The Recent Activities carried out by Focal Point of Veterinary Products in Korea

- Focused on the introduction of quality and safety control system of VMP in Korea -

Animal and Plant Quarantine Agency (QIA)
QIA
(Animal and Plant Quarantine Agency)

General Service Division

Planning & Coordination Division

Animal Disease Status Control Center

Center for AI Control and Prevention

- Dep. Animal Disease Control & Quarantine
  - Animal Disease Control
  - Animal Quarantine
  - Veterinary Epidemiology
  - Animal Disease Diagnostic
  - Import Risk Assessment
  - Animal Protection & Welfare
    - Veterinary Pharmaceutical Management
    - Veterinary drugs and biologics

- Dep. Plant Quarantine
  - Plant Quarantine
  - Export Management
  - Risk Management
  - Plant Pest Control
  - Plant Quarantine Technology

- Dep. Animal & Plant health research
  - Research Planning
  - Bacterial Disease
  - Foot and Mouth Disease
  - Viral Disease
  - Avian Disease
  - Foreign Animal Disease
  - Center for RMD Vaccine Research

- 3 Departments, 24 Divisions, 5 Center for Animal Disease Control
- 6 Regional offices, 22 District offices
Responsibilities of Related Organizations

- Implement of the Pharmaceutical Affairs Act
- Implement of the Act on Medical Devices
- Shaping Animal Drug Policies
- Implementation of the Handling Rules of Animal Medicines, etc.
- Animal Medicine Wholesalers
- Pharmaceutical Inspection of Animal Drugs Dealers
- Municipal government (province, city, Country, ward office)
- Regulating
- Approval
- KVGMP
- Reevaluation
- Recall
- National inspection
- Pharmacovigilance
The function of Ministries for Medicines
The category of Veterinary Products

- **Veterinary Drugs**
  - Antibiotics, Insecticide,
  - Analgesics, Antiphlogistic,
  - Cough Remedy, Expectorant, etc.

- **Quasi-drugs**
  - Pet cleaners such as Oral Refrigerant,
  - Bath Substances/Detergents/Deodorants,
  - Disinfectants for Animal Sheds Pesticide,
  - Vitamins, Sanitary Goods such as Surgical Drapes, etc.

- **Medical Devices**
  - Radioactive Diagnosis Device,
  - Physical Therapy Instruments,
  - Blood Analyzer, Surgery Instruments,
  - Radio-frequency Identification (RFID), etc.
Evaluate safety, efficacy and stability of each veterinary drug and Biologics
## Related Regulations for Veterinary medicinal products

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<td>Acts (2)</td>
<td>▪ Pharmaceutical Affairs Act, The Act on Medical Devices (Ministry of Health and Welfare, MFDS)</td>
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<tr>
<td>Enforcement Decree (1)</td>
<td>▪ Enforcement Decree on Facility Standards of Manufacturer, Importers and Distributors of Animal Medicines (Minister of Agriculture, Food and Rural affairs)</td>
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<td>▪ Handling Rules of Animal Medicines and Others (Minister of Agriculture, Food and Rural affairs)</td>
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<td></td>
<td>▪ 23 Including the Guideline on Production and Item Permission of Veterinary Drugs (Commissioner of the QIA)</td>
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II. Veterinary Products Approval

No. of Licensed Manufacturers and Importers (DEC. 2014)

481 companies

Quasi-Drugs for Animals
70(15%)
(62 Man./8 Imp.)

Medical devices for Animals
189(40%)
(92 Man./97 Imp.)

Veterinary Drugs
222(45%)
(76 Man./146 Imp.)
<table>
<thead>
<tr>
<th>Division</th>
<th>Domestic Products</th>
<th>Import Products</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veterinary Drugs</td>
<td>6,139 (77%)</td>
<td>1,863 (23%)</td>
<td>8,002 (100%)</td>
</tr>
<tr>
<td>Quasi - Drugs</td>
<td>1,998 (52%)</td>
<td>1,851 (48%)</td>
<td>3,849 (100%)</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>256 (19%)</td>
<td>1,104 (81%)</td>
<td>1,360 (100%)</td>
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<tr>
<td>Total</td>
<td>8,393 (64%)</td>
<td>4,818 (36%)</td>
<td>13,211 (100%)</td>
</tr>
</tbody>
</table>
Quality and safety control system of VMP in Korea

