WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

Monitoring on quality of veterinary medicinal products (post-marketing surveillance)

Chinese Taipei

Bureau of Animal and Plant Health Inspection and Quarantine,

Council of Agriculture, Executive Yuan

Animal Health Inspection Division

Veterinary Medicinal Products Section

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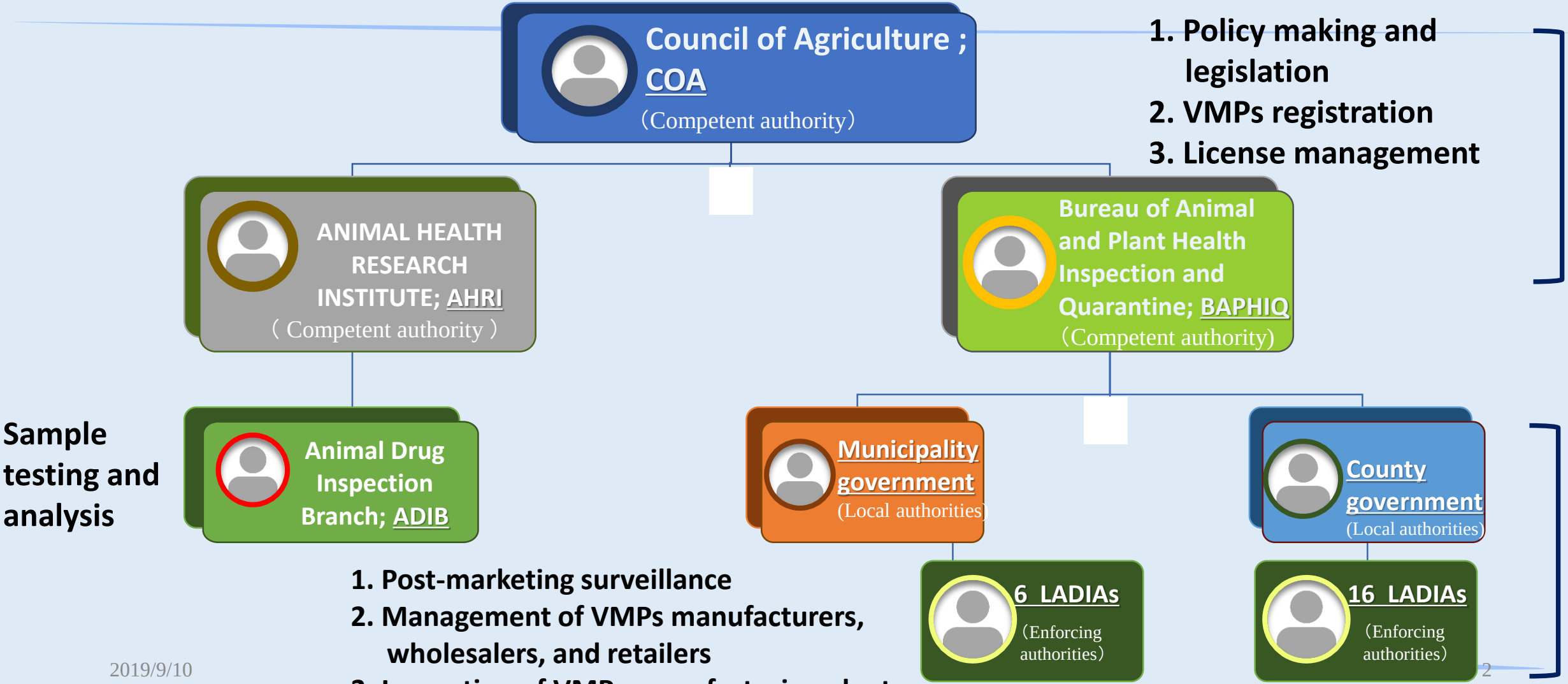
