

[National Emblem of the Republic of Indonesia]

REGULATION OF THE MINISTER OF AGRICULTURE OF THE REPUBLIC OF
INDONESIA

NUMBER 14/PERMENTAN/PK.350/5/2017

CONCERNING

CLASSIFICATION OF VETERINARY MEDICINES

BY THE GRACE OF GOD ALMIGHTY

THE MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA,

Considering : a. whereas, the Decree of the Minister of
Agriculture Number 806/Kpts/TN.260/12/94
concerning Classification of Veterinary
Medicines, in its implementation has not
been in compliance with the development
of science and technology in the
veterinary medicine;

b. whereas, based on the considerations as
referred to in letter a and to implement
the provisions of Article 22 paragraph
(5), Article 49 paragraph (2), and
Article 51 paragraph (4) of Law Number 18
of 2009 concerning Livestock and
Veterinary Health as amended by Law
Number 41 of 2014 concerning Amendment to
Law Number 18 of 2009 concerning
Livestock and Veterinary Health, it is
necessary to stipulate Regulation of the



Minister of Agriculture concerning
Classification of Veterinary Medicines;

- In view of :
1. Law Number 8 of 1999 concerning Consumer Protection (State Gazette of the Republic of Indonesia of 1999 Number 42, Supplement to the State Gazette of the Republic of Indonesia Number 3821);
 2. Law Number 18 of 2009 concerning Livestock and Veterinary Health (State Gazette of the Republic of Indonesia of 2009 Number 84, Supplement to the State Gazette of the Republic of Indonesia Number 5015) as amended by Law Number 41 of 2014 concerning Amendment to Law Number 18 of 2009 concerning Livestock and Veterinary Health (State Gazette of the Republic of Indonesia of 2014 Number 338, Supplement to the State Gazette of the Republic of Indonesia Number 5619);
 3. Law Number 18 of 2012 concerning Food (State Gazette of the Republic of Indonesia of 2012 Number 227, Supplement to the State Gazette of the Republic of Indonesia Number 5360);
 4. Law Number 23 of 2014 concerning Regional Government (State Gazette of the Republic



of Indonesia of 2014 Number 244, Supplement to the State Gazette of the Republic of Indonesia Number 5587) as amended several times most recently by Law Number 9 of 2015 concerning the Second Amendment to Law Number 23 of 2014 concerning Regional Government (State Gazette of the Republic of Indonesia of 2015 Number 58, Supplement to the State Gazette of the Republic of Indonesia Number 5679);

5. Government Regulation Number 102 of 2000 concerning National Standardization (State Gazette of the Republic of Indonesia of 2000 Number 199, Supplement to the State Gazette of the Republic of Indonesia Number 4020);
6. Government Regulation Number 95 of 2012 concerning Veterinary Public Health and Animal Welfare (State Gazette of the Republic of Indonesia of 2012 Number 214, Supplement to the State Gazette of the Republic of Indonesia Number 5356);
7. Government Regulation Number 3 of 2017 concerning Veterinary Authority (State Gazette of the Republic of Indonesia of



2017 Number 20, Supplement to the State Gazette of the Republic of Indonesia Number 6019);

8. Presidential Regulation Number 7 of 2015 concerning Organization of State Ministries (State Gazette of the Republic of Indonesia of 2015 Number 8);
9. Presidential Regulation Number 45 of 2015 concerning Ministry of Agriculture (State Gazette of the Republic of Indonesia of 2015 Number 85);
10. Regulation of the Minister of Agriculture Number 43/Permentan/OT.010/8/2015 concerning Organization and Work Procedures of the Ministry of Agriculture (State Gazette of the Republic of Indonesia of 2015 Number 1243);

DECIDED:

To stipulate : REGULATION OF THE MINISTER OF AGRICULTURE CONCERNING CLASSIFICATION OF VETERINARY MEDICINES

CHAPTER I

GENERAL PROVISIONS

Article 1



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

1. Veterinary Medicines mean preparations that can be used to medicate animals, relieve symptoms, or modify chemical processes in the body including biological, pharmacoseutic, premix, and natural medicine preparations.
2. Classification of Veterinary Medicines means classification of Veterinary Medicines based on the level of hazard of Veterinary Medicines in their use.
3. Use of Veterinary Medicines means medical action taken to increase animal immunity, prevention and healing of animal diseases, improvement of veterinary health, recovery efforts for veterinary health using veterinary medicine, and/or giving Veterinary Medicines in feed, drinking water, drops, topical or parenteral in order to improve veterinary health and growth in accordance with types of preparations and classifications.
4. Animal means an animal or fauna with all or part of its life cycle on land, water, and/or air, whether raised or living in its habitat.
5. Biology means Veterinary Medicines produced through biological processes in animals or animal tissues to arouse immunity, diagnose a disease or cure disease



through an immunological process, among others in the form of vaccine, sera (antisera), genetically modified products, and biological diagnostic materials.

6. Pharmaceutics means Veterinary Medicines produced through non-biological processes, among others vitamin, hormone, enzyme, antibiotic, and other chemotherapeutics, antihistamine, antipyretic, and anesthetic used based on pharmacological work power.
7. Premix means preparations containing veterinary medicine materials processed into Feed Additive or Feed Supplement, which is mixed into animal feeds or drinking water that the dosage and use must be qualified, safe, and nutritious.
8. Natural Medicines mean natural materials or ingredients in the form of plant materials, animal materials, mineral materials, galenic preparations or mixtures of these materials which are used as Veterinary Medicines.
9. Hard Medicines mean Veterinary Medicines that if the giving is not in accordance with the provisions, it may arouse hazard to animals and/or humans who consume the animal products.
10. Limited Over-the-Counter Medicines mean Hard Medicines for animals treated as Over-the-Counter Medicines for certain types of animals provided that



- they shall be supplied in the number, dosage rules, dosage preparations, and certain ways of giving and marked with a special warning sign.
11. Over-the-Counter Medicines mean veterinary medicines that can be used freely by everyone in animals.
 12. Certain Veterinary Medicines mean Veterinary Medicines that result in residues in Animal products and result in health problems on people who consume Animal products.
 13. Feed Supplements mean a substance that is naturally contained in the feed but the amount needs to be increased by adding it to the feed.
 14. Antibiotics mean substances produced by microorganisms naturally, semi-synthetic or synthetic that in small amounts it can inhibit or kill bacteria.
 15. Feed Additives mean feed raw materials that do not contain nutrition or nutrient, the purpose of which is mainly for a particular purpose.
 16. Minister means the Minister implementing governmental affairs in the Veterinary Medicines.
 17. Service means a regional work unit in the province or regency/ city serving the function of Veterinary Medicines.



CHAPTER II

VETERINARY MEDICINE

Part One

General

Article 2

Veterinary Medicines based on types of preparations can be classified into:

- a. Biological
- b. Pharmaceuticals;
- c. Premix; and
- d. Natural medicines.

Article 3

Veterinary Medicines as referred to in Article 2, based on the level of hazard in their use and effect, are classified into:

- a. Hard Medicines;
- b. Limited Over-the-Counter Medicines; and
- c. Over-the-Counter Medicines.

Article 4

Veterinary Medicines as referred to in Article 2, potentially harming human health shall be prohibited from being used in cattle whose products are for human consumption.



Part Two

Hard Medicines

Article 5

- (1) Hard Medicines as referred to in Article 3 letter a which used for security of animal diseases and/or treatment of sick animals can be obtained only by a veterinarian's prescription.
- (2) The use of Hard Medicines must be carried out by veterinarians or veterinary health personnel under the supervision of veterinarians.

Article 6

Hard Medicines as referred to in Article 5 are set out in Appendix I, which is an inseparable part of this Ministerial Regulation.

Article 7

Veterinary Medicines given in a parenteral manner shall be classified as Hard Medicines.

Article 8

Diagnostic materials shall be classified as Hard Medicines, in case:

- a. containing materials including in the classification of Hard Medicines; and/or



- b. form of preparations and usage procedures can be classified as Hard Medicines.

Part Three

Limited Over-the-Counter Medicines

Article 9

- (1) Limited Over-the-Counter Medicines as referred to in Article 3 letter b used for the treatment of certain types of animals can be obtained only by a veterinarian's prescription.
- (2) Use of Limited Over-the-Counter Medicines as referred to in paragraph (1) must be carried out by veterinarians or veterinary health personnel under the supervision of veterinarians.

Article 10

Limited Over-the-Counter Medicines as referred to in Article 9 are set out in Appendix II, which is an inseparable part of this Ministerial Regulation.

Article 11

- (1) Hard Medicines as referred to in Article 5 and Limited Over-the-Counter Medicines as referred to in Article 9 shall be provided by producers, importers, distributors and/or depots of Veterinary Medicines.



- (2) Producers, importers, distributors, and depots of Veterinary Medicines as referred to in paragraph (1) must have a business license of Veterinary Medicines.

Part Four

Over-the-Counter Medicines

Article 12

Over-the-Counter Medicines as referred to in Article 3 letter c shall be used for animals freely without a veterinarian's prescription.

Article 13

- (1) Over-the-Counter Medicines as referred to in Article 12 shall be provided by producers, importers, distributors, depots, and/or Veterinary Medicine stores.
- (2) Producers, importers, distributors, depots, and Veterinary Medicine stores as referred to in paragraph (1) must have a business license of Veterinary Medicines.

Article 14

Business license of Veterinary Medicines as referred to in Article 11 paragraph (2) and Article 13 paragraph (2)



shall be in accordance with the provisions of laws and regulations.

Part Five

Prohibited Veterinary Medicines

Article 15

- (1) Prohibition of the use of Veterinary Medicines against cattle whose products are for human consumption as referred to in Article 4 shall be carried out:
- a. to prevent Veterinary Medicine residues in cattle;
 - b. to prevent health problems on humans consuming cattle products;
 - c. since it is difficult to be degraded from the body of the target animal;
 - d. since it causes hypersensitive, carcinogenic, mutagenic, and teratogenic effects in Animals and/or humans;
 - e. to prevent the use of alternative treatment for humans;
 - f. to prevent the emergence of pathogenic microbial resistance; and/or
 - g. since it is not environmentally friendly.
- (2) Prohibition of Veterinary Medicines as referred to in paragraph (1) shall be carried out to:



- a. usage procedures; and/or
- b. active substance of Veterinary Medicines.

Article 16

- (1) Veterinary Medicines as referred to in Article 15 paragraph (2) letter a, in the form of feed additive antibiotics shall consists of:
 - a. finished products as Feed Additive; or
 - b. raw materials of Veterinary Medicines shall be mixed into in feed.
- (2) Veterinary Medicines as referred to in paragraph (1) shall be prohibited from being used as feed additive antibiotics.

Article 17

- (1) In case for therapeutic purposes, antibiotics can be mixed in feed with therapeutic dosage and the length of use shall be maximum of 7 (seven) days.
- (2) Veterinary Medicine mixing in feed for therapeutic purposes as referred to in paragraph (1) shall be in accordance with instructions and under the supervision of Veterinarian.

Article 18



Any prohibited Veterinary Medicines based on active substances thereof as referred to in Article 15 paragraph

(2) letter b shall include:

- a. certain hormones; and
- b. specific Veterinary Medicines.

Article 19

- (1) In case for therapeutic and reproductive purposes, the active substances of Veterinary Medicines as referred to in Article 18 letter a may be used.
- (2) The use of active substances of Veterinary Medicines as referred to in paragraph (1) shall be given only in a parenteral manner in accordance with instructions and under the supervision of Veterinarian.

Article 20

Any prohibited Veterinary Medicines as referred to in Article 16 paragraph (1) letter a and Article 18 are set out in Appendix III, which is an inseparable part of this Ministerial Regulation.

Article 21

- (1) Prohibition of Veterinary Medicines that is not set forth in Appendix III as referred to in Article 20 shall be prohibited by the Minister who is mandated



to the Director General of Livestock and Veterinary Health on behalf of the Minister.

- (2) The Director General of Livestock and Veterinary Health in determining the prohibition as referred to in paragraph (1) shall be carried out in the form of the Resolutions of Minister based on the recommendations of the Veterinary Health Commission (KOH).

CHAPTER III

COACHING AND SUPERVISION

Article 22

- (1) Coaching on the application of classification and use of Veterinary Medicines shall be carried out by:
- a. regent/ mayor implemented by the head of regency/ city service;
 - b. governor implemented by the head of Provincial service; and
 - c. Minister implemented by Director General of Livestock and Veterinary Health
- in compliance with their authority.
- (2) Coaching as referred to in paragraph (1) shall be carried out through technical guidance, supervision, dissemination and socialization, as well as sustainable advocacy.



- (3) Coaching as referred to in paragraph (2) shall be carried out on individuals or corporations conducting activities in the livestock and veterinary health.

Article 23

- (1) Supervision of the application of classification and use of Veterinary Medicines shall be carried out by:
- a. regent/ mayor implemented by the head of regency/ city service;
 - b. governor implemented by the head of Provincial service; and
 - c. Minister implemented by Director General of Livestock and Veterinary Health
- in compliance with their authority.
- (2) Implementation of supervision as referred to in paragraph (1), shall be carried out by the Veterinary Medicine supervisor.

Article 24

- (1) In case the Veterinary Medicines have been classified as Over-the-Counter Medicines or Limited Over-the-Counter Medicines, based on the results of supervision in the field as referred to in Article 23 being suspected to have efficacy and impact as Hard Medicines, a study shall be conducted by the Veterinary Medicine Commission.



- (2) Based on the study of Over-the-Counter Medicines as referred to in paragraph (1), in the event that the results are declared to have efficacy and impact as Hard Medicines, it shall be classified as Limited Over-the-Counter Medicines or Hard Medicines.
- (3) Based on the study of Limited Over-the-Counter Medicines as referred to in paragraph (1), in the event that the results are declared to have efficacy and impact as Hard Medicines, it shall be classified as Hard Medicines.
- (4) Veterinary Medicines as referred to in paragraph (2) and paragraph (3) shall revoke the registration number, and in the event that it will be circulated, it must be re-registered.
- (5) Veterinary Medicine registration as referred to in paragraph (4) shall be regulated in accordance with the provisions of laws and regulations.

Article 25

The procedures for supervision as referred to in Article 23 shall be carried out in accordance with the provisions of laws and regulations.

CHAPTER IV

SANCTION PROVISIONS

Article 26



Each person violating the provisions of Article 5 paragraph (2), Article 9 paragraph (2), Article 11 paragraph (2), Article 13 paragraph (2), Article 16 paragraph (2), Article 18, and Article 24 paragraph (4) shall be subject to sanctions in accordance with the provisions of laws and regulations.

CHAPTER V

TRANSITIONAL PROVISIONS

Article 27

- (1) Veterinary Medicines as referred to in Article 20 in the form of:
 - a. finished products as Feed Additives; and
 - b. beta 1 - adrenergic agonist group,having a registration number and is still valid, shall be declared in full force and effect until December 31, 2017.
- (2) In the event that the validity period of registration number as referred to in paragraph (1) has expired before December 31, 2017, it shall be prohibited to be re-registered.
- (3) In the event that the registration number as referred to in paragraph (1) is still in the registration process, the registration process shall be terminated.



Article 28

The Director General of Livestock and Veterinary Health may issue an approval letter of importation to import Veterinary Medicines as referred to in Article 27 until September 30, 2017.

Article 29

Veterinary Medicines as referred to in Article 28 after December 31, 2017 shall be prohibited from being circulated and used.

CHAPTER VI

CLOSING PROVISIONS

Article 30

When this Ministerial Regulation comes into force, the Decree of the Minister of Agriculture No.806/Kpts/TN.260/12/94 concerning Classification of Veterinary Medicines, shall be revoked and declared null and void.

Article 31

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

For public cognizance, it is ordered to promulgate this Ministerial Regulation by placing it in the State Gazette of the Republic of Indonesia.



Stipulated in Jakarta

on May 9, 2017

THE MINISTER OF AGRICULTURE OF
THE REPUBLIC OF INDONESIA,

[*signed*]

AMRAN SULAIMAN

Promulgated in Jakarta

on May 12, 2017

DIRECTOR GENERAL

OF LAWS AND REGULATIONS

THE MINISTRY OF LAW AND HUMAN RIGHTS OF

THE REPUBLIC OF INDONESIA,

[*signed*]

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2017 NUMBER 683



APPENDIX I

REGULATION OF THE MINISTER OF AGRICULTURE

OF THE REPUBLIC OF INDONESIA

NUMBER 14/PERMENTAN/PK.350/5/2017

CONCERNING

CLASSIFICATION OF VETERINARY MEDICINES

LIST OF HARD MEDICINES

NO.	VETERINARY MEDICINES CONTAINING ACTIVE SUBSTANCE	REMARKS
1	Antibiotics	
	a. Antibacterial: 1) Aminoglycoside. 2) Beta Lactam. 3) Macrolide. 4) Peptide Group. 5) Quinolone. 6) Sulfonamide. 7) Tetracycline. 8) Flavopospolipol. 9) Lincosamide.	
	b. Anti mycobacterium: 1) Aminosalicylic acid. 2) Dapsone (Diaminodifenilsulfon).	



	<p>3) Ethambutol.</p> <p>4) Ethionamide.</p> <p>5) Isoniazide.</p> <p>6) Capreomycin.</p> <p>7) Clofazimine.</p> <p>8) Methaniazide.</p> <p>9) Pyrazinamide.</p> <p>10) Prothionamide.</p> <p>11) Rifabutin.</p> <p>12) Rifaximin.</p> <p>13) Rifamisin.</p> <p>14) Rifampicin.</p> <p>15) Rifapentine.</p> <p>16) Cycloserine.</p>	
	<p>c. Antifungal:</p> <p>1) Amphotericin B.</p> <p>2) Dichlorophen.</p> <p>3) Griseofulvin.</p> <p>4) Imidazole.</p> <p>5) Natamycin.</p> <p>6) Nystatin.</p>	
2.	Anti parasitic	
	<p>Anti parasitic:</p> <p>1) Organochlorine group.</p> <p>2) Organophosphate group.</p>	



	<p>3) Carbamate group.</p> <p>4) Pyrethrin and Pyrethroid group.</p> <p>5) Ivermectin.</p> <p>6) Formamidine.</p>	
3.	<p>Antiprotozoal</p> <p>Antiprotozoal:</p> <p>1) Amprolium.</p> <p>2) Toltrazuril.</p> <p>3) Diclazuril.</p> <p>4) Ivermectin.</p> <p>5) Isometamidium chloride.</p> <p>6) Quinapyramine sulphate.</p> <p>7) Lasalocid.</p>	
4.	<p>Anthelmintic</p> <p>Anthelmintic:</p> <p>1) Levamisole.</p> <p>2) Albendazole.</p> <p>3) Fenbendazole.</p> <p>4) Mebendazole.</p> <p>5) Flubendazole.</p> <p>6) Oxfendazole.</p> <p>7) Praziquantel.</p> <p>8) Closantel.</p> <p>9) Febantel.</p> <p>10) Pyrantel.</p>	



	11) Ivermectin. 12) Doramectin. 13) Dihydroavermectin. 14) Niclosamide. 15) Nitroxylnil. 16) Clorsulon. 17) Moxidectin. 18) Selamectin. 19) Metaflumizone. 20) Rafoxanide.	
5.	Analgesics and Antipyretics	
	Analgesics and Antipyretics: 1) Non-Narcotic Group. 2) Narcotic Group.	
6.	Anti-Inflammation	
	Anti-Inflammation: 1) NSAID (Non Steroid Anti-Inflammation Drugs) class. 2) Corticosteroid group.	
7.	Antihistamine	
	Antihistamine: 1) Antihistamine receptor 1 (AH1). 2) Antihistamine receptor 2 (AH2).	
8.	Depressant in the central nervous system	



Depressant:

- 1) Alfaxalone (alfadolon).
- 2) Alfentanil.
- 3) Amethocaine.
- 4) Acepromazine.
- 5) Acetazolamide.
- 6) Azaperon.
- 7) Barbiton.
- 8) Barbiturate.
- 9) Benzodiazepine.
- 10) Benzocaine.
- 11) Bupivacaine.
- 12) Buprenorphine.
- 13) Butacaine.
- 14) Butamben picrate.
- 15) Butyrophenone.
- 16) Butorphanol.
- 17) Detomidine.
- 18) Diazepam.
- 19) Diethyl ether.
- 20) Droperidol.
- 21) Enflurane.
- 22) Ethyl chloride.
- 23) Ethylene.
- 24) Etomidate.