<table>
<thead>
<tr>
<th>Development</th>
<th>Approval</th>
<th>Distribution</th>
<th>Use in field</th>
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<tbody>
<tr>
<td>Rules for quality, safety, etc</td>
<td>Examination for approval</td>
<td>Manufacturing and import</td>
<td>Evaluation control</td>
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<tr>
<td>Rules for Authorization holders</td>
<td>License for marketing holder</td>
<td>Assay standard</td>
<td>Reevaluation</td>
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<tr>
<td>Rules for handling</td>
<td>Review of Clinical test</td>
<td>National assay</td>
<td>Reexamination</td>
</tr>
<tr>
<td>Rules for Inspection &amp; Guidance</td>
<td>GLP (on review)</td>
<td>GMP for manufacturing &amp; importing license</td>
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<td></td>
<td>GCP</td>
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<tr>
<td></td>
<td>Raw materials (DMF, BGMP) Final Products(GMP, biologics GMP)</td>
<td></td>
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<td></td>
<td>Prescriptionsystem</td>
<td></td>
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<td></td>
<td>GSP</td>
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<td></td>
<td>PMS</td>
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<td></td>
<td>GVP (Good Vigilance Practice)</td>
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<tr>
<td></td>
<td>National assay</td>
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<td></td>
<td>Inspection &amp; sampling on site</td>
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<td></td>
<td>Restriction Of veterinary use</td>
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<td></td>
<td>Post marketing surveillance</td>
<td></td>
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<tr>
<td>Methods</td>
<td>Before Approval</td>
<td>After Approval</td>
<td></td>
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<td>-------------------------------------------</td>
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</tr>
<tr>
<td>Review for approval</td>
<td>(Including facilities inspection)</td>
<td></td>
<td></td>
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<tr>
<td>National inspection</td>
<td></td>
<td>(Biological only)</td>
<td></td>
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<tr>
<td>Operation of KVGMG</td>
<td></td>
<td></td>
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<tr>
<td>Self Audit</td>
<td></td>
<td></td>
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<tr>
<td>Random inspection for distributive drugs</td>
<td></td>
<td></td>
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<tr>
<td>Reevaluation for the permitted drugs</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Reexamination for the new drugs</td>
<td></td>
<td>(Within 6 years)</td>
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</tr>
<tr>
<td>Recall defective products</td>
<td></td>
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</tbody>
</table>
Application items for Veterinary Products To be Manufactured or imported

Veterinary Pharmaceutical Division

Department in charge of technical review

Decide if it is subject to safety and efficacy evaluation

Review based on the guideline on production and item permission of animal medicines (within 10 days)

- Conforming
  - Permitted

- Non-conforming
  - Complement/Reject

Evaluation of safety and effectiveness (Department in charge of technical) review
90 days for new medicines/60 days for document submission

- Conforming
  - Permitted

- Non-conforming
  - Complement/Reject

Flow of Marketing Approval Procedure
Safety and Efficacy Evaluation (1)

Technical Review of Animal Drugs

Evaluation conducted to grant item permission in regard to the documents submitted for the permission(change) of items, pursuant to the related rules

Related Laws

- Guideline on manufacturing and item permission of animal drugs
  Details on standards for permitting the production and items

- The outline on investigation of animal drugs
  Review process/period/operation of technical review committee

- Safety and effectiveness examination of animal drugs
  Details on review such as targets and required documents
Safety and Efficacy Evaluation (2)

Required Documents

1. Origin, discovery and development background
2. Structure, physical & chemical properties
3. Safety
4. Foreign country cases
5. Comparison with domestic similar products
6. Pharmaceutical activities
7. Clinical tests
8. Toxicity
9. Residual substances
Efficacy Evaluation

Evaluation Categories

- **Document on pharmaceutical activities**
  - Efficacy test
  - General pharmaceutical test
  - Absorption, dispersion,
  - Metabolism and excretion tests

- **Clinical test results**
  - Results of safety test on target animal
Safety Evaluation

Evaluation Categories

Data on toxicity
- Acute/Sub-acute/Chronic toxicity data
- Data on reproductive toxicity, mutagenicity, and carcinogenicity, Other special toxicity data (topical and inhalant toxicity)

Clinical test results
- Based on MRLs (Maximal residual limits)
- Data on the residual analysis and withdrawal period
- Impact on the natural environment
Standards and Test Evaluation

Evaluation Categories

- Physical and chemical properties
- Structural determination
- Safety data
- Test methods
- Comparison with similar domestic products
- The present uses abroad
National Inspection (batch release assay) of vet. biologics

Separate inspections are conducted by the laboratories designated by the government to supply safe and efficacious animal drugs (Biologicals)

Related Laws

- Articles 53 and 85 of the Pharmaceutical Affairs Act
  - Specify rules and regulations on national inspection animal drugs
- Articles 27 to 41 of the Handling Rules of Animal drugs, etc.
  - Specify details on the extent of national inspection for animal drugs
KVGMP (Korean Veterinary Good Manufacturing Practice)(1)-Definition

