthetic Aluminum Silicate	3000
	Synthetic Hydrotalcite	4000

(Crude Drugs)

Classification	Active ingredient	Maximum daily dose (g)	
		Extract	Powder
Group I	Lumbricus	3	2
	Licorice(Glycyrrhiza)	5	1.5
	Cinnamon Bark	5	1
	Peony Root	5	2
	Moutan Root Bark	6	2
	Valerian Root and Rhizome	6	2
	Zanthoxylum Peel	2	1
	Ginger	3	1
	Citrus Unshius Peel	5	3

Active ingredients

- Available types of active ingredients are listed in previous slide
- Specification of active ingredients listed should be referred to the Pharmacopoeia or Official Compendium specified by MFDS
- At least 1 active ingredient in Group I and II listed must be used
- Up to 3 active ingredients in Group I can be combined
- Only 1 active ingredient in Group III can be used
- Ibuprofen in Group II must not combine with any other ingredients in Group I
- Quantity are described for each group and combinations

Dosage Form

- **Tablets**(including chewable, effervescent), **capsules, pills**, **granules and powders** (including fine granule).
  - When chewable tablets are over 1.5cm in diameter, the round shape with a hole at the center(doughnut) is only accepted.

Indication

- Described within as follows

1) Relief headache, toothache, pain after dental extraction, sore throat, earache, joint pain, nuralgia, lumbago, muscular pain, pain due to stiff shoulders, contusion pain, bone fracture pain, sprain pain, dysmenorrhea and traumatic pain.

2) Relief of chills and fever

Dosage and Administrations

- **Once a day administration**
  - Take medicines once a day, avoid taking medicines on an empty stomach.
- **Twice a day administration**
  - Take medicines twice a day with an interval of at least 6 hours between doses, avoid taking medicines on an empty stomach.
- **Three times a day administration**
  - Take medicines three times a day with an interval of at least 4 hours between doses, avoid taking medicines on an empty stomach.
- **Other rules are described in the monograph**.

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Summary

- OTC Drug Monograph was established **to facilitate efficiency of management of approval and notification for pharmaceuticals in 1994**.
- **14 therapeutic categories** are listed in OTC monograph and **14 categories** in Quasi-drugs monograph
- OTC Monograph and Quasi-drugs Monograph **has many benefits for health authority, industry and public**
- MFDS has plans **to extend categories and ingredients**.

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Thank you

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