

A Study Visit on Registration Policies of Veterinary Vaccines



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Outline

- **Motivation and Objectives**
- **Visiting Countries and Organizations**
- **Expected Outcomes**
- **Current Situation of Veterinary Vaccine Production in Taiwan**
- **Discussion Topics**

Motivation and Objectives

- EU and USA are the main markets and production countries of veterinary vaccines. In order to improve Taiwan's registration system, we plan to understand the aforementioned countries' registration requirements of veterinary vaccines, especially new veterinary immunobiologics for future reference.

Visiting Countries and Organizations

- **UK**
 - European Medicines Agency
- **USA**
 - Center for Veterinary Biologics

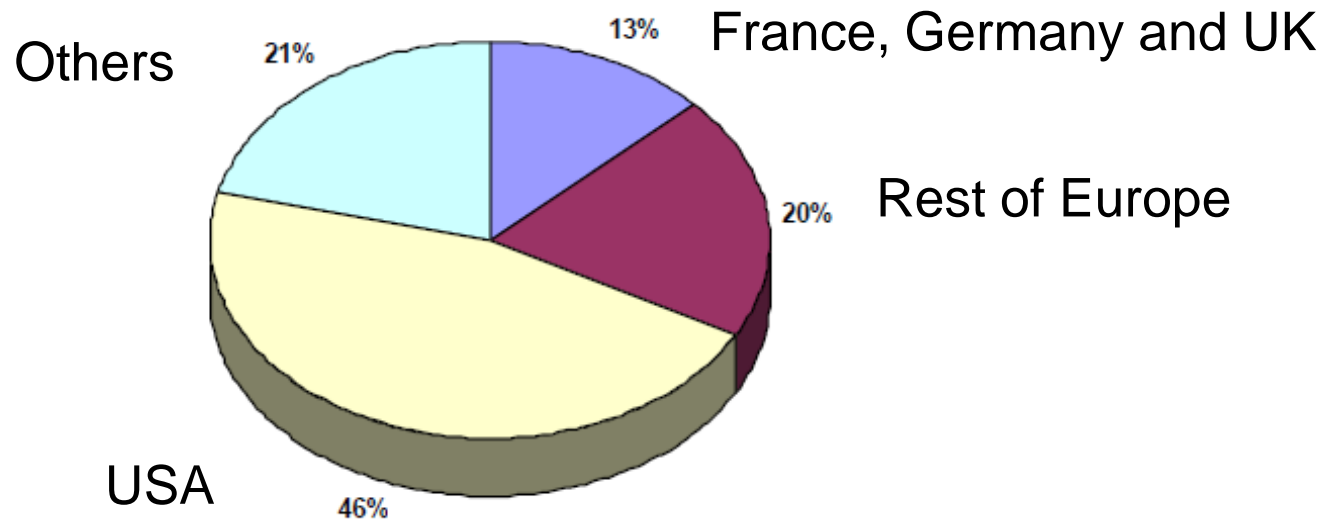
Expected Outcomes

- **To understand:**

- Mission, work, organization, personnel of veterinary vaccine authorities. (CVB & EMA)
- Registration requirements and procedure for veterinary vaccine registration.(CVB & EMA)
- Management, risk assessment, and registration requirements and procedure for gene-modified veterinary biologics. (CVB & EMA)
- Policy and registration requirements for veterinary vaccines indicated for minor use/minor species. (CVB & EMA)
- Does the authority issue any veterinary biologics license for export only. If yes, what are the policy and registration requirements for veterinary biologics for export only. (CVB & EMA)
- Registration requirements and procedure for veterinary biologics, e.g. hormone, protein, peptide and cytokine. (EMA)
- Registration requirement differences between centralized, mutual-recognition and decentralized procedure for veterinary medicinal products.(EMA)

