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PRESIDENT OF THE REPUBLIC OF INDONESIA

GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA NUMBER 78 OF 1992 CONCERNING VETERINARY MEDICINES

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Considering : a. whereas, in order to further improve the health and production of livestock, it is necessary to provide adequate veterinary medicines in terms of both quantity and quality in the manufacture, supply and distribution;

b. whereas, with technological advances in the veterinary medicines, there are currently many new types of veterinary medicines found the regulation of which has not been accommodated in Government Regulation Number 17 of 1973 concerning Manufacture, Distribution, Supply, Use of Vaccines, Sera, and Diagnostic Materials for Animals;

c. whereas, in connection with this matter, it is deemed necessary to re-regulate the

provisions regarding veterinary medicines by a Government Regulation;

In view of : 1. Article 5 paragraph (2) of the 1945 Constitution;

2. Law Number 6 of 1967 concerning Basic Provisions on Livestock and Veterinary Health (State Gazette of 1967 Number 10, Supplement to the State Gazette Number 2824);

3. Government Regulation Number 15 of 1977 concerning Rejection, Prevention, Eradication and Treatment of Animal Diseases (State Gazette of 1977 Number 20, Supplement to the State Gazette Number 3101);

4. Government Regulation Number 22 of 1983 concerning Veterinary Public Health (State Gazette of 1983 Number 28, Supplement to the State Gazette Number 3253);

5. Government Regulation Number 17/1986 concerning the Authority for Regulation, Fostering and Industrial Development (State Gazette Number 23/1986, Supplement to the State Gazette Number 3330);

DECIDED:

To stipulate : GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA CONCERNING VETERINARY MEDICINES.

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Government Regulation, the following terms shall have meanings assigned to them below:

1. Veterinary medicines mean medicines that are specifically used for animals.
2. Manufacture means the process of processing, mixing and changing the form of raw materials for veterinary medicines into veterinary medicines.
3. Supply means the process of procurement and/or ownership and/or possession and/or storage of veterinary medicines in a place or room with a view to distribution.
4. Distribution means the process of activities with regard to trade, transportation and delivery of veterinary medicines.
5. Business Entity means a state-owned or regionally owned, private enterprises or cooperatives.
6. Minister means the Minister in charge of veterinary health.

Article 2

(1) The Government conducts research and development activities on veterinary medicines and raw materials for veterinary medicines.

(2) The Government encourages and fosters private parties to conduct research and development activities for veterinary medicines and their raw materials.

CHAPTER II

PURPOSE OF USE, GROUP AND CLASSIFICATION OF VETERINARY MEDICINES

Article 3

Veterinary medicines according to their intended use are used for:

a. determining the diagnosis, preventing, curing and eradicating animal diseases;

b. reducing and eliminating symptoms of animal diseases;

c. helping soothe, numbing, euthanizing, and stimulating animals;

d. eliminating abnormalities or beautifying the bodies of the animals;

e. spurring improvement in the quality and production of animal products;

f. improving animal reproduction.

Article 4

(1) Veterinary medicines are classified in biological, pharmaceutical and premix preparations.

(2) In addition to the classes of veterinary medicines as referred to in paragraph (1) there are also classes of natural medicines.

(3) Further provisions regarding natural medicines as referred to in paragraph (2) shall be regulated by the Minister.

Article 5

(1) Biological preparations as referred to in Article 4 paragraph (1) are manufactured through biological processes in animals or animal tissues to cause immunity, diagnose diseases or cure diseases with an immunologic process.

(2) Pharmaceutical preparations as referred to in Article 4 paragraph (1) include, among others, vitamins, hormones, antibiotics and other chemotherapeutics, antihistaminic drugs, antipyretics, anesthetics used based on pharmacological performance.

(3) Premix preparations as referred to in Article 4 paragraph (1) include animal feed additives and animal feed supplements mixed in animal food or animal drinks.

