



6 Mei 2019
6 May 2019
P.U. (B) 237

WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN
DI BAWAH PERATURAN 31

*NOTIFICATION OF EXEMPTION
UNDER REGULATION 31*

DISIARKAN OLEH/
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JABATAN PEGUAM NEGARA/
ATTORNEY GENERAL'S CHAMBERS

AKTA JUALAN DADAH 1952

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

PEMBERITAHUAN PENGECCUALIAN DI BAWAH PERATURAN 31

PADA menjalankan kuasa yang diberikan oleh peraturan 31 Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 [*P.U. (A) 223/1984*], Menteri, setelah berunding dengan Pihak Berkuasa, mengecualikan Intervet (M) Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 15 Mei 2019 hingga 31 Disember 2022 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada pengilang yang dinyatakan dalam Jadual;
- (b) keluaran itu hendaklah dijual, dibekalkan dan diimport tidak melebihi kuantiti yang dinyatakan dalam Jadual;
- (c) keluaran itu hendaklah diimport hanya bagi maksud dan kegunaan doktor veterinar berdaftar dan dibekalkan dan dijual hanya kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam bagi tiap-tiap pengimportan keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan; dan
- (e) suatu laporan mengenai penjualan, pembekalan, pengimportan dan pemilikan keluaran itu hendaklah dihantar kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan pada tiap-tiap bulan tidak lewat daripada lima belas hari bulan pada bulan yang berikutnya.

JADUAL

Keluaran Yang Dikecualikan

	<i>Nama Keluaran</i>	<i>Kuantiti</i>	<i>Pengilang</i>
1.	Bravecto 112.5mg tablet kunyah untuk anjing saiz sangat kecil (2-4.5kg)	60,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
2.	Bravecto 250mg tablet kunyah untuk anjing saiz kecil (melebihi 4.5-10kg)	60,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
3.	Bravecto 500mg tablet kunyah untuk anjing saiz sederhana (melebihi 10-20kg)	195,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
4.	Bravecto 1000mg tablet kunyah untuk anjing saiz besar (melebihi 20-40kg)	195,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
5.	Bravecto 1400mg tablet kunyah untuk anjing saiz sangat besar (melebihi 40-56kg)	195,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
6.	Bravecto 112.5mg Spot-on Solution untuk anjing saiz sangat kecil (2-4.5kg)	60,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
7.	Bravecto 250mg Spot-on Solution untuk anjing saiz kecil (melebihi 4.5-10kg)	60,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
8.	Bravecto 500mg Spot-on Solution untuk anjing saiz sederhana (melebihi 10-20kg)	195,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat

9.	Bravecto 1000mg Spot-on Solution untuk anjing saiz besar (melebihi 20-40kg)	195,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
10.	Bravecto 1400mg Spot-on Solution untuk anjing saiz sangat besar (melebihi 40-56kg)	195,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
11.	Bravecto 112.5mg Spot-on Solution untuk kucing saiz kecil (1.2-2.8kg)	145,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
12.	Bravecto 250mg Spot-on Solution untuk kucing saiz sederhana (melebihi 2.8-6.25kg)	300,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
13.	Bravecto 500mg Spot-on Solution untuk kucing saiz besar (melebihi 6.25-12.5kg)	300,000 pipet	Patheon Manufacturing Services LLC, Amerika Syarikat
14.	Posatex, titis suspensi telinga untuk anjing	20,000 botol	Vet Pharma Friesoythe GmbH, Jerman
15.	Imizol	30,000 vial	Vet Pharma Friesoythe GmbH, Jerman
16.	Dexafort	25,000 vial	Vet Pharma Friesoythe GmbH, Jerman
17.	Vivitonin 50mg tablet bersalut nipis untuk anjing	2,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria
18.	Vivitonin 100mg tablet bersalut nipis untuk anjing	2,000 biji tablet	Intervet GesmbH (MSD Animal Health), Austria

19.	Dolorex 10mg/ml larutan bagi suntikan untuk kuda, anjing dan kucing	2,000 vial	Intervet International GmbH, Jerman
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Bertarikh 25 April 2019
[KKM.R.600-1/3/72]ld.2(8); PN(PU2)269A/VI]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Menteri Kesihatan