Current Situation of Veterinary Vaccine Production in the World

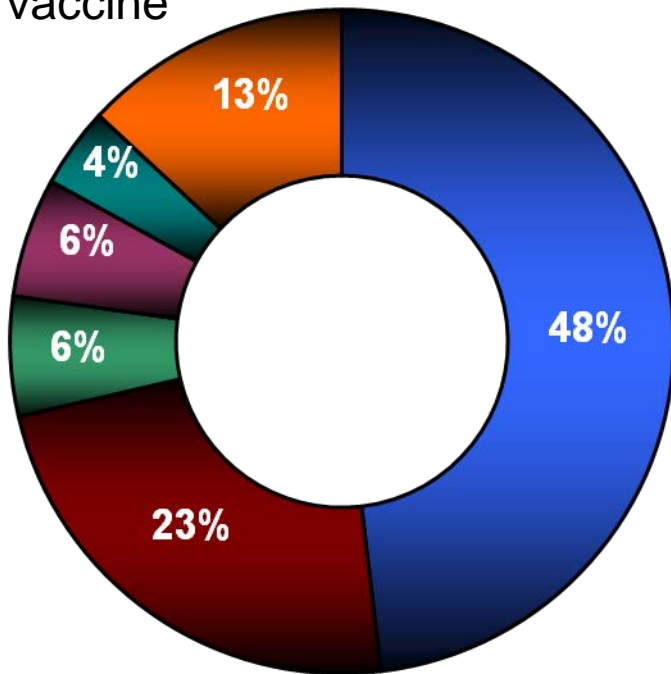
- According to the estimates of Biotechnology Associates, the global market for veterinary vaccines was about USD 4.2 billion in 2010 and the research company predicts this figure to reach USD 6.2 billion in 2017.
- Veterinary Vaccine Market by Geography, 2010:



Source : TriMark Publication

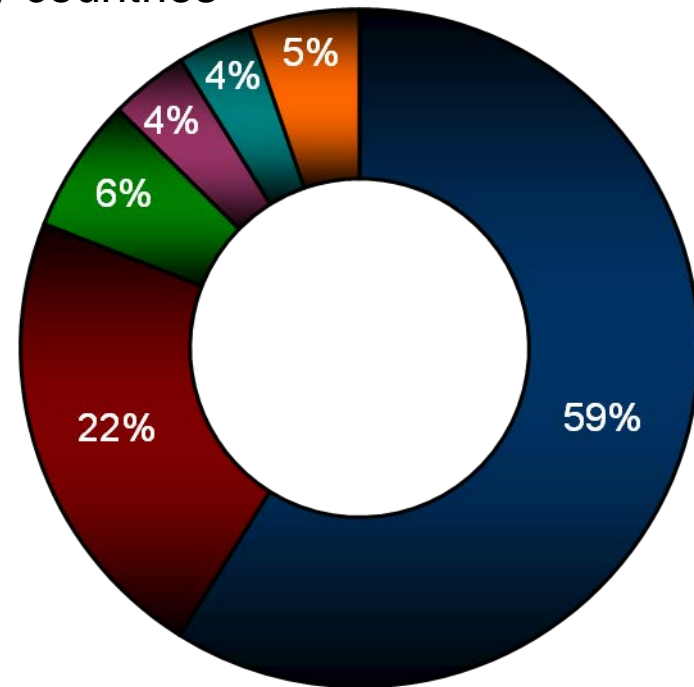
Current Situation of Veterinary Vaccine Production in Taiwan