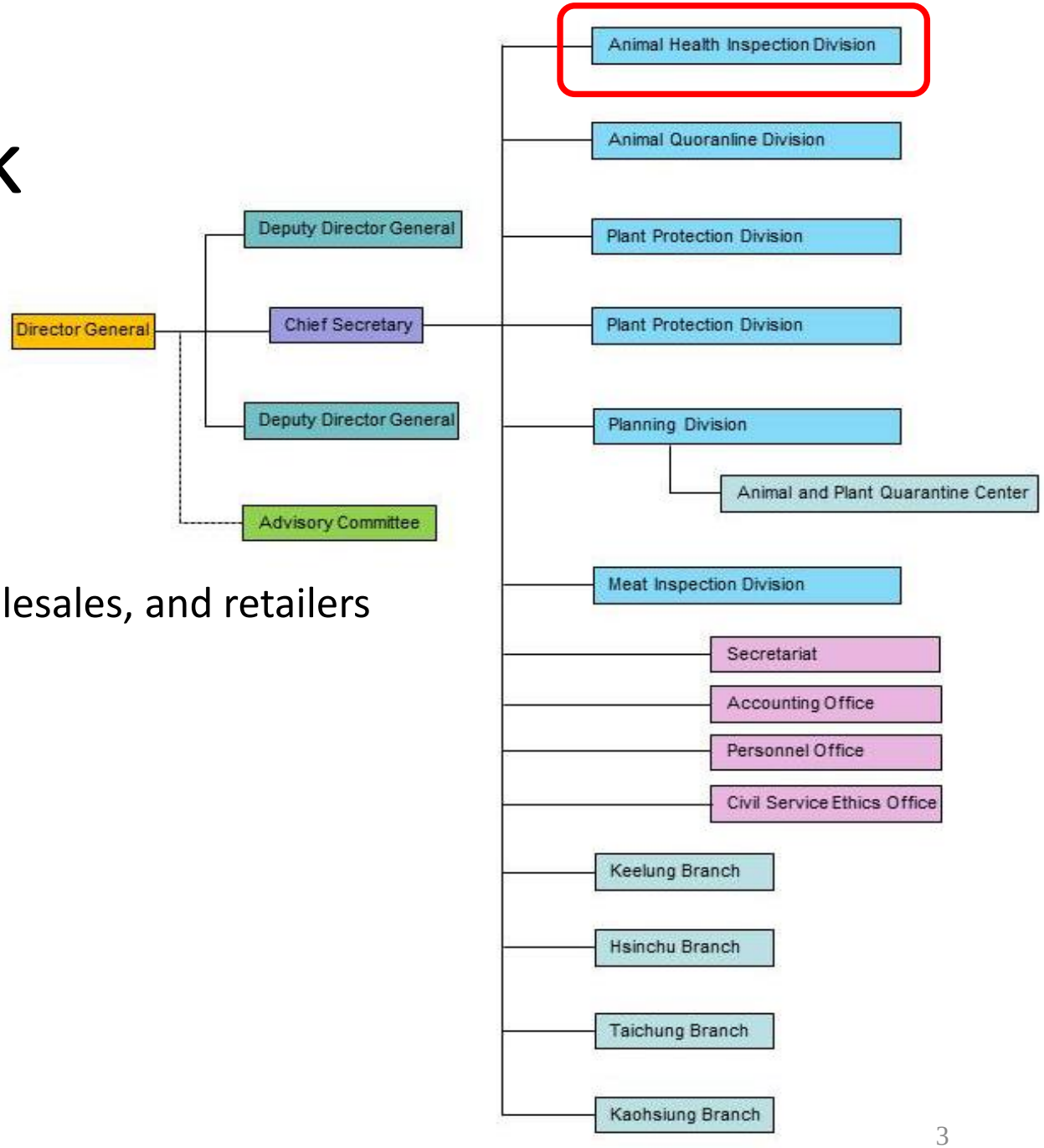
Regulatory framework



Regulatory framework

- BAPHIQ-VMPs
  - Animal Health Inspection Division
    - VMPs registration
    - License management
    - Management of manufacturing, wholesales, and retailers
    - Post-marketing surveillance
    - AMU and AMR surveillance
    - Residue monitoring

