Veterinary Vaccine Registration in Thailand

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Outline

- Laws and Regulations for Veterinary Vaccine
- Drug Registration Procedures
- Technical Data Needed for Approval
- Lot Release Approval

LEGAL BASIS

- **Article 79** of Drug Act B.E.2510 clearly defines that no drug can be manufactured in or imported into the Kingdom of Thailand unless it obtains a marketing authorization from Thai Food and Drug Administration (TFDA).

- **Article 79.** Any person licensed to produce or import drugs who wished to produce or import drugs whose modern drugs or traditional drugs or traditional drugs is required first to apply to the competent officer for registration of the formula. Upon receipt of certificate of formula registration, the Drug may be produced or imported.

Terminology of Biological Products

The products are manufactured by;

- Growth of strains of microorganism and eukaryotic cells
- Extraction of substances from biological tissue including human, animal, and plant tissue (allergen)
- Recombinant DNA or rDNA techniques
- Hybridoma techniques
- Propagation of microorganisms in embryo or animal
- Derived from blood and plasma

Registration Procedures

- Step 1 : Application for the permission to import or manufacture drug sample intended to be registered.
  - Required Documents
    - Application form to be completely filled by authorized licensee
    - Certificate of Free sale, GMP (In case of imported drug)
    - Drug formula
    - Drug labeling and packaging

- Step 2: Application for the approval of granted credential certificate.

Submission Documents

- Form (Kor Tor Yor 3)
  - Available through Thai FDA website
  - Administrative Documentation Package
  - Technical data for approval
    - Quality documentation
    - Efficacy documentation
    - Safety documentation
  - Submission fee 1000 Thai baht+ Evaluation fee 123,000 Thai bath
  - Timelines 160 working days

Kor Tor Yor 3

Administrative Documentation

- Application form (MA-1)
  - Name of Product, Name of active substance and excipients
  - Pharmaceutical form, Strength
  - Name and address of the applicant/Importer
  - Name and address of the manufacturers and the sites involved in the different stages of the manufacturers, testing and release
- A package insert
- A proposed labelling
- Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (COPP)
- Applicant declarations and Authorization Letter
- Copy of Licensee Certificate

Quality documentation

- Composition of the product
- Method of preparation: manufacturing method, in-process control tests and validation incl. batch analysis
- Starting materials
- Adjuvants and excipients: specifications, suitability and safety data
- Control tests during the manufacturing process
- Control tests on finished product
- Batch-to-batch consistency
- Stability of the finished product

Safety documentation

Laboratory Studies

- Safe administration of a single dose/ overdose
- Special requirements for live vaccines
  - Spread of the vaccine strain
  - Dissemination in the vaccinated animal
  - Reversion to virulence of attenuated vaccines

Field Studies

Efficacy documentation

Laboratory Trials

- Well-controlled laboratory conditions by challenge

Field Trials

- Both safety and efficacy may be investigated in the same field study
- Efficacy items that cannot be studied well under laboratory conditions
- At least cover major uses: most critical route, most relevant of target species

- Standard/Requirements and Recommendations
  - Other relevant International Guidelines (WHO, EMA, VICH)

VICH guidelines available- Biologically

- GL 17: Stability Biotechnological/Biological Veterinary Medicinal Products
- GL 25, 26: Testing of residual formaldehyde, residual moisture
- GL 34: Test for the detection of Mycoplasma contamination
- GL 40: Test procedures and acceptance criteria for new active substances and products: Biotechnological/Biological Veterinary Medicinal Products
- GL 41: Examination of live vaccines in target animals for absence of reversion to virulence
- GL 44: Target animal safety testing for veterinary live and inactivated vaccines
- GL 50: Criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use

Issued consider after getting MA

- Lot release certificate
  - Certificate of Lot release (issued by NRAs or Qualified person)
  - Details of vaccine transportation from Manufacturer to Thailand

Questions