Import value percentage for 2011 by countries, excluding FMD vaccine



- USA
- Netherlands
- France
- Italy
- Hungary
- Others

Export value percentage for 2011 by countries



- Spain
- Malaysia
- Japan
- Philippines
- Thailand
- Others

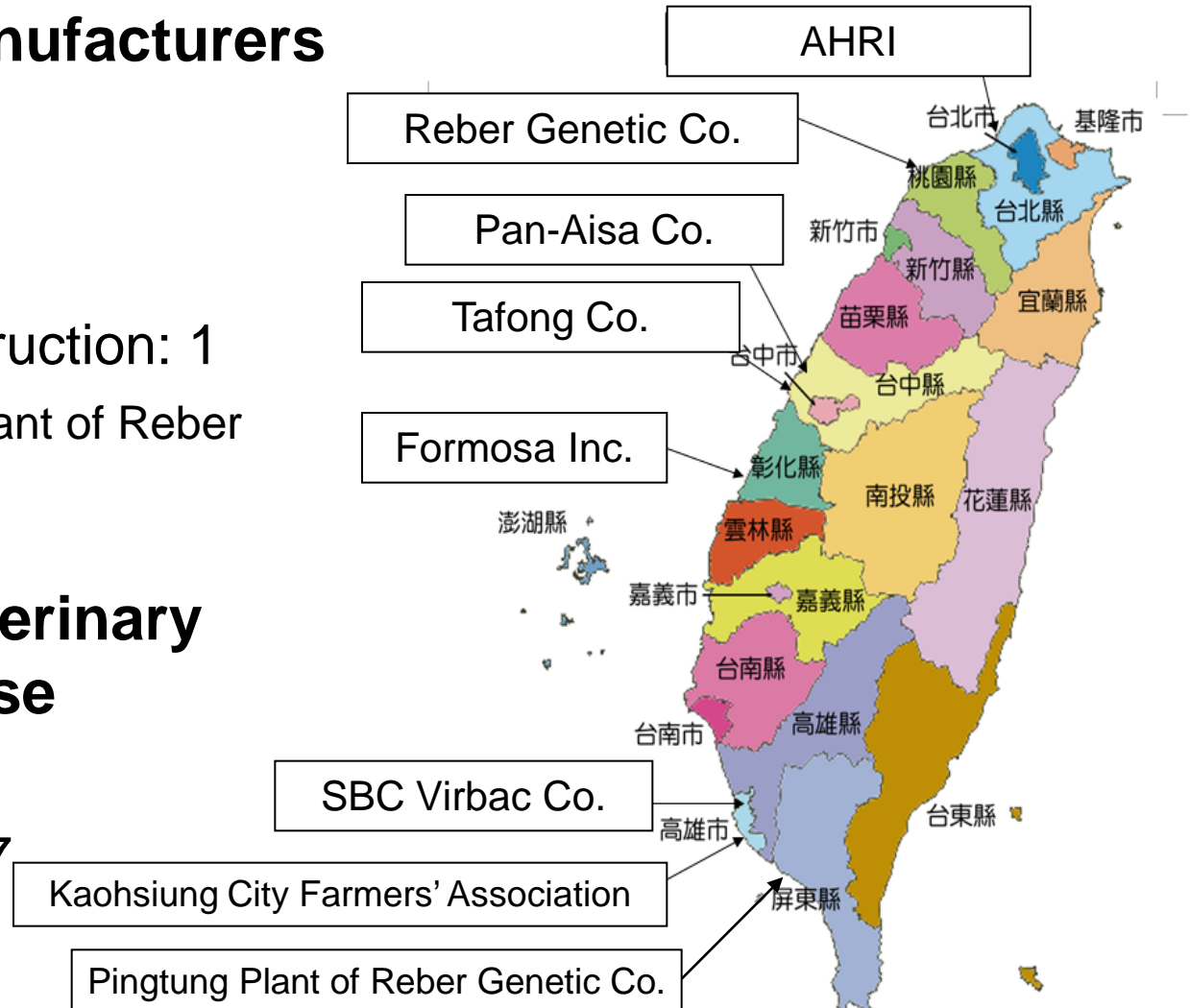
Current Situation of Veterinary Vaccine Production in Taiwan (cont. 1)

