Brief Introduction for Approval System of Antimicrobials in Japan

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Antimicrobials for animal use in Japan

1. Antimicrobial Veterinary Drugs

   ⇒Under the Pharmaceutical and Medical Devices Act

2. Antimicrobial Feed Additives

   ⇒Under the Law Concerning Safety Assurance and Quality Improvement of Feeds

Pharmaceutical and Medical Devices Act

(The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics)

(Revision of Pharmaceutical Affairs Law)

- Objectives of this Act is

  - to regulate matters pertaining to drugs, quasi-drugs, cosmetics, medical devices, and regenerative and cellular therapy products.

  - to ensure their quality, efficacy and safety.

  - to regulate each stage of development, manufacturing /importing, marketing, retailing, and usage.

- The same Act regulates medicinal products for human use, and veterinary medicinal products (VMPs)

Veterinary Antimicrobial-Control Systems

<Before Manufacturing/Importing>

1）Marketing Approval System

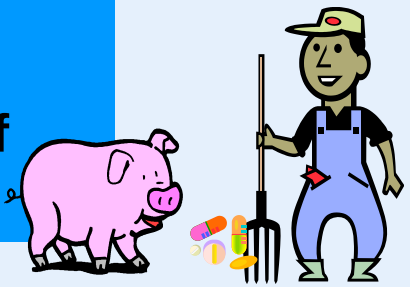
- prohibit distribution of unapproved drug

<Usage of antimicrobials>

Residual aspects

3）Restrictions for usage of antimicrobials in the food-producing animals

- establish usage standards of antimicrobials



<At the retailing>

2）Prescription system

- prohibit selling drug without prescription of veterinarian‥

Veterinarian

- shall not prescribe without consultation

(by The Veterinary Act)

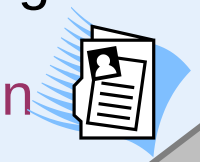
2）Prescription system of Antimicrobials

Veterinarian

①Issue the prescription based on the diagnosis/ consultation

Livestock Farmer

②Order drug following prescription



Licensed Retailer

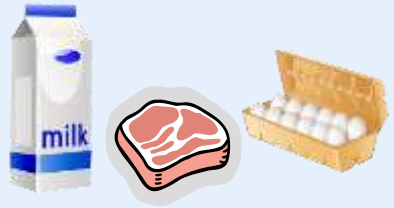
③Sell drug only to livestock farmer with prescription

④Use antimicrobials in accordance with regulations on usage of drugs

3）Restriction for usage of Antimicrobials in the food-producing animals
-Residual Aspect-

Standard on restriction for usage of veterinary drugs used for food-producing animals,

- Cattle, pigs, poultry, hourse, fish or bees,
- to assure the public health safety in administration of antimicrobials etc.
- to specify drugs that can be used in the target animals, with administration dosages and withdrawal times.



Example of Standard of Restriction for usage of Veterinary drugs

Drugs	Target animal	Dosage	Prohibition period for use
Ampicillin (in feed)	Cattle	-Administration not more than 24mg /kg bw /day	For 5 day before killing for food
	Pig	-Administration not more than 24mg /kg bw/day	For 5 day before killing for food
	Chicken	-Administration not more than 40mg /kg bw/day	For 2 day before killing for food