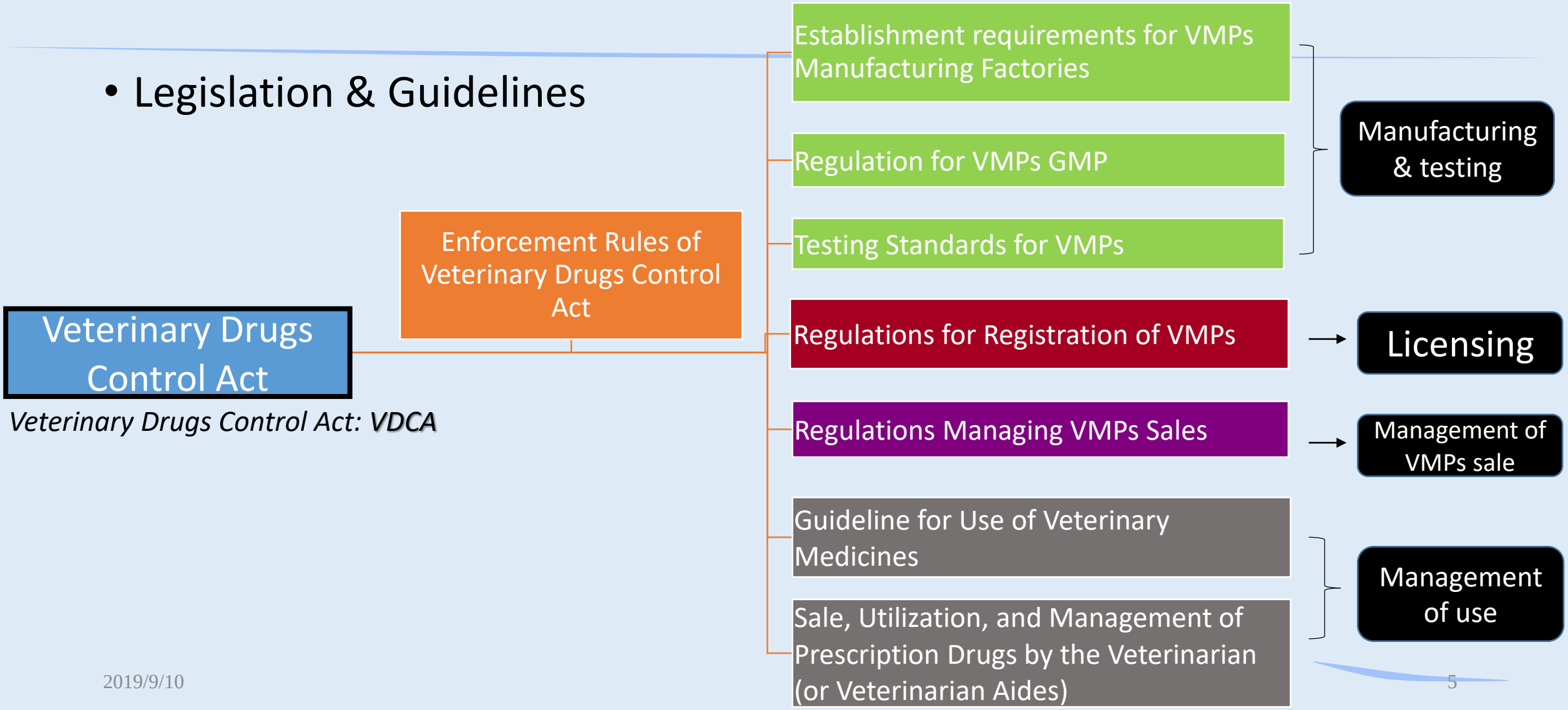


Regulatory framework

- AHRI
- ADIB
  - Sample testing and analysis
- 22 LADIAs
  - Post-marketing surveillance
  - Management of VMPs manufacturers, wholesalers, and retailers
  - Inspection of VMPs manufacturing plants

