

Ministerial Order to Specify Cases to be Exempted from the Application of the Provisions Concerning the Prohibition of Use of Pharmaceuticals and Regenerative Medicine Products under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
(Order of the Ministry of Agriculture, Forestry and Fisheries No. 70 of 2003)

Based on the provisions of Article 83-3 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the Ministerial Order to Specify Cases to be Exempted from the Application of the Provisions Concerning the Prohibition of Use of Pharmaceuticals under the Pharmaceutical Affairs Act is established as follows.

Ministerial Order to Specify Cases to be Exempted from the Application of the Provisions Concerning the Prohibition of Use of Pharmaceuticals and Regenerative Medicine Products under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

Cases specified by the Order of the Ministry of Agriculture, Forestry and Fisheries set forth in the proviso to Article 83-3 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Act") are as follows:

- (i) cases where pharmaceuticals (meaning pharmaceuticals other than those where, on the immediate container or capsule, the matters prescribed in Article 50 of the Act (including as applied pursuant to Article 83, paragraph (1) of the Act following the deemed replacement of terms) are indicated; the same applies hereinafter) or regenerative medicine products (meaning regenerative medicine products other than those where, on the immediate container or capsule, the matters prescribed in Article 65-2 of the Act (including as applied pursuant to Article 83, paragraph (1) of the Act following the deemed replacement of terms) are indicated; the same applies hereinafter) are used on the animals concerned (meaning the animals concerned prescribed in Article 14, paragraph (2), item (iii), (b) of the Act as applied pursuant to Article 83, paragraph (1) of the Act following the deemed replacement of terms; the same applies hereinafter) for research purposes ;

- (ii) cases where veterinarians use pharmaceuticals (excluding those containing the substances listed in the Appended Table as their active components; the same applies in the following item) or regenerative medicine products on the animals concerned to which the veterinarians provide medical care for the purpose of medical practices of diagnosis, treatment or prevention of diseases thereof;
- (iii) cases where owners of the animals concerned or other persons who manage the animals concerned (excluding carriers by means of railway, tramway, automobile, ship or aircraft who have been entrusted with the transportation of those animals concerned) use the pharmaceuticals or regenerative medicine products prescribed by the veterinarians who provided medical care to those animals concerned, while following the instructions given by those veterinarians concerning their dosage, administration and other necessary care for use and handling;
- (iv) cases where prefectural animal health inspectors or animal quarantine officers use biological preparations or regenerative medicine products produced or imported by the national government or prefectures, in cases falling under Article 213, paragraph (1), item (iv) or Article 214, paragraph (1), item (iii) of the Regulations for Veterinary Drugs (Order of the Ministry of Agriculture, Forestry and Fisheries No. 107 of 2004), for the purpose of carrying out inspection, injection or medication pursuant to the provisions of Article 5, paragraph (1), Article 6, paragraph (1), or Article 31, paragraph (1) of the Act on Domestic Animal Infectious Diseases Control (Act No. 166 of 1951) in the case of prefectural animal health inspectors, or for the purpose of carrying out injection or medication set forth in Article 6, paragraph (1) or Article 31, paragraph (1) of the same Act pursuant to the provisions of Article 46, paragraph (1) of the same Act or carrying out inspection, injection or medication under Article 5, paragraph (1), Article 6, paragraph (1) or Article 31, paragraph (1) of the same Act pursuant to the provisions of Article 48 of the same Act in the case of animal quarantine officers.

Supplementary Provisions

This Ministerial Order comes into effect as of July 30, 2003.

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 107 of December 24, 2004) [Extract]

(Effective Date)

Article 1 This Ministerial Order comes into effect as of the date on which the Act Partially Amending the Pharmaceutical Affairs Act and the Blood Donation Brokerage Control Act (hereinafter referred to as the "Amendment Act") comes into effect (April 1, 2005).

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 43 of May 30, 2013)

This Ministerial Order comes into effect as of the day on which six months have elapsed from the date of promulgation.

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 58 of November 18, 2014) [Extract]

(Effective Date)

Article 1 This Ministerial Order comes into effect as of the date on which the Act Partially Amending the Pharmaceutical Affairs Act, etc. (hereinafter referred to as the "Amendment Act") comes into effect (November 25, 2014).

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 57 of May 27, 2015)

This Ministerial Order comes into effect as of August 21, 2015.

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 1 of January 25, 2016)

This Ministerial Order comes into effect as of March 18, 2016.

Supplementary Provisions (Order of the Ministry of Agriculture, Forestry and Fisheries No. 39 of June 30, 2017)

This Ministerial Order comes into effect as of August 23, 2017.

Appended Table

(i) Ipronidazole;

- (ii) Olaquinox;
- (iii) Carbadox;
- (iv) Coumaphos;
- (v) Chloramphenicol;
- (vi) Clorsulon;
- (vii) Chlorpromazine;
- (viii) Diethylstilbestrol;
- (ix) Dimetridazole;
- (x) Nitrofurazone;
- (xi) Nitrofurantoin;
- (xii) Furazolidone;
- (xiii) Furaldone;
- (xiv) Malachite green;
- (xv) Metronidazole;
- (xvi) Ronidazole