- **Number of Manufacturers**

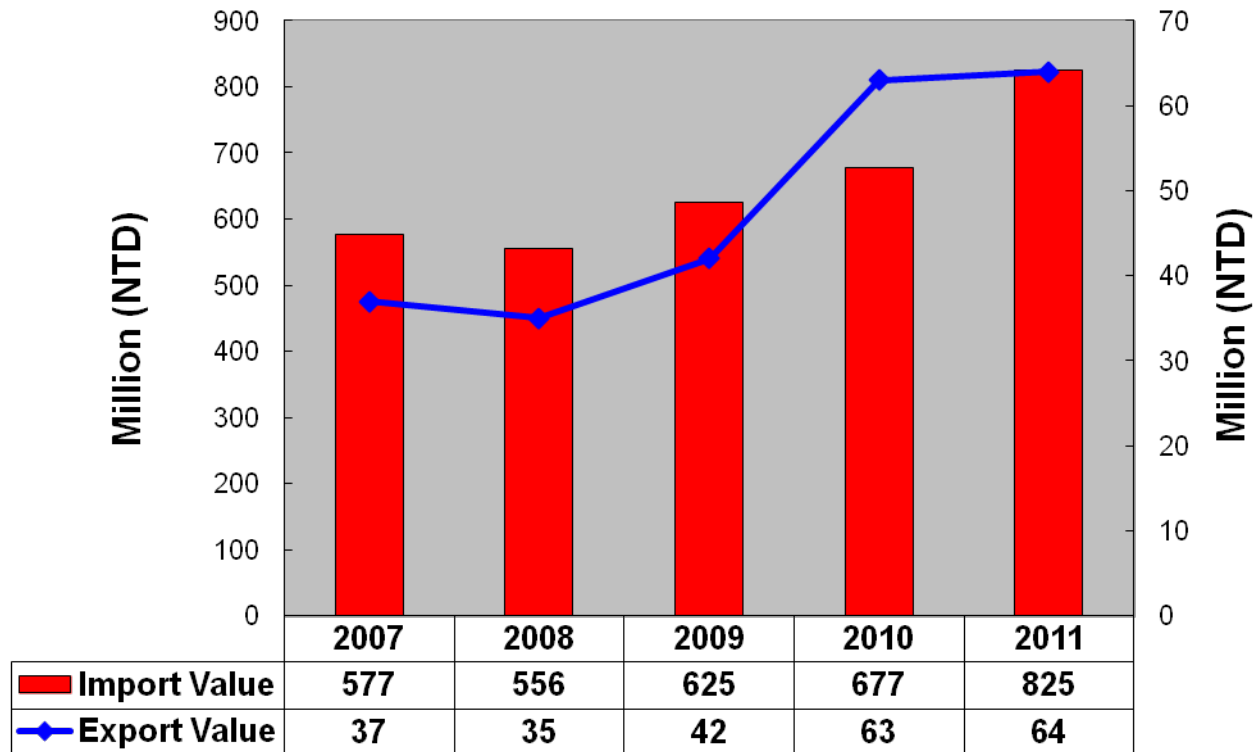
- Private: 6
- Public: 1
 - AHRI
- Under Construction: 1
 - Pingtung Plant of Reber Genetic Co.

- **Number of Veterinary Vaccine License**

- Local : 220
- Foreign : 467



Current Situation of Veterinary Vaccine Production in Taiwan (cont. 2)



Million NTD

- ◆ The Taiwan market for veterinary vaccines is about 2.2 billion NTD. About NTD 0.22~3.3 billion comes from local products.
- ◆ The export value is NTD 37,220,000 in 2007, increasing to 63,840,000 NTD in 2011.

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 3)