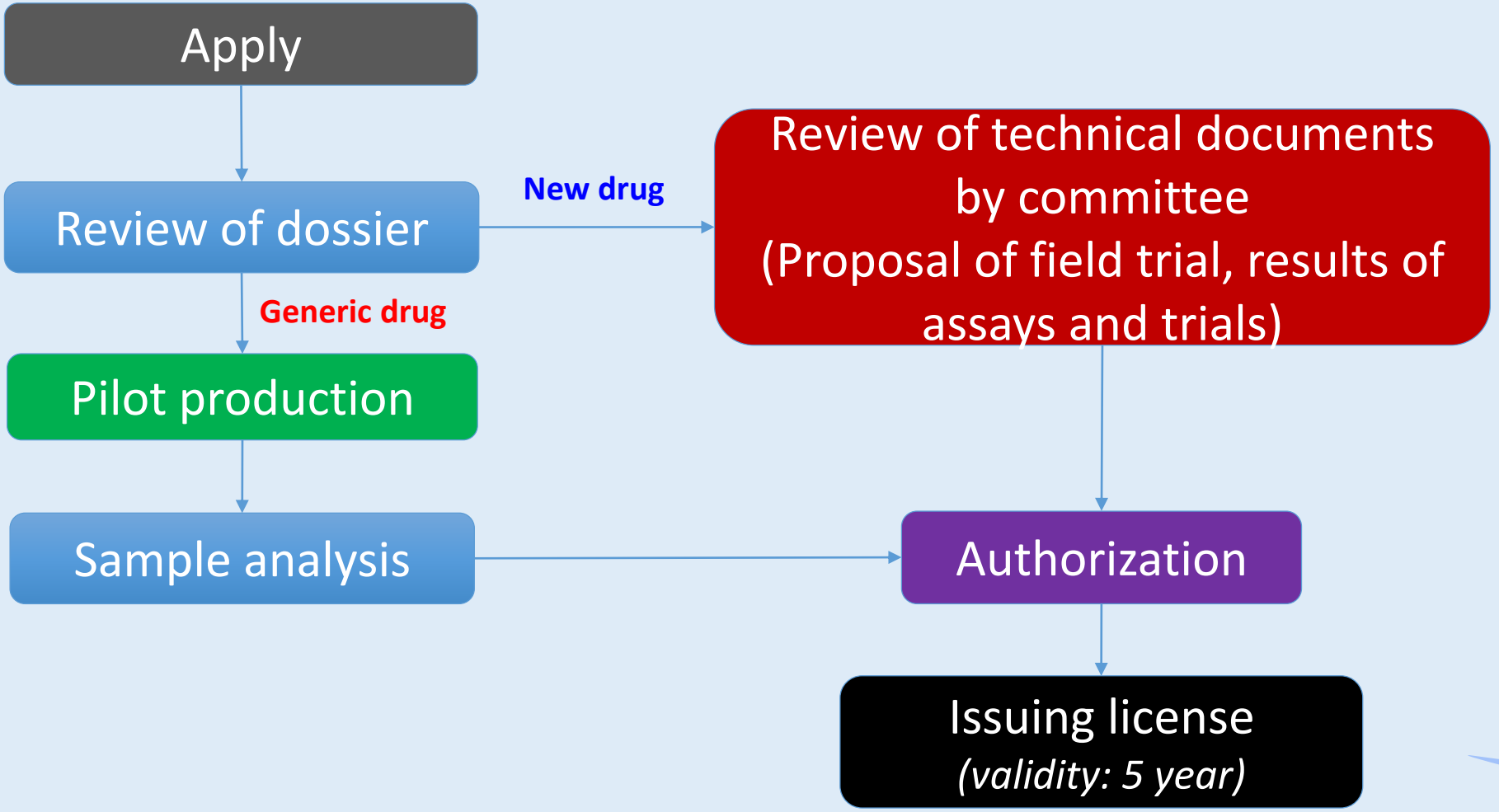
Regulatory framework

- Legislation & Guidelines



Veterinary Drugs Control Act: VDCA

Approval process of VMPs registration



Information of VMPs industry

- Manufacturing plants/ factories:
  - Pharmaceuticals: 34
  - Biologicals: 8
- VMPs Wholesalers and Retailers: 2,099
- VMP licenses:

