



22 Februari 2019
22 February 2019
P.U. (B) 103

WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN
DI BAWAH PERATURAN 31

*NOTIFICATION OF EXEMPTION
UNDER REGULATION 31*

DISIARKAN OLEH/
PUBLISHED BY
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 Rhone Ma Malaysia Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 1 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada syarikat Merial, Lyon, Perancis;
- (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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; 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>
1.	Previcox (57mg) tablet kunyah untuk anjing	54,780 biji tablet
2.	Nexgard Spectra (9mg/2mg) tablet kunyah untuk anjing 2-3.5kg	9,400 biji tablet
3.	Nexgard Spectra (19mg/4mg) tablet kunyah untuk anjing melebihi 3.5-7.5kg	14,400 biji tablet
4.	Nexgard Spectra (38mg/8mg) tablet kunyah untuk anjing melebihi 7.5-15kg	27,000 biji tablet
5.	Nexgard Spectra (75mg/15mg) tablet kunyah untuk anjing melebihi 15-30kg	27,000 biji tablet
6.	Nexgard Spectra (150mg/30mg) tablet kunyah untuk anjing melebihi 30-60kg	13,200 biji tablet

Bertarikh 28 Januari 2019
[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

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 Rhone Ma Malaysia 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 1 March 2019 to 31 December 2021 subject to the following conditions:

- (a) the products shall be imported only from the company of Merial, Lyon, France;
- (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 solely 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>
1.	Previcox (57mg) chewable tablets for dogs	54,780 tablets
2.	Nexgard Spectra (9mg/2mg) chewable tablets for dogs 2-3.5kg	9,400 tablets
3.	Nexgard Spectra (19mg/4mg) chewable tablets for dogs more than 3.5-7.5kg	14,400 tablets
4.	Nexgard Spectra (38mg/8mg) chewable tablets for dogs more than 7.5-15kg	27,000 tablets
5.	Nexgard Spectra (75mg/15mg) chewable tablets for dogs more than 15-30kg	27,000 tablets
6.	Nexgard Spectra (150mg/30mg) chewable tablets for dogs more than 30-60kg	13,200 tablets

Dated 28 January 2019

[KKM.R.600-1/3/72]ld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health



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WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT
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AKTA JUALAN DADAH 1952

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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 Zoetis Malaysia Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 1 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada pengeksport 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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; 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>Pengeksport</i>
1.	Revolution Plus (15mg/2.5mg)	66,000 tiub	Zoetis Inc., Amerika Syarikat
2.	Revolution Plus (30mg/5mg)	195,000 tiub	Zoetis Inc., Amerika Syarikat
3.	Revolution Plus (60mg/10mg)	12,000 tiub	Zoetis Inc., Amerika Syarikat
4.	Simparica Tablet Kunyah (5mg)	12,000 biji tablet	Zoetis Inc., Amerika Syarikat
5.	Simparica Tablet Kunyah (10mg)	33,000 biji tablet	Zoetis Inc., Amerika Syarikat
6.	Simparica Tablet Kunyah (20mg)	57,000 biji tablet	Zoetis Inc., Amerika Syarikat
7.	Simparica Tablet Kunyah (40mg)	45,000 biji tablet	Zoetis Inc., Amerika Syarikat
8.	Simparica Tablet Kunyah (80mg)	57,000 biji tablet	Zoetis Inc., Amerika Syarikat
9.	Simparica Tablet Kunyah (120mg)	12,000 biji tablet	Zoetis Inc., Amerika Syarikat

10.	Cytopoint (10mg) larutan bagi suntikan untuk anjing	11,000 vial	Zoetis Inc., Belgium
11.	Cytopoint (20mg) larutan bagi suntikan untuk anjing	17,000 vial	Zoetis Inc., Belgium
12.	Cytopoint (30mg) larutan bagi suntikan untuk anjing	19,000 vial	Zoetis Inc., Belgium
13.	Cytopoint (40mg) larutan bagi suntikan untuk anjing	4,000 vial	Zoetis Inc., Belgium

Bertarikh 28 Januari 2019
[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

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- (a) the products shall be imported only from the exporter 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 solely 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>Exporter</i>
1.	Revolution Plus (15mg/2.5mg)	66,000 tubes	Zoetis Inc., United States of America
2.	Revolution Plus (30mg/5mg)	195,000 tubes	Zoetis Inc., United States of America
3.	Revolution Plus (60mg/10mg)	12,000 tubes	Zoetis Inc., United States of America
4.	Simparica Chewables (5mg)	12,000 tablets	Zoetis Inc., United States of America
5.	Simparica Chewables (10mg)	33,000 tablets	Zoetis Inc., United States of America
6.	Simparica Chewables (20mg)	57,000 tablets	Zoetis Inc., United States of America
7.	Simparica Chewables (40mg)	45,000 tablets	Zoetis Inc., United States of America
8.	Simparica Chewables (80mg)	57,000 tablets	Zoetis Inc., United States of America

9.	Simparica Chewables (120mg)	12,000 tablets	Zoetis Inc., United States of America
10.	Cytopoint (10mg) solution for injection for dogs	11,000 vials	Zoetis Inc., Belgium
11.	Cytopoint (20mg) solution for injection for dogs	17,000 vials	Zoetis Inc., Belgium
12.	Cytopoint (30mg) solution for injection for dogs	19,000 vials	Zoetis Inc., Belgium
13.	Cytopoint (40mg) solution for injection for dogs	4,000 vials	Zoetis Inc., Belgium

Dated 28 January 2019
[KKM.R.600-1/3/72]ld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health



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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, mengeccualikan Elanco Malaysia Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 1 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada pengeksport 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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; dan
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JADUAL

Keluaran Yang Dikecualikan

	<i>Nama Keluaran</i>	<i>Kuantiti</i>	<i>Pengeksport</i>
1.	Milbemax (4/10mg) tablet bersalut nipis untuk kucing saiz kecil dan anak kucing	1,355,000 biji tablet	Elanco, Perancis
2.	Milbemax (16/40mg) tablet bersalut nipis untuk kucing saiz kecil dan anak kucing	1,355,000 biji tablet	Elanco, Perancis
3.	Onsior (5mg) untuk anjing	2,310,000 biji tablet	Elanco, Perancis
4.	Onsior (10mg) untuk anjing	1,750,000 biji tablet	Elanco, Perancis
5.	Onsior (20mg) untuk anjing	1,750,000 biji tablet	Elanco, Perancis
6.	Onsior (40mg) untuk anjing	1,165,000 biji tablet	Elanco, Perancis
7.	