1）Marketing Approval of Medicinal Products

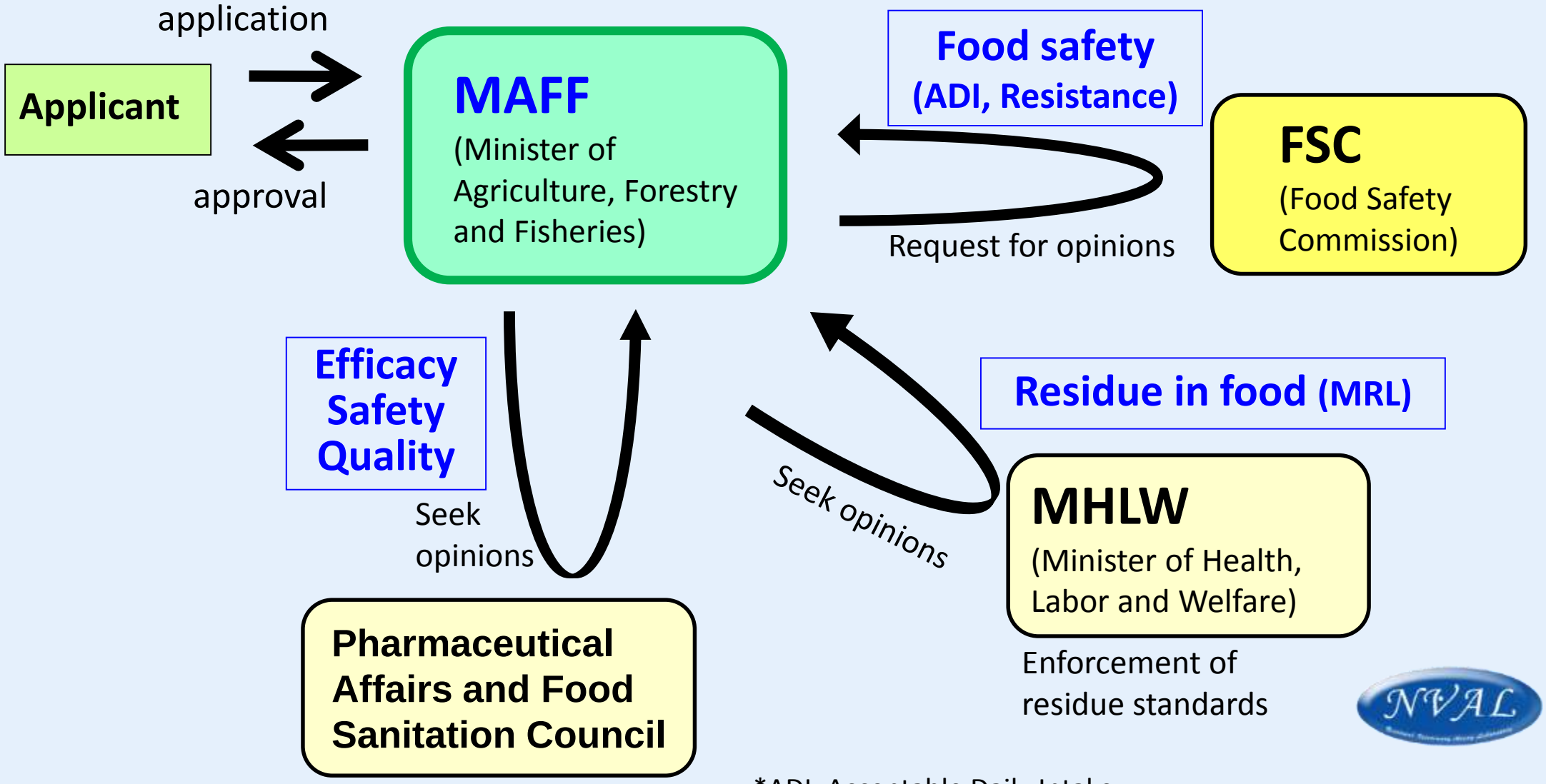
[Article 14 of the Act]

A person intending to market a medicinal product, quasi-drug, or cosmetic shall, for each product, obtain marketing approval of the Minister with respect to its marketing.

- **The approval shall not be granted when the drug;**
  - **does not possess effects indicated in the dossier,**
  - **has harmful action outweighing its effects,**
  - **does not have appropriate quality.**

- **Before providing an approval, the Minister shall seek the opinion of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC).**

Approval Process for Veterinary Medicinal Products (VMPs)



*ADI, Acceptable Daily Intake;
*MRL, Maximum Residue Level

Data Required for application

1. Origin and background of the discovery
2. Physical and chemical properties (Incl. quality control methods) ⇐ GL27
3. Manufacturing protocol
4. Stability
5. Toxicity (GLP)
6. Target Animal Safety (GLP)
7. Pharmacological action (Efficacy) ⇐ GL27
8. Absorption, distribution, metabolism and excretion
9. Clinical trials (GCP)
10. Residue (GLP)

Marketing approval of VMPs

With these data

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* **Efficacy / Safety**
  (poisonous drugs / powerful drugs?, Prescription drug ?)
* **Quality** (Shelf-life, Storage condition, Quality control methods)
* **Dosage, Administration route, Indications** (Target animals, Target diseases, dosing interval, restrictions (e.g. not for pregnancy) etc.)
* **Precautions**
  (Withdrawal time, adverse reactions etc.)