Standards(Regulations) that must be observed in relation to product quality in all the processes and procedures to supply quality-ensured drugs in Korea

*KVGMP is in accordance with GMP of WHO*

Targets for manufacturing and quality control

- Manufacturing facilities and management of raw/subsidiary materials
- Control of manufacture, packaging, storage and distribution
- Handling consumer complaints in distribution and recall
KVGMP(2) - Purpose

To ensure safety of animal medicines
- Prevent side effects in human body due to animal drugs
- Prevent human poisoning due to contamination of foreign substances

To strengthen effectiveness of animal medicines
- Maximize efficacy for the target animal and disease through correct uptake and use of the drug

To maintain stability of animal medicines
- Maintain efficacy by preventing deterioration caused by air, humidity, bacteria, and other factors
Minimize man-made errors

- Appropriate working space
- SOP observance, Double/Cross check
- Thorough identification and recording

Prevention of Contamination

- Facilities to prevent cross contamination and air-conditioning facilities
- Sanitary education/Individual healthcare/limitation of access to work places

Thorough calibration/validation

- Appropriate layout of facilities
- Calibration/Validation
Monitoring & Surveillance Program

Subject: Veterinary Pharmacovigilance

- Animal hospitals [city/regional]
- Shops/Service Companies of medical devices [city/regional]
- Wholesalers of animal medicines [city/regional]
- Animal pharmacies [city/regional]
- Manufacturers (Importers) of drugs and others QIA
- Manufacturers (Importers) of medical devices QIA
What is Self-audit Program?

A management system to supply high quality animal medicines through voluntary audit and quality control by the manufacturers and importers, themselves.
Market Statistics

Total 803 (mil. $)

- **Swine**: 264 (33%)
- **Others**: 262 (33%)
- **Avian**: 88 (11%)
- **Fish**: 20 (2%)
- **Companion**: 69 (9%)
- **Bovine**: 99 (12%)

※ Raw material and Exported are included
Domestic Market

- VMPs: 64%
- Feed Additives: 36%

※ Raw material and Exported are excluded

<table>
<thead>
<tr>
<th>Year</th>
<th>(mil. $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>483</td>
</tr>
<tr>
<td>2011</td>
<td>506</td>
</tr>
<tr>
<td>2012</td>
<td>518</td>
</tr>
<tr>
<td>2013</td>
<td>499</td>
</tr>
<tr>
<td>2014</td>
<td>554</td>
</tr>
<tr>
<td>2015</td>
<td>575</td>
</tr>
</tbody>
</table>
EXPORT STATUS

Raw Materials
101 (47%)

Chemicals
71 (33%)

Biologicals
26 (12%)

Others
5 (8%)

Total 214 (mil. $)

63 Companies ➔ 103 Countries
# Response to Antimicrobial Resistance

## Launch of National Program

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>'02</td>
<td>Report of Korea Consumer Protection Board&lt;br&gt;Antimicrobial Resistant Bacteria in Food</td>
</tr>
<tr>
<td>'02</td>
<td>The Office for Government Policy Coordination&lt;br&gt;Convene a Council for Development of National Strategies for Food Safety</td>
</tr>
<tr>
<td>'03</td>
<td>Launch NARMP with Relevant Government Offices in Korea&lt;br&gt;KFDA, MOHW, KCDC, MiFAFF, KCPB &amp; General Hospital</td>
</tr>
</tbody>
</table>

The Office for Government Policy Coordination<br>Convene a Council for Development of National Strategies for Food Safety

Launch NARMP with Relevant Government Offices in Korea

KFDA, MOHW, KCDC, MiFAFF, KCPB & General Hospital

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Ministry for Food, Agriculture, Forestry and Fisheries

Korea Centers for Disease Control and Prevention

Institute of Health and Environment

MINISTRY FOR HEALTH, WELFARE AND FAMILY AFFAIRS

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[Image of government buildings and icons]
The amount of use of antimicrobials


down

down↓↓

28 AGP ban (‘05.5)

Total (ton)

9 AGP ban (‘11.7)

: phase out all antibiotics

Vet. Prescription (‘13.8)

: 20 antibiotics

(Source: KAHPA)
The antimicrobial resistance in live animals and their carcasses

% resistant isolates

Year and number of isolates

- Cattle
- Pigs
- Poultry

Ampicillin
Gentamicin
Streptomycin
Ceftiofur
Ciprofloxacin
Tetracycline
Trimethoprim/Sulfamethoxazole
Chloramphenicol

Cattle carcasses
Pig carcasses
Chicken carcasses

Year and number of isolates
Recent activities related with international cooperation

1. Joining meeting held by OIE, VICH and renovating several guidelines

2. Technical cooperation with Japan and China
Thank you for your attention