SALE OF DRUGS ACT 1952

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

NOTIFICATION OF EXEMPTION UNDER REGULATION 31

IN exercise of the powers conferred by regulation 31 of the Control of Drugs and Cosmetics Regulations 1984 [*P.U. (A) 223/1984*], the Minister, after consultation with the Authority, exempts Intervet (M) Sdn. Bhd. from the application of subregulation 7(1) in relation to the sale, supply, importation and possession of the veterinary products as described in the Schedule with effect from 15 May 2019 to 31 December 2022 subject to the following conditions:

- (a) the products shall be imported only from the manufacturer as specified in the Schedule;
- (b) the products shall be sold, supplied and imported not exceeding the quantity specified in the Schedule;
- (c) the products shall be imported only for the purposes and use of a registered veterinary surgeon and supplied and sold only to a registered veterinary surgeon;
- (d) a copy of the Custom's import form for every importation of the products shall be sent within thirty days from the date of importation to the Senior Director of Pharmaceutical Services, Ministry of Health; and
- (e) a report on the sale, supply, importation and possession of the products shall be sent to the Senior Director of Pharmaceutical Services, Ministry of Health every month not later than the fifteenth of the following month.

SCHEDULE

Exempted Products

	<i>Product Name</i>	<i>Quantity</i>	<i>Manufacturer</i>
1.	Bravecto 112.5mg chewable tablets for very small dogs (2-4.5kg)	60,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
2.	Bravecto 250mg chewable tablets for small dogs (more than 4.5-10kg)	60,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
3.	Bravecto 500mg chewable tablets for medium-sized dogs (more than 10-20kg)	195,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
4.	Bravecto 1000mg chewable tablets for large dogs (more than 20-40kg)	195,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
5.	Bravecto 1400mg chewable tablets for very large dogs (more than 40-56kg)	195,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
6.	Bravecto 112.5mg Spot-on Solution for very small dogs (2-4.5kg)	60,000 pipettes	Patheon Manufacturing Services LLC, United States of America
7.	Bravecto 250mg Spot-on Solution for small dogs (more than 4.5-10kg)	60,000 pipettes	Patheon Manufacturing Services LLC, United States of America

8.	Bravecto 500mg Spot-on Solution for medium-sized dogs (more than 10-20kg)	195,000 pipettes	Patheon Manufacturing Services LLC, United States of America
9.	Bravecto 1000mg Spot-on Solution for large dogs (more than 20-40kg)	195,000 pipettes	Patheon Manufacturing Services LLC, United States of America
10.	Bravecto 1400mg Spot-on Solution for very large dogs (more than 40-56kg)	195,000 pipettes	Patheon Manufacturing Services LLC, United States of America
11.	Bravecto 112.5mg Spot-on Solution for small cats (1.2-2.8kg)	145,000 pipettes	Patheon Manufacturing Services LLC, United States of America
12.	Bravecto 250mg Spot-on Solution for medium-sized cats (more than 2.8-6.25kg)	300,000 pipettes	Patheon Manufacturing Services LLC, United States of America
13.	Bravecto 500mg Spot-on Solution for large cats (more than 6.25-12.5kg)	300,000 pipettes	Patheon Manufacturing Services LLC, United States of America
14.	Posatex, ear suspension drops for dogs	20,000 bottles	Vet Pharma Friesoythe GmbH, Germany
15.	Imizol	30,000 vials	Vet Pharma Friesoythe GmbH, Germany
16.	Dexafort	25,000 vials	Vet Pharma Friesoythe GmbH, Germany

17.	Vivitonin 50mg film-coated tablets for dogs	2,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
18.	Vivitonin 100mg film-coated tablets for dogs	2,000 tablets	Intervet GesmbH (MSD Animal Health), Austria
19.	Dolorex 10mg/ml solution for injection for horse, dog and cat	2,000 vials	Intervet International GmbH, Germany

Dated 25 April 2019
 [KKM.R.600-1/3/72]ld.2(8); PN(PU2)269A/VI]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health