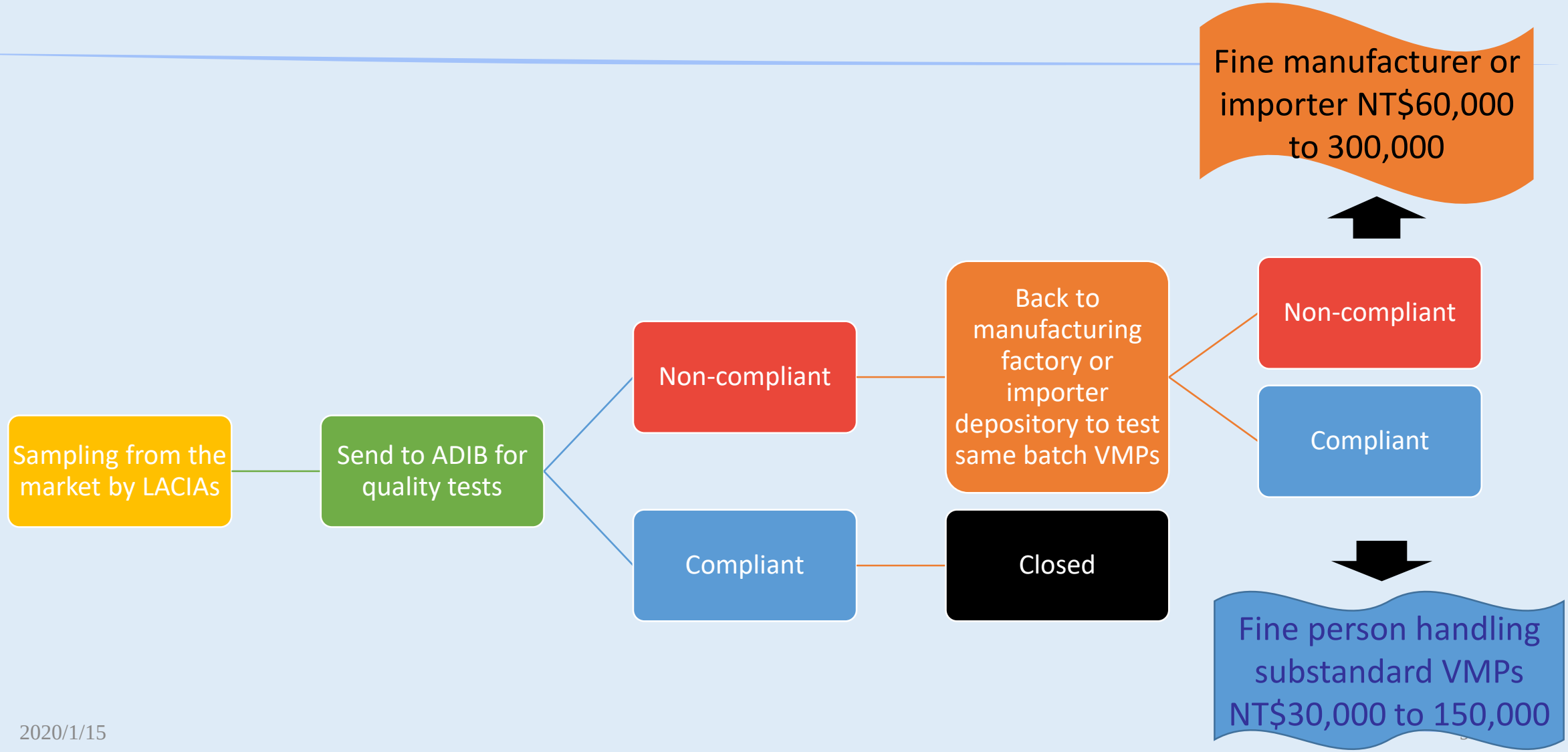
API: active pharmaceutical ingredient

Category	Valid licenses (No.)			Subtotal
	Manufacturing	Import	Export only	
APIs	9	70	1	80
Pharmaceuticals	3,292	528	75	3,895
Biologicals	230	309	2	541
Total	4,516			