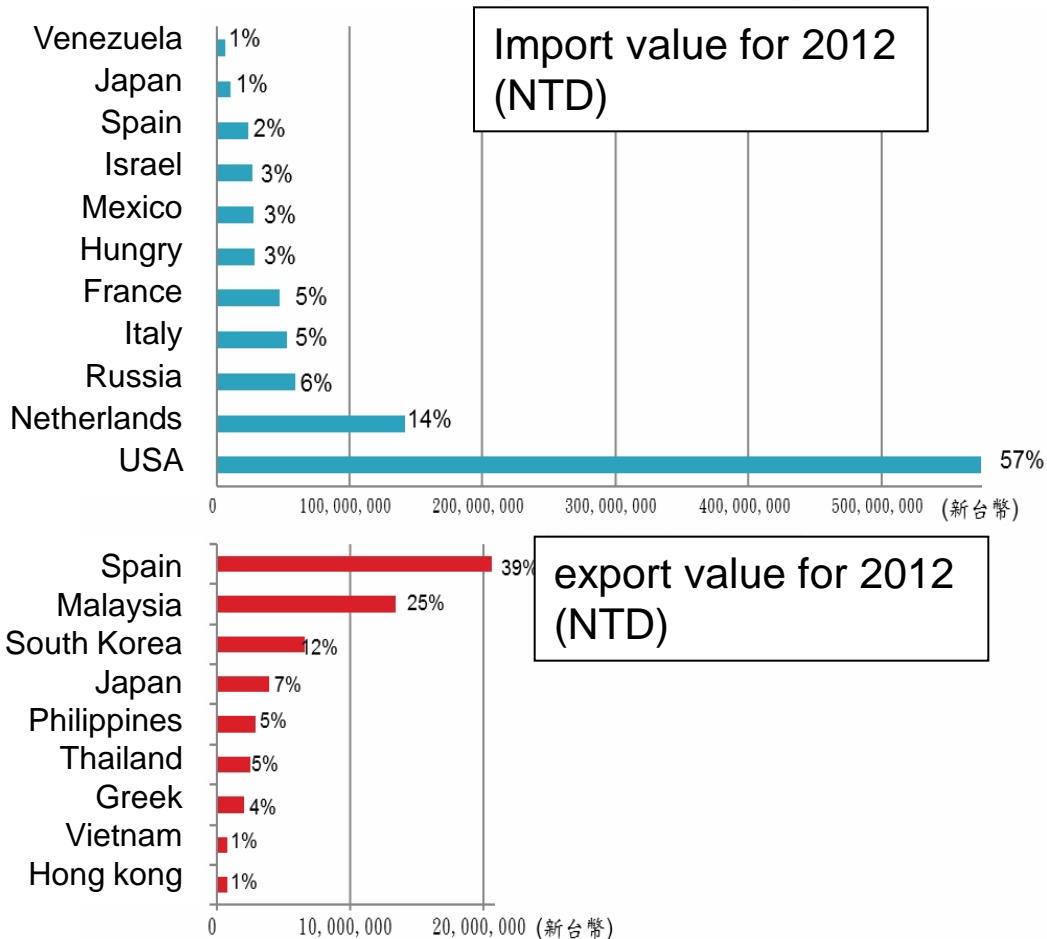
Units : NT\$ million

Items	2011		2012			
	Value of export	Value of import	Value of export	Value of import	Value of Export (Growth) (%)	Value of import (Growth) (%)
FMD vaccine	0.0	33.3	0.0	59.5	0%	78.7%
Other veterinary Vaccines	63.8	792.1	53.5	946.3	-16%	19.5%

- ❑ Importing growth rate of FMD vaccine is about 80%.
- ❑ Importing growth rate of other veterinary vaccines is about 20%, exporting growth rate is -16%
- ❑ The factors of low exporting rate are:
 - ❑ Old production facilities
 - ❑ Small production scale
 - ❑ Legislation of vaccine registration in importing countries
 - ❑ Animal disease distribution, etc.

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 4)

- In 2012, the top five of import countries were USA, Netherlands, Russia, Italy and France. The top five export countries were Spain, Malaysia, South Korea, Japan and Philippines.
- There is room for improvement of export for Taiwan.



Source : Customs Administration and TASTRLMA

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 5)

- **The Top 5 Veterinary Vaccines Produced in Taiwan**

- **Swine**

- Hog cholera
 - Porcine reproductive and respiratory syndrome
 - Swine Erysipelas
 - Actinobacillus pleuropneumonia
 - Pseudorabies

- **Poultry**

- Newcastle disease
 - Infectious coryza
 - Infectious bursal disease
 - Infectious bronchitis
 - Avian pox

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 6)

Research Topics for Veterinary Vaccines in Taiwan

- **Swine**
 - Actinobacillus pleuropneumonia, Atrophic rhinitis, Pseudorabies, Hog cholera, Japanese encephalitis, Porcine teschovirus, Salmonellosis, Porcine circovirus, Porcine reproductive and respiratory syndrome
- **Poultry**
 - Newcastle disease (genotype 7), Infectious bronchitis, Infectious bursal disease
- **Fowl**
 - Duck viral hepatitis, Riemerella anatipestifer
- **Aquatic animals**
 - Iridovirus, Nervous necrosis virus, Vibriosis, Streptococcosis

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 7)

- **Free Economic Pilot Zones (FEPZs) in Taiwan**
 - FEPZs are trial zones for a free economy, with liberalization, internationalization and forward vision as their defining concepts. In FEPZs, all restrictions on the flow of goods, people, capital, information and knowledge are greatly relaxed, and market opening is carried out.
 - **Key ideas are:**
 - Liberalization
 - Internationalization
 - Forward looking-Choosing industrial activities that possess development potential and demonstrational functions, and that are able to create more economic benefits. (e.g. animal vaccine & aquarium fish)
 - **Ultimate Goal:** Taiwan will eventually become a free trade island

Current Situation of Veterinary Vaccine Production in Taiwan (cont. 8)

- **Progress of FEPZs**
 - The Ping-tung Agricultural Biotechnology Park (PABP) devotes great efforts to enlist business in recent year. PABP has signed a cooperation contract with Lohmann Animal Health GmbH & co. KG, which was the top 4 company in poultry vaccine production, on July 8th, 2013 (vaccine of *Mycoplasma hyopneumoniae*).
 - Many big agriculture-related companies are evaluating to station in FEPZs. It may be useful to promote expansion of the contract production areas. We also hope it could promote our veterinary vaccine products to international markets, especially in SEA countries.



**Thank you
for your
attention!**