Article 6

(1) Based on the classification of hazards caused in its use, veterinary medicines are divided into:

a. prescription medicines, veterinary medicines which if the use is not in accordance with the provisions can cause danger to animals and/or humans who consume the animal products.

b. limited over-the-counter medicines, prescription medicines for animals that are treated as over-the-counter medicines for certain types of animals with provided that they are supplied in number, dosage rules, dosage forms and certain ways of use and given a special warning sign.

c. over-the-counter medicines, veterinary medicines that can be used freely by everyone in animals.

(2) Further provisions regarding the classification of veterinary medicines as referred to in paragraph (1) shall be stipulated by the Minister.

Article 7

(1) The use of prescription medicines must be carried out by veterinarians or other people with instructions from and under the supervision of veterinarians.

(2) The use of limited over-the-counter medicines or over-the-counter medicines is to be carried out by everyone by following the prescribed usage instructions.

CHAPTER III

MANUFACTURE, SUPPLY AND DISTRIBUTION OF VETERINARY MEDICINES

Article 8

(1) The manufacture of veterinary medicines includes the processes of processing raw materials, semi-finished materials, and/or finished materials into ready-to-use veterinary medicines.

(2) The manufacture of veterinary medicines as referred to in paragraph (1) must meet the requirements regarding raw materials, locations, buildings, room settings, equipment, experts, and the manufacturing process.

(3) Further provisions regarding the requirements as referred to in paragraph (2) shall be determined by the Minister.

Article 9

(1) Veterinary medicines that can be supplied and/or distributed are only duly registered veterinary medicines.

(2) Further provisions regarding registration as referred to in paragraph (1) shall be determined by the Minister.

Article 10

(1) Veterinary medicines in inventory and/or distribution must be packaged in certain containers and/or packaging that are equipped with tags and marked and labeled with "medicine for animals only" which can be clearly read.

(2) The marking as referred to in paragraph (1) must also be included in the accompanying brochure.

(3) Further provisions regarding the marking requirements on packaging, containers, wrappings, tags and brochures as referred to in paragraph (1) and paragraph (2) shall be determined by the Minister.

Article 11

(1) Business entities and individuals are prohibited from supplying or distributing medicines that are not suitable for use.

(2) Veterinary medicines that are not suitable for use as referred to in paragraph (1) include:

a. veterinary medicine preparations that do not pass quality testing based on quality standards

set by the Government, at the time of registration, before distribution and in distribution;

b. veterinary medicine preparations that are not tested for quality, whereas according to the provisions they must be tested;

c. veterinary medicine preparations that have experienced physical changes;

d. expired veterinary medicine preparations.

CHAPTER IV

REGISTRATION AND TESTING OF VETERINARY MEDICINE QUALITY

Article 12

(1) In the framework of quality control, veterinary medicines to be distributed must have passed the quality testing conducted for registration.

(2) Veterinary medicines that have been registered can be re-tested for quality at any time.

(3) Further provisions regarding the terms and procedures for testing for registration of veterinary medicines as referred to in paragraph (1) shall be determined by the Minister.

Article 13

(1) Testing of quality of veterinary medicines as referred to in Article 12 shall be conducted based on quality standards stipulated by the Government.

(2) Quality testing as referred to in paragraph (1) shall be carried out by an agency appointed by the Minister.

Article 14

(1) Fees required for registration and testing of quality of veterinary medicines as referred to in Article 9 and Article 12 shall be borne by the owner of veterinary medicines, the amount of which is to be determined by the Minister.

(2) The procedures for collection and the amount of registration fees shall be determined by the Minister upon approval by the Minister of Finance.

(3) Registration fees as referred to in paragraph (1) shall constitute state revenue and must be deposited to the State Treasury.

CHAPTER V

LICENSING

Article 15

(1) Manufacture and/or supply and/or distribution of veterinary medicines by business entities or

individuals shall be carried out based on business licenses granted by the Minister.

(2) Further provisions regarding the terms and procedures for granting of business licenses as referred to in paragraph (1) shall be determined by the Minister.

Article 16

(1) Research institutions or higher education institutions conducting research and development of veterinary medicines for the benefit of science, and Government agencies which in carrying out their duties are technically related to veterinary medicines may perform their activities without permission.