Post-marketing surveillance of VMPs

- Annual projects
- Random sampling
  - Pharmaceuticals: 135 products/yr
  - Biologicals: 55 products/yr
- Qualification based on Testing Standards for VMPs
  - Pharmaceuticals: API content test
  - Biologicals: quality tests

Scheme of VMPs post-marketing surveillance



Penalties for substandard VMPs

- VDCA Article 30.3
  - Regarding the entity that deals with (manufactures, imports or repackages; displays or stockpiles to sell or intent to sell substandard drugs, the municipal competent authority is to publicize the (1) name and address of the entity, (2) name and address of the person in charge, (3) names of the drugs and (4) specifics of the offense. Regarding a major or repeat offender, the original license-issuing agency may annul each specific veterinary drug license or dealership license.

Penalties for substandard VMPs

- VDCA Article 36
  - 36.1 The person manufacturing or importing substandard veterinary drugs is subject to a fine of NT$60,000 to NT$300,000.
  - 36.2 The person handling substandard veterinary drugs – repacking, selling, transporting, holding for oneself or others, brokering, assigning to a third party, or displaying/caching with intent to sell – is subject to a fine of NT$30,000 to NT$150,000.

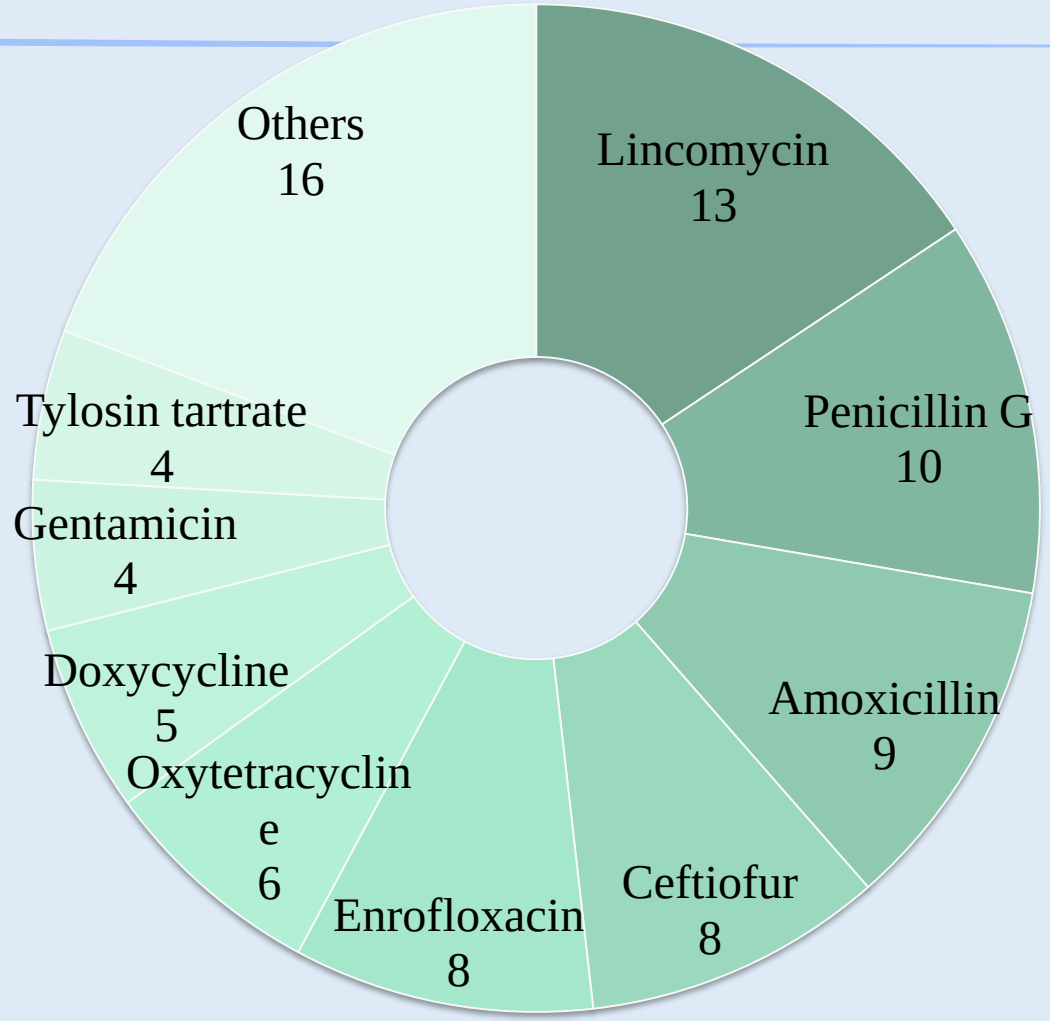
Results of pharmaceutical post-marketing surveillance

