Veterinary Medicinal Product Control in Thailand

Legal Control and Regulation on Veterinary Medicinal Products

Manufacture, importing, registration and distribution of human and animal drugs are regulated under Drug Act 1967 (B.E. 2510) and its six revised versions.

Definition of Drugs in Drug Act 1967 (B.E. 2510)

"**Drugs**" means:

(1) Substances recognized by pharmacopoeias notified by the Minister.

(2) Substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness.

(3) Substances which are pharmaceutical substances or semi-pharmaceutical substances.

(4) Substances intended to affect the health, structure of function of the human or animal body.

Substances under (1) (2) or (4) shall not include:

(a) Those intended for use in agriculture or industry as notified by the Minister,

(b) Those intended for use as food for human, operating goods, medical apparatus, cosmetics or device for use in the practice of medicine and a component thereof,

(c) Those intended for use in science laboratory for research, analysis or verification of disease which in not directly done to the human body.

The Drug Act comprises the following important features.

I. Drugs are classified into two major groups – modern and traditional drugs.
Modern Drugs are further divided into four categories, namely (1) household remedies of which sale requires no licence; (2) ready – packed drugs sold in stores by nurses or other medical professions; (3) dangerous drugs; and (4) specially controlled drugs. Drugs which may possess a potentially harmful effect to health, if misused, will be enlisted in the last category of which sale requires a prescription. Dangerous drugs can be bought without

prescription but must be dispensed by pharmacists or veterinarians/pharmacists for veterinary medicinal products.

Traditional drugs are the group of those intended to be used in indigenous treatment as monographed in the official pharmacopoeia of traditional medicines or those or declared by the Minister of Public Health as traditional drugs or those permitted to be registered as traditional drugs. The control and registration of drugs in this group are less stringent than those of the modern drugs.

II. The Ministry of Public Health is authorized in the Government Gazettes, the list of specially – controlled drugs, the list of dangerous drugs as well as the lists of particular drugs requiring additional labeling (e.g. expiration date, warning, etc.)

III. Licensing for manufacturing, importation and sale of drugs is required by law. Applications for permission and licences are in accordance with the rules, measures and conditions as prescribed in the Ministerial Regulations.

IV. Duties of licensees and pharmacists on duty at the place of production, importation or sale of drugs are also described including duty of veterinarian at the place of sale of veterinary drug. For instance, a licensee who produces modern drugs must have each batch of finished products analyzed for quantities of their active constituents before the products can be released to the market.

V. Licensees must register the drugs before they can manufacture or import them. Details of the drugs and their formulas, as being registered, cannot be altered without approval or permission from the authorities.

VI. The Minister is empowered to either suspend or revoke the licence if the licensee vidate the Act.

Licensing

The Drug Act requires that any persons who wish to sell, produce or import drugs into the Kingdom must obtain licences from the licensing authorities. Bureau of drug control under Food and Drug administration office, Ministry of Public Health is the licensing authority for manufacture, import and selling of drugs in Bangkok metropolitan and its territories. Provincial

Health Offices are the licensing authorities for manufacture and import of traditional drugs and sale of drugs in other provinces.

Application for a licence must be submitted to the licensing authority. Buildings and facilities will then be inspected. A licence will be given after the inspection has confirmed that the applicant has adequate capabilities of doing such business, and he/she can secure appropriate facilities and personnel for that purpose.

There are nine different categories of licences:

- Licence to produce modern drugs
- Licence to sell modern drugs
- Licence to as a wholesaler of modern drugs
- Licence to sell ready – packed modern drugs which are neither in the categories of dangerous nor specially – controlled drugs
- Licence to sell ready – packed modern veterinary drugs
- Licence to import modern drugs
- Licence to manufacture traditional drugs
- Licence to sell traditional drugs
- Licence to import traditional drugs

Structure of the Veterinary Medicinal Products Control

Thai FDA is in charge of licensing including GMP inspection and monitoring the drug manufacturing, importing distributing, marketing and supply to ensure that they are all conformed to Drug Act.. Moreover, FDA also empowers relevant officials of Department of Livestock Development (DLD) and Department of Fisheries (DOF) to enforce the Drug Act relating to post-marketing of veterinary drugs / biologics.

In addition to the officers of Thai FDA, the officer authorized by drug law from the Ministry of Public Health as well as from the Ministry of Agriculture and Cooperative can also inspect premises for drug manufacture, importing, selling or any premises suspected to violate the law and can take samples to conduct an analysis.

Thai FDA Website https://www.fda.moph.go.th/Pages/HomeP_D2.aspx

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The main roles responsibilities of Thai – FDA and DLD can be summarized into 2 parts:

1. **Pre-marketing control of veterinary medicinal products** : directly control by Drug Control Division, Thai – FDA, Ministry of Public Health and Bureau of Drug and Narcotic, Department of Medical Science, Ministry of public health.

   This part of the roles deal mainly on issuances of notifications, setting up quality standard, inspection and testings before approval and granting of licences for business operation and registration certificates of controlled products.

2. **Post-marketing monitoring and surveillance of veterinary medicinal products** :

   responsible both by Thai – FDA and Department of Livestock development.

   Monitoring and checking whether the approved products in the domestic market really conform to the proclaimed quality and safety. The post – marketing activities also cover surveillance programs to watch for unforeseen hazards, abuse, or any unsafe for use cases.

Department of Livestock Development (DLD) also set

1. Animal Feed and Veterinary Products Control Division (AFVC)
2. Veterinary drug assay division in Bureau of Quality Control of Livestock Products
3. Veterinary biologic assay division in National Animal Health Institute to co-operate with Thai FDA on veterinary drugs/biologics supervision.

- Department of Livestock development , Ministry of Agriculture and Cooperatives responsible for control
  - **Manufacturing of medicated feed**
  - The use of drug , vaccine and medicated feed at farm
  - post-marketing surveillance of veterinary drugs / vaccine
  - pre-marketing control of veterinary biological products (when requested by Thai FDA)

DLD also be member of Drug Committee and Veterinary drug sub-committee at Thai FDA

The Control of Drug Using at Farm

With respect to the Ministerial Notification of Ministry of Agriculture and Cooperatives on Livestock Farm Standard of Thailand, the livestock standard farms must have the veterinary supervisor to look after animal health. the administration of veterinary medicine to animals must be prescribed by farm veterinary supervisor as regulated by the Ministerial Notification of Ministry of Agriculture and Cooperatives on Livestock Farm Standard of Thailand. Farm veterinary supervisor must have his prescription records kept at least two years, and presented when required by the DLD.

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