(2) Further provisions regarding the manufacture and/or supply and/or distribution of veterinary medicines carried out by research institutions, higher education institutions and Government agencies as referred to in paragraph (1) shall be stipulated by the Minister.

Article 17

(1) A business entity or individual holding a business license for manufacturing and/or supplying and/or

distributing veterinary medicines can expand its business.

(2) Expansion of the business of manufacturing veterinary medicines as referred to in paragraph (1) shall be in the form of:

a. increasing the number of production units; and/or

b. increasing the number of production equipment; and/or

c. adding the types of veterinary medicines manufactured.

(3) Expansion of the business of supplying and/or distributing veterinary medicines shall be in the form of:

a. adding types of veterinary medicines to be supplied and/or distributed; and/or

b. increasing the area of supply and/or distribution of veterinary medicines; and/or

c. opening branches of business for the supply and/or distribution of veterinary medicines in other places.

Article 18

A business license that has been granted to a business entity or individual as referred to in Article 15 shall expire because:

a. the business entity concerned is dissolved;

b. the holder of an individual business license passes away, and his/her heir does not state his/her intention to continue the business within 90 (ninety) days after the death of the business license holder;

c. it is revoked by the Minister in case:

1. it does not conduct business activities within 1 (one) year after the business license is granted;

2. it no longer conducts business activities for 1 (one) consecutive year;

3. it does not meet the conditions stated in the business license and the applicable laws and regulations;

4. the business license has been transferred without a written approval from the Minister.

CHAPTER VI

SUPERVISION

Article 19

(1) The Minister shall supervise the manufacture, supply, distribution and use of veterinary medicines.

(2) In the context of carrying out supervision as referred to in paragraph (1) the Minister may appoint a veterinary medicine supervisor to carry out veterinary medicine supervision.

(3) The veterinary medicine supervisor as referred to in paragraph (2) shall be appointed and dismissed by the Minister.

Article 20

(1) In carrying out veterinary medicine supervision as referred to in Article 19, a veterinary medicine supervisor is authorized to:

a. check the fulfillment of provisions under the business license for the manufacture, supply and distribution of veterinary medicines.

b. conduct an examination of how to manufacture good veterinary medicines;

c. conduct an examination of veterinary medicines, facilities and places of storage in the supply and distribution, including the equipment and means of transportation;

d. check the use of veterinary medicines;

e. take samples of raw materials and veterinary medicines for testing their efficacy and safety.

(2) If in the examination as referred to in paragraph (1) an irregularity is found, the Minister or the veterinary medicine supervisor may instruct to:

a. temporarily stop the animal medicine manufacturing activities;

b. prohibit the distribution of the veterinary medicines;

c. withdraw the veterinary medicines from distribution;

d. stop the use of veterinary medicines which are not in accordance with the provisions.

(3) Further provisions regarding the terms and procedures for supervision as referred to in paragraph (1) and paragraph (2) shall be regulated by the Minister.

CHAPTER VII

TRANSITIONAL PROVISIONS

Article 21

With the enactment of this Government Regulation, all laws and regulations as the implementation of Government Regulation Number 17 of 1973 shall remain in effect, as long as they do not conflict with this Government Regulation or have not been amended or revoked based on this Government Regulation.

CHAPTER VIII

CLOSING PROVISIONS

Article 22

As from the date of entry into force of this Government Regulation, Government Regulation Number 17 of 1973 concerning Manufacture, Supply, Distribution and Use of Vaccines, Sera and Biological Diagnostic Materials for Animals is declared invalid.

Article 23

This Government Regulation shall come into force on the date of promulgation.