Pharmaceuticals	API	Sampling products	Non-compliant products	Compliant rate
Antibiotics		**83**	**4**	**95.18%**
	Penicillin G		3	
	Doxycycline		1	
Others		**285**	**3**	**98.95%**
	Oxytocin		1	
	Disinfectant		2	
Total		**368**	**7**	**98.10%**

Reference period: Jan 1st to Dec 31th, 2019

Composition of antibiotic samples

Others	No.
Kanamycin	3
Trimethoprim	3
Cephalexin	2
Erythomycin	2
Florfenicol	2
Ampicillin	1
Colistin	1
Tiamulin	1
Tilmicosin	1



Reference period: Jan 1st to Dec 31th, 2019

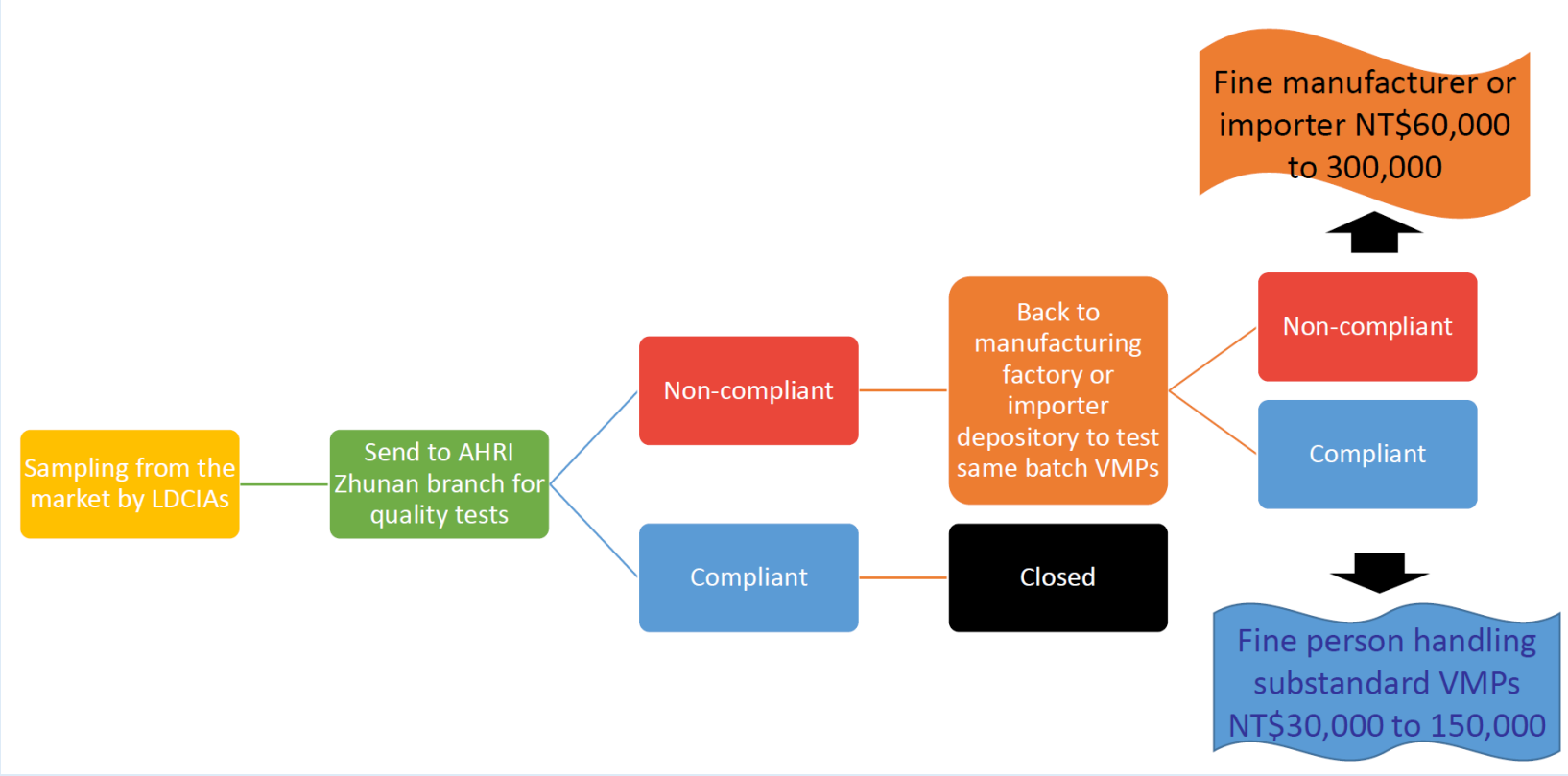
Non-compliant pharmaceuticals

License No.	API	Batch No.	Dosage	Non-compliant cause
00146	Penicillin G	75P716	Suspended injection	API <90% labeled content
00146	Penicillin G	Y03-0011	Suspended injection	API <95% labeled content
05564	Penicillin G	8230912	Suspended injection	API <95% labeled content
07934	Doxycycline	JAC005P	Powder	API <95% labeled content
06240	Oxytocin	801019	Injection	No API
02455	Disinfectant	194001	Solution	pH value < specification
02455	Disinfectant	194002	Solution	pH value < specification

Reference period: Jan 1st to Dec 31th, 2019

Non-compliant pharmaceuticals

- Products in violation of the regulations were sent to the LADIAs for further investigations and/or legal actions



Results of biological post-marketing surveillance

Assays/vaccines	Livestock	Poultry	Compliant rate
Efficacy	13	2	100%
Antigen content	12	26	100%
Live cell count (bacteria)	0	2	100%
Total	25	30	100%

Reference period: Jan 1st to Dec 31th, 2019

Interventions for substandard VMPs

- VDCA Article 29
  - (1) if it is made domestically and – upon inspection – can be modified and made usable, the municipal competent authority shall send personnel to supervise the original manufacturer to modify the drug before a set deadline;
  - (2) if it is imported with approval, the authority shall have it sealed and put in custody while the central competent authority orders the importer to initiate a goods-for-return process with the original overseas manufacturer.

Interventions for substandard VMPs

- VDCA Article 43
  - Substandard veterinary drugs uncovered under this Act – if not modified or returned by a deadline set according to Article 29 – may be confiscated for destruction.

Summary

- Regular inspections of VMPs manufacturing plants are conducted to secure the quality control for production.
- Post-marketing surveillance is implemented to ensure VMPs quality in the market and continuously supported by annual projects.
- Manufactured and imported biologicals are requested for batch-by-batch sample testing, guaranteeing 100% compliant rate of biologicals in the market.

Questions