

## TERMS AND PROCEDURES FOR THE ISSUANCE OF ANIMAL MEDICINE BUSINESS PERMIT

(Agriculture Minister Regulation No. 18/Permentan/OT.140/4/2009, dated April 8, 2009)

WITH THE BLESSING OF THE ONE AND ONLY GOD,  
THE MINISTER OF AGRICULTURE,

Considering:

- a. that with the issuance of Agriculture Minister Decision Letter No. 324/Kpts/TN.120/4/1994, terms and procedures for the issuance of Animal Medicine Business Permit had been stipulated;
- b. that due to changes of the organization of the Department of Agriculture, and with the stipulation of Government Regulation No. 38 Year 2007 concerning Division of Government Affairs between the Government, Provincial Government, and Regency/City Government, it is necessary to review arrangements on terms and procedures on the issuance of Animal Medicine Business Permit with a regulation of the Agriculture Minister;

In view of:

1. Law No. 6 Year 1967 concerning Main Provisions of Husbandry and Animal Health (Statute Book Year 1967 No. 10, Supplement to R.I. Statute Book No. 2824);
2. Law No. 8 Year 1999 (**BN No. 4013 pages 1A -3A etc**) concerning Consumer Protection (Statute Book Year 1999 No. 42, Supplement to R.I. Statute Book No. 3821);
3. Law No. 32 Year 2004 (**BN No. 7183 pages 1A-11A etc**) concerning Regional Government (Statute Book Year 2004 No. 125, Supplement to R.I. Statute Book No. 4437);
4. Government Regulation No. 78 Year 1992 concerning Animal Medicines (Statute Book Year 1992 No. 129, Supplement to R.I. Statute Book No. 3509);
5. Government Regulation No. 38 Year 2007 concerning Division of Government Affairs between the Government,

Provincial Regional Government, and Regency/City Government (Statute Book Year 2007 No. 82, Supplement to R.I. Statute Book No. 4737);

6. Presidential Decree No. 187/M Year 2004 (**BN No. 7128 pages 30A-31A**) concerning Formation of Indonesia United Cabinet;
7. Presidential Regulation No. 9 Year 2005 (**BN No. 7182 pages 2A-23A**) concerning Position, Mission, Functions, Organizational Structure, and Work Procedure of State Ministries of the Republic of Indonesia, in conjunction with Presidential Regulation No. 62 Year 2005;
8. Presidential Regulation No. 10 Year 2005 concerning Organization Units and Missions of Echelon - I of State Ministries of the Republic of Indonesia;
9. Agriculture Minister Regulation No. 299/Kpts/OT.140/7/2005 concerning Organization and Work Procedure of the Department of Agriculture, in connection with Agriculture Minister Regulation No. 11/Permentan/OT.140/2/2007, and Agriculture Minister Regulation No. 22/Permentan/OT.140/4/2008;
10. Agriculture Minister Regulation No. 341/Kpts/OT.140/9/2005 concerning Organization Accessories and Work Procedure of the Department of Agriculture, in conjunction with Agriculture Minister Regulation No. 12/Permentan/OT.140/2/2007;

D E C I D E S :

To stipulate :

TERMS AND PROCEDURE ON THE ISSUANCE OF ANIMAL  
MEDICINE BUSINESS PERMIT.

### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

In this Regulation, what is meant by:

1. Animal . . . . .

1. Animal medicines are medicines particularly used for animals.
2. Animal Medicine Business Permit is a statement in writing issued by the official having the authority to Indonesian citizens or business entities to carry out business in the field of production, supply, circulation, import and/or export of animal medicines.
3. Production is an activity process in the processing, mixing and/or changing of animal medicine raw material to become animal medicines.
4. Supply is an activity process in the procurement, ownership, control, and/or storage of animal medicines in a place or room with the purpose to be circulated.
5. Circulation is an activity process related with trade, transportation and/or delivery of animal medicines.
6. Import of animal medicines, hereinafter referred to as import, is a series of activities to import animal medicines from overseas into the territory of the Republic of Indonesia.
7. Export of animal medicines, hereinafter referred to as export, is a series of activities to export animal medicines overseas from the territory of the Republic of Indonesia.
8. Producers of animal medicines are Indonesian citizens or business entities performing business on the production, supply, and/or circulation of animal medicines.
9. Importers of animal medicines are Indonesian citizens or business entities performing business on the import of animal medicines from overseas into the territory of the Republic of Indonesia.
10. Exporters of animal medicines are Indonesian citizens or business entities performing business on the export of animal medicines overseas from the territory of the Republic of Indonesia.
11. Distributors are Indonesian citizens or business entities carrying out the supply and/or circulation of animal medicines from producers or importers.
12. Animal medicine depot or pet-shop, hereinafter referred to as depot, is a business unit performing business on the supply and/or circulation of animal medicines from distributors.
13. Animal medicine stores, hereinafter referred to as stores, are business units performing business on the supply and/or circulation of animal medicines other than strong drugs.
14. Biological diagnostic substances are biological preparations used to diagnose diseases on animals.
15. Head of the Center is the Head of Permits and Investment Center of the Department of Agriculture.
16. Service is the agency in charge of functions on husbandry and/or animal health in a province or regency/city.

#### Article 2

- (1) This regulation is purported as a legal basis for the provision of permits and the performance of animal medicine business activities for government officers and business performers.
- (2) This regulation has the following objectives:
  - a. to protect consumers from animal medicines not meeting requirements of quality, merit, and safety;
  - b. to provide business certainty for Indonesian citizens or business entities to perform activities in the field of animal medicine business
  - c. to prevent the entry and spread of contagious animal diseases.

#### CHAPTER II

##### ISSUANCE OF ANIMAL MEDICINE BUSINESS PERMIT

#### Article 3

- (1) Animal medicine business covers the following activities:
  - a. production of animal medicines;
  - b. supply of animal medicines;
  - c. circulation of animal medicines;
  - d. import of animal medicines from overseas; and/or
  - e. export of animal medicines overseas.

- (2) The animal medicine business referred to in paragraph (1) may be performed by Indonesian citizens or business entities.

#### Article 4

- (1) Animal medicine business permits are issued by the official having the authority to Indonesian citizens or business entities to perform business in the field of animal medicines.
- (2) Issuance of Animal Medicine Business Permit referred to in paragraph (1) for producers, importers, and/or exporters is by the Director General of Husbandry on behalf of the Agriculture Minister.
- (3) Issuance of Animal Medicine Business Permit referred to in paragraph (1) for distributors is by the Governor.
- (4) Issuance of Animal Medicine Business Permit referred to in paragraph (1) for depots and/or stores is by the Regent/Mayor.

### CHAPTER III

#### REQUIREMENTS OF ANIMAL MEDICINE

##### BUSINESS PERMIT

#### Article 6

In order to obtain Animal Medicine Business Permit, Indonesian citizens or business entities must meet administrative requirements and technical requirements.

#### Article 7

The administrative requirements referred to in Article 6, are as follows:

1. Producers of animal medicines on biological, pharmaceutical, premix and/or natural preparations must possess:
  - a. Taxpayer Basic Number (NPWP = Nomor Pokok Wajib Pajak);
  - b. Right of Building Use (HGB = Hak Guna Bangunan);
  - c. Business Location Permit Letter (SITU = Surat Izin Tempat Usaha);
  - d. Nuisance Act Permit (H.O);
2. Importers must possess:
  - a. Taxpayer Basic Number (NPWP);
  - b. Right of Building Use (HGB);
  - c. Business Location Permit Letter (SITU);
  - d. Nuisance Act Permit (H.O);
  - e. *Company Registration Proof (TDP)*; (TDP = Tanda Bukti Daftar Perusahaan);
  - f. Trade Business Permit Letter (SIUP = Surat Izin Usaha Perdagangan);
  - g. Citizen Identification Card / Company Management Identification Card;
  - h. Approval letter on environmental management efforts and monitoring efforts (UKL/UPL);
  - i. Recommendation from Provincial and Regency/City Heads of Service; and
  - j. Recommendation from the local regional management of Indonesia Animal Medicine Association and/or Central Animal Medicine Association.
3. Exporters must possess:
  - a. Means / equipment to carry out business activities;
  - b. Taxpayer Basic Number (NPWP);
  - c. Right of Building Use (HGB);

- d. Business location permit/business location permit letter (SITU);
  - e. Nuisance Act permit (H.O);
  - f. Company Registration Proof (TDP);
  - g. Trade Business Permit Letter (SIUP);
  - h. Citizen Identification Card / Company Management Identification Card;
  - i. Recommendation from Provincial and Regency/City Heads of Service of the location of the head office of the company concerned if the location of warehouses and office are in one province;
  - j. Recommendation from Provincial and Regency/City Heads of Service for exporters using warehouses outside of the location of its head office; and
  - k. Recommendation from the local regional management of Indonesia Animal Medicine Association and/ or Central Animal Medicine Association.
4. Distributors must possess:
- a. Means / equipment to carry out business activities;
  - b. Taxpayer Basic Number (NPWP);
  - c. Right of Building Use (HGB);
  - d. Business Location Permit Letter (SITU);
  - e. Nuisance Act Permit (HO);
  - f. Company Registration Proof (TDP);
  - g. Trade Business Permit Letter (SIUP);
  - h. Recommendation from Provincial and Regency/City Heads of Service;
  - i. Recommendation from the local regional management of Indonesia Animal Medicine Association;
  - j. Recommendation from Indonesia Central Animal Medicine Association if there are no Indonesia Animal Medicine Association in the area;; and
  - k. Appointment letter from the producer or importer.
5. Depot or Pet-shop of animal medicines must possess:
- a. Means / equipment to carry out business activities;
  - b. Taxpayer Basic Number (NPWP);
  - c. Business location permit/business location permit letter (SITU);
  - d. Company Registration Proof;
  - e. Trade Business Permit Letter (SIUP); and
  - f. Recommendation from the local regional management of Indonesia Animal Medicine Association; if there are no Animal Medicine Association in the area, then the recommendation shall be issued by Indonesia Central Animal Medicine Association.
6. Stores of animal medicines must possess:
- a. Means / equipment to carry out business activities;
  - b. Taxpayer Basic Number (NPWP);
  - c. Business location permit/business location permit letter (SITU); and
  - d. Trade Business Permit Letter (SIUP).

#### Article 6

The technical requirements referred to in Article 5 are:

1. Producers of animal medicine biological preparations, pharmaceutical, premiks and/or natural medicines, must possess:
  - a. Factory of animal medicines, means / equipment to carry out business activities;
  - b. Quality testing laboratory and storage places of animal medicines;
  - c. Veterinarians and pharmacists working full time as technical responsible parties.

Producers not possessing a factory of animal medicines may use the service of other parties possessing certificate on methods of producing good animal medicines (CPOHB), and/or laboratory for testing animal medicine quality of other parties having been accredited.
2. Importers of animal medicines must possess:
  - a. means / equipment to carry out business activities;
  - b. storage places of animal medicines that can assure the maintenance of quality; and
  - c. veterinarians or pharmacists working full time as technical responsible parties.

3. Exporters of animal medicines must possess:
  - a. means / equipment to carry out business activities;
  - b. storage places of animal medicines that can assure the maintenance of quality;
  - c. veterinarians or pharmacists working full time as technical responsible parties.
4. Distributors of animal medicines must possess:
  - a. storage places of animal medicines that can assure the maintenance of quality;
  - b. veterinarians or pharmacists working full time as technical responsible parties.
5. Depot or Pet-shop of animal medicines must possess:
  - a. storage places of animal medicines that can assure the maintenance of quality;
  - b. veterinarians or pharmacists working not on full time basis, or pharmacist assistants working full time as technical responsible parties.
6. Stores of animal medicines must possess storage places to secure the quality, merit, and safety of animal medicines.

#### CHAPTER IV

#### PROCEDURE ON THE ISSUANCE OF ANIMAL MEDICINE BUSINESS PERMIT

##### Article 8

- (1) Application for Animal Medicine Business Permit as meant in Article 4 paragraph (2) shall be submitted to the Minister thru the Head of Center with copies to the Director General of Husbandry, using Model-1 form.
- (2) After receiving the application referred to in paragraph (1), Head of the Center shall within a period of no later than three (3) work days accounted for from receiving the application letter, immediately give an answer whether it is accepted, postponed or rejected.

##### Article 9

- (1) An application shall be accepted as referred to in Article 8 paragraph (2) if it meets the administrative requirements referred to in Article 6.

- (2) An application shall be postponed as referred to in Article 8 paragraph (2) if there are still some shortages of the administrative requirements referred to in paragraph (1), which must be equipped and notified to the applicant by the Head of the Center in writing using Model-2 form.
- (3) Within a period of no later than five (5) work days accounted for from receiving the notification referred to in paragraph (2), the applicant must have completed the shortages of requirements.
- (4) If within the period referred to in paragraph (3) the applicant did not complete the shortage of the administrative requirements, the application will be deemed as being withdrawn.
- (5) An application shall be rejected as referred to in Article 8 paragraph (2) if the administrative requirements referred to in paragraph (1) are not correct.
- (6) Rejection of the application referred to in paragraph (5) shall be notified to the applicant by the Head of the Center accompanied with reasons for the rejection in writing, using Model-3 form.

##### Article 10

An application having met the administrative requirements meant in Article 9 paragraph (1) shall be submitted to the Director General of Husbandry by the Head of the Center to be studied as of the fulfillment of its technical requirements.

##### Article 11

- (1) After receiving the application from the Head of the Center meant in Article 10, the Director General of Husbandry shall perform a study on the technical requirements.
- (2) In the performance of the technical study, the Director General of Husbandry, within a period of no later than 20 (twenty) work days, must have provided an answer: accepted, or rejected.

## Article 13

- (1) An application shall be accepted as referred to in Article 11 paragraph (2), if it meets the technical requirements meant in Article 7.
- (2) For an application that is accepted as referred to in paragraph (1), a business permit will be issued in the form of a decision of the Agriculture Minister signed by the Director General of Husbandry on behalf of the Agriculture Minister as shown in Model-4 form.
- (3) The decision referred to in paragraph (2) shall be delivered to the applicant thru the Head of the Center.
- (4) The business permit referred to in paragraph (2) remains in force for the duration the permit holder still carry on activities.

## Article 14

- (1) An application shall be rejected as referred to in Article 11 paragraph (2) if the technical requirements meant in Article 7 are not met.
- (2) Rejection of an application as referred to in paragraph (1) will be given by the Director General of Husbandry to the applicant accompanied with reasons in writing thru the Head of the Center.

## Article 15

- (1) Individuals or business entities intending to expand business activities must have an expansion permit.
- (2) The expansion permit referred to in paragraph (1) can be obtained in accordance with the terms and procedure referred to in Chapters III and IV.

## Article 16

The expansion of business meant in Article 15 covers:

- a. expansion of animal medicine business as producer in the form of adding production units in other places or locations; and/or
- b. expansion of animal medicine business as producer in the form of adding the number of production means, adding the types of animal medicines produced.

## Article 17

Holders of Animal Medicine Business Permit referred to in Article 13 paragraph (2) are obliged to submit reports periodically once in every three (3) months on its business activities to the Director General of Husbandry thru the Head of the Center.

## Article 18

A permit holder intending to move its location must notify in writing to the party issuing the permit.

## Article 19

- (1) The business permit referred to in Article 13 paragraph (2) may be transferred after receiving an approval of the party issuing the permit.
- (2) The transfer referred to in paragraph (1) shall be performed in accordance with applicable legislations.

## Article 20

Holders of Animal Medicine Business Permit referred to in Article 13 paragraph (2) are obliged to submit reports periodically once in every three (3) months on its business activities to the Director General of Husbandry thru the Head of the Center.

## CHAPTER V

## REVOCATION OF ANIMAL MEDICINE BUSINESS PERMIT

## Article 21

A business permit will be revoked if:

- a. It is proved that it has no manpower responsible on technicalities;
- b. in a period of one (1) year after the issuance of the Animal Medicine Business Permit, no activities were performed;
- c. it is proved that it produced, supplied and/or circulated animal medicines illegally;
- d. location of the animal medicine business was removed without the approval of the party issuing the permit;
- e. transferred the business permit without a written approval from the party issuing the permit;

- f. did not meet the provisions set forth in the business permit;
- g. did not make any report on activities in succession in a period of one (1) year;

#### Article 22

- (1) *Revocation of Animal Medicine Business Permit as meant in Article 21 letter a, letter b, or letter g shall be made after giving a warning in writing three (3) times in succession with an interval of 50 (fifty) work days respectively, were not heeded by the permit holder.*
- (2) *Revocation of Animal Medicine Business Permit referred to in paragraph (1) shall be made in the form of a decision of the Agriculture Minister signed by the Director General on behalf of the Minister as shown in Model-5 form.*

#### CHAPTER VI

##### OTHER PROVISIONS

#### Article 23

For the purpose of protecting the national interest, and to assist the tackling of animal diseases in other countries, the production of biological preparations where in its isolate parent species are not available in Indonesia, it can be produced under separate requirements and must meet a high biological safety level.

#### CHAPTER VII

##### TRANSITIONAL PROVISIONS

#### Article 24

- (1) *Application for Animal Medicine Business Permit being under process before the stipulation of this regulation shall be performed in accordance with provisions of Agriculture Minister Decision Letter*

*No. 324/Kpts/TN.120/4/94 concerning Terms and Procedures for the Issuance of Animal Medicine Business Permit.*

- (2) *Animal Medicine Business Permits already issued before the stipulation of this regulation is declared as still applicable, however must be conformed to this regulation.*

#### CHAPTER VIII

##### CLOSING

#### Article 25

With the stipulation of this regulation, Agriculture Minister Decision Letter No.: 324/Kpts/TN.120/4/94 concerning Terms and Procedures on the Issuance of Animal Medicine Business Permit, is revoked and declared as not in effect.

#### Article 26

This regulation commences to come to effect from the date of stipulation.

For public cognizance, this Agriculture Minister Regulation shall be announced in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

On April 8, 2009

AGRICULTURE MINISTER,

*sgd.*

ANTON APRIYANTONO

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