For public cognizance, this Government Regulation shall be promulgated by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

on December 24, 1992

PRESIDENT OF THE REPUBLIC OF INDONESIA

signed

SOEHARTO

Promulgated in Jakarta

on December 24, 1992

MINISTER/STATE SECRETARY OF

THE REPUBLIC OF INDONESIA

signed

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PRESIDENT OF THE REPUBLIC OF INDONESIA

ELUCIDATION

TO

GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA

NUMBER 78 OF 1992

CONCERNING

VETERINARY MEDICINES

I. GENERAL

For the successful implementation of national development, development in livestock has an important role as one of the efforts to provide sources of animal protein in the food sector.

To be able to provide good sources of animal protein in terms of both quantity and quality, efforts are needed to increase livestock production. Efforts to increase livestock production cannot be separated from efforts to improve animal health. In addition to dependence on other factors, the supply of adequate veterinary medicines in terms of both quantity and quality is one of the very determining factors in animal health.

The very rapid development in livestock in general and animal health in particular needs to be balanced with the development in veterinary medicines at an equal level.

The development in veterinary medicines in line with the rapid development in animal health as mentioned above needs to be balanced with the best guidance and regulation of the manufacturing, supply, distribution and use activities.

Government Regulation Number 17/1973 concerning Manufacture, Distribution, Supply and Use of Vaccines, Sera and Biological Diagnostic Materials for Animals only regulates some veterinary medicines in the form of biological preparations.

Meanwhile, in an effort to improve animal health, in addition to veterinary medicines that are derived from biological preparations, veterinary medicines from pharmaceutical preparations and premix preparations are also needed. Guidance by the Government to interested parties in the manufacture, supply, distribution and use of veterinary medicines in the broad sense that include biological, pharmaceutical and premix preparations is necessary so that the supply of veterinary medicines to the public can be guaranteed to be smooth at all times in types, adequate quantity and quality and safe in use, with affordable prices for the community. This situation will support efforts to increase livestock production, which is expected to increase incomes of livestock breeders and at the same time improve community nutrition through the availability of animal protein in sufficient

quantity and good quality. Any mistakes in the manufacture, supply, distribution and use of veterinary medicines will have a negative impact on society in general and efforts to increase livestock production in particular.

The scope of guidance and regulation in this Government Regulation covers the activities of manufacturing, supplying, distributing, and using veterinary medicines in the sense of including raw materials which in their original condition have been used as veterinary medicines and their specific purpose in veterinary medicines. Regarding raw materials for veterinary medicines that can be used both for general health needs and for the purposes of veterinary medicines, the guidance is provided in a coordinated and integrated manner by the Ministry of Health and the Ministry of Agriculture.

In addition to the three types of veterinary medicines, natural medicines are also used, which refer to native medicines both from within the country and those from other countries. Taking into account all aspects related to the development of the manufacture, supply, distribution and use of veterinary medicines, it is necessary to make security efforts in the form of provisions that must be adhered to in the manufacturing, supply, distribution, and use of veterinary medicines as well as other technical requirements that must be met

properly by manufacturers, dealers, or use of veterinary medicines.

This Government Regulation regulates the manufacture, supply, distribution and use of veterinary medicines in a broad sense, which include biological, pharmaceutical and premix preparations, and it is an improvement to Government Regulation Number 17 of 1973.

II. ARTICLE BY ARTICLE

Article 1

Number 1

Self-explanatory

Number 2

In the definition, the processing, mixing and changing activities of forms can be cumulative or independent of each other followed by filling and packaging activities.

The definition of raw materials for veterinary medicines in general are all substances or chemicals in the form of active ingredients, additives and auxiliary materials used to manufacture veterinary medicines. However, there are raw materials as active ingredients which when they are not/ not yet mixed with other ingredients are veterinary medicines, if

they have been packaged and labeled "drugs for animals only".

Number 3

The definition of procurement covers domestic and imported production.

Number 4

Self-explanatory

Number 5

Self-explanatory

Number 6

Self-explanatory

Article 2

Paragraph (1) and paragraph (2)

The research and development of veterinary medicines and their raw materials aim to find new technologies related to the process of manufacturing veterinary medicines and their raw materials in order to improve the efficacy and safety of veterinary medicines for animals, as well as the health of people who consume materials derived from animals.

