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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 My Vet Care 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.	Canaural titis suspensi telinga untuk anjing dan kucing (1 x 15ml)	80,000 botol	Dales Pharmaceuticals Limited, United Kingdom
2.	Canaural titis suspensi telinga untuk anjing dan kucing (10 x 15ml)	80,000 botol	Dales Pharmaceuticals Limited, United Kingdom
3.	Canaural titis suspensi telinga untuk anjing dan kucing (1 x 25ml)	80,000 botol	Dales Pharmaceuticals Limited, United Kingdom
4.	Canaural titis suspensi telinga untuk anjing dan kucing (1 x 100ml)	80,000 botol	Dales Pharmaceuticals Limited, United Kingdom
5.	Framixin antibiotik salap telinga dan mata 5g	80,000 bekas	Dechra Veterinary Products Pty. Ltd., Australia
6.	Framixin H antibiotik anti- radang salap telinga dan mata 5g	80,000 bekas	Dechra Veterinary Products Pty. Ltd., Australia
7.	Vetropolycin 3.5g	80,000 tiub	Altaire Pharmaceuticals Inc., Amerika Syarikat
8.	Vetropolycin HC 3.5g	80,000 tiub	Altaire Pharmaceuticals Inc., Amerika Syarikat

9.	Prevomax 10mg/ml (10ml) larutan bagi suntikan untuk anjing dan kucing	20,000 vial	Produlab Pharma B.V., Belanda
10.	Prevomax 10mg/ml (20ml) larutan bagi suntikan untuk anjing dan kucing	20,000 vial	Produlab Pharma B.V., Belanda
11.	Prevomax 10mg/ml (25ml) larutan bagi suntikan untuk anjing dan kucing	20,000 vial	Produlab Pharma B.V., Belanda
12.	Prevomax 10mg/ml (50ml) larutan bagi suntikan untuk anjing dan kucing	20,000 vial	Produlab Pharma B.V., Belanda
13.	Phenoleptil 12.5mg tablet untuk anjing	160,000 biji tablet	Produlab Pharma B.V., Belanda
14.	Phenoleptil 25mg tablet untuk anjing	160,000 biji tablet	Produlab Pharma B.V., Belanda
15.	Phenoleptil 50mg tablet untuk anjing	160,000 biji tablet	Produlab Pharma B.V., Belanda
16.	Phenoleptil 100mg tablet untuk anjing	160,000 biji tablet	Produlab Pharma B.V., Belanda
17.	Isoflurin 1000mg/g (250ml) wap sedutan, cecair	12,000 botol	Chemical Iberica PV, Sepanyol

Bertarikh 25 April 2019
[KKM.R.600-1/3/72 Jld.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 My Vet Care 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.	Canaural ear suspension drops for dogs and cats (1 x 15ml)	80,000 bottles	Dales Pharmaceuticals Limited, United Kingdom
2.	Canaural ear suspension drops for dogs and cats (10 x 15ml)	80,000 bottles	Dales Pharmaceuticals Limited, United Kingdom
3.	Canaural ear suspension drops for dogs and cats (1 x 25ml)	80,000 bottles	Dales Pharmaceuticals Limited, United Kingdom
4.	Canaural ear suspension drops for dogs and cats (1 x 100ml)	80,000 bottles	Dales Pharmaceuticals Limited, United Kingdom
5.	Framixin ear and eye ointment antibiotic 5g	80,000 containers	Dechra Veterinary Products Pty. Ltd., Australia
6.	Framixin H ear and eye ointment antibiotic anti-inflammatory 5g	80,000 containers	Dechra Veterinary Products Pty. Ltd., Australia
7.	Vetropolycin 3.5g	80,000 tubes	Altaire Pharmaceuticals Inc., United States of America
8.	Vetropolycin HC 3.5g	80,000 tubes	Altaire Pharmaceuticals Inc., United States of America

9.	Prevomax 10mg/ml (10ml) solution for injection for dogs and cats	20,000 vials	Produlab Pharma B.V., The Netherlands
10.	Prevomax 10mg/ml (20ml) solution for injection for dogs and cats	20,000 vials	Produlab Pharma B.V., The Netherlands
11.	Prevomax 10mg/ml (25ml) solution for injection for dogs and cats	20,000 vials	Produlab Pharma B.V., The Netherlands
12.	Prevomax 10mg/ml (50ml) solution for injection for dogs and cats	20,000 vials	Produlab Pharma B.V., The Netherlands
13.	Phenoleptil 12.5mg tablets for dogs	160,000 tablets	Produlab Pharma B.V., The Netherlands
14.	Phenoleptil 25mg tablets for dogs	160,000 tablets	Produlab Pharma B.V., The Netherlands
15.	Phenoleptil 50mg tablets for dogs	160,000 tablets	Produlab Pharma B.V., The Netherlands
16.	Phenoleptil 100mg tablets for dogs	160,000 tablets	Produlab Pharma B.V., The Netherlands
17.	Isoflurin 1000mg/g (250ml) inhalation vapour, liquid	12,000 bottles	Chemical Iberica PV, Spain

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