The guidance for research and development of raw materials that can be used for veterinary medicine purposes and for general health purposes is carried out in a coordinated manner

by the Minister and other Ministers in charge of public health.

The Government also encourages and provides assistance to private businesses to conduct research and development of veterinary medicines.

Article 3

Letter a

Diagnosis is all activities, both individuals and groups, in the field and in the laboratory in an effort to determine the type or cause of an animal disease.

Prevention of animal diseases means all actions to prevent the emergence, outbreak and spread of cases of animal diseases.

Cure means all actions taken by administering veterinary medicines to restore animal's physiological condition to normal. Physiology means a condition in which all organs of animal's body can function in a balanced manner.

Eradication of animal diseases means all actions to eliminate the emergence or occurrence, outbreak and spread of cases of animal diseases.

Letter b

Self-explanatory

Letter c

Euthanasia means an attempt by a veterinarian to alleviate the suffering of an incurable, sick animal by killing it.

Letter d

Self-explanatory

Letter e

Self-explanatory

Letter f

The meaning of animal reproduction is animal breeding. Improving animal reproduction means improving various factors that affect animal breeding. For example: suppressing infertility diseases, coping with diseases of large animal breeding organs.

Article 4

Paragraph (1)

Self-explanatory

Paragraph (2)

The group of natural medicines includes native Indonesian (domestic) medicines and native medicines from other countries for animals that do not contain synthetic chemicals and have no clinical data and do not include narcotics or prescription medicines and their efficacy and

use are known empirically (resulting from experiences or own experiments).

Paragraph (3)

Self-explanatory

Article 5

Paragraph (1)

Biological preparations include vaccines, as well as (anti-sera) and biological diagnostic materials.

Vaccine is a biological preparation used to cause immunity to an animal disease.

Sera (anti-sera) is a biological preparation in the form of blood serum containing immune substances derived from animals used to prevent, cure or diagnose diseases in animals caused by bacteria, viruses or other microorganisms with a view to nullifying the toxin power.

Biological diagnostic material is a biological preparation used to diagnose a disease in an animal.

Paragraph (2)

Self-explanatory

Paragraph (3)

The meaning of animal feed supplement is a substance that is naturally contained in animal

feed but the amount needs to be increased through administration in animal feed, for example vitamins, minerals and amino acids.

The meaning of animal feed additive is a substance that is naturally not present in animal feed and its intended use is primarily as a growth booster. A new substance can be used as a feed additive after going through scientific studies, for example certain antibiotics, including bacitracines, virginiamisina and flavomycin.

Article 6

Paragraph (1)

Letter a

The meaning of prescription medicines for animals includes veterinary medicines that contain antibiotics which if used excessively or less than the specified dose will pose a danger of resistance (increased immunity to disease).

Letter b

The meaning of limited over-the-counter medicines for animals includes sulfa (sulfakuinoxalin). Unless there are dosage rules and how to use them, over-the-counter medicines are given special

warning signs such as "do not give to egg laying chickens"

Letter c

The meaning of over-the-counter medicines is medicines that can be used freely because there are no side effects.

Paragraph (2)

The classification of veterinary medicines is based on the results of scientific studies.

Article 7

Paragraph (1)

The meaning of use is any activity that involves the use of veterinary medicines in accordance with their functions and uses.

Paragraph (2)

Self-explanatory

Article 8

Paragraph (1)

Self-explanatory

Paragraph (2)

Self-explanatory

Paragraph (3)

Self-explanatory

Article 9

Paragraph (1)

Supply and/or distribution of veterinary medicines both for veterinary medicines made domestically and for veterinary medicines imported from abroad.

Paragraph (2)

Self-explanatory

Article 10

Paragraph (1)

Packaging is a number that indicates the volume or weight or a certain amount of a veterinary medicine preparation in one container, either wrapped or not wrapped or in several containers in one wrapping.

A container is an object along with a lid that is used to place a veterinary medicine and is in direct contact with the veterinary medicine that it holds, and is not applied.

Wrapping is an object used to wrap a container.

Marking is a statement in the form of writing or sign on a veterinary medicine container and/or wrapping, tag and brochure.

Paragraph (2)

Self-explanatory

Paragraph (3)

Self-explanatory

Article 11

Paragraph (1)

Self-explanatory

Paragraph (2)

Self-explanatory

Article 12

Paragraph (1)

Registration of veterinary medicines to be distributed is made for monitoring the quality of veterinary medicines. Therefore, testing the quality of veterinary medicines is made as a series of registration activities in the context of licensing simplification.

Paragraph (2)

Re-testing the quality of registered veterinary medicines to be carried out at all times is intended to guarantee the quality of the medicines, so that they remain in accordance with the standards set by the Government.

Paragraph (3)

Self-explanatory

Article 13

Paragraph (1)

Self-explanatory

Paragraph (2)

Self-explanatory

Article 14

Paragraph (1)

The costs of registering and testing the quality of veterinary medicines are not solely borne by the Government. Because the registration and testing activities of veterinary medicines are essentially services to the owners of veterinary medicines, the owners of relevant veterinary medicines are charged with the costs of registration and quality testing.

These costs include costs for the purposes of procuring the medicine quality testing materials.

Paragraph (2)

Self-explanatory

Paragraph (3)

Self-explanatory

Article 15

Paragraph (1)

The meaning of business license in this provision is a written statement in a certain form from the Minister or an appointed official that gives the right to the person concerned to do business in manufacturing and/or supplying and/or distributing veterinary medicines.

This license is a special license that is associated with the technical interests of veterinary medicines, in addition to licenses issued by other agencies based on applicable laws and regulations, for example SIUP (Trading Business License).

Paragraph (2)

In determining the conditions and procedures for business licenses, provisions regarding the transfer of business licenses shall also be regulated.

Article 16

Paragraph (1)

Self-explanatory

Paragraph (2)

Self-explanatory

Article 17

Paragraph (1)

Self-explanatory

Paragraph (2)

Letter a

Increasing the number of production units is increasing the preparation forms from the existing ones, for example, it initially only has a powder unit and then it is added with an oral liquid unit.

Letter b

Increasing the number of production equipment certainly results in an increase in installed production capacity.

Letter c

Adding the types of veterinary medicines manufactured means adding the types of medicines based on pharmacological power.

Paragraph (3)

In the context of expanding the business of manufacturing and/or supplying and/or distributing veterinary medicines, the requirements and procedures for obtaining a business expansion license related to the manufacture and/or supply and/or distribution of veterinary medicines can be carried out in various ways, each of which requires different requirements and procedures.

Article 18

Self-explanatory

Article 19

Paragraph (1)

Self-explanatory

Paragraph (2)

Self-explanatory

Paragraph (3)

Self-explanatory

Article 20

Paragraph (1)

Letter a

Self-explanatory

Letter b

The meaning of how to manufacture good animal medicines (good manufacturing practices) is a system related to making veterinary medicine manufacturing including:

1. lay-out;
2. regulating the traffic of people, raw materials and veterinary medicines and related facilities;
3. workforce expertise qualifications;
4. equipment;
5. manufacturing methods, quality testing and storage;
6. quality testing laboratory;
7. storage of raw materials and veterinary medicines.

Letter c

Self-explanatory

Letter d

The use of veterinary medicines that are not in accordance with applicable

regulations will have a negative impact on animals and humans who consume animal products (meat, eggs, and milk), for example the inappropriate use of antibiotics will cause resistance, allergies, super infections, the possibility of cancer and others. Therefore, the use of veterinary medicines needs to be monitored.

Letter e

Self-explanatory

Paragraph (2)

Self-explanatory

Paragraph (3)

Provisions regarding the requirements and procedures for supervision are needed so that the implementation does not lead to different perceptions among supervisors.

Article 21

Self-explanatory

Article 22

Self-explanatory

Article 23

Self-explanatory

SUPPLEMENT TO THE STATE GAZETTE OF THE REPUBLIC OF INDONESIA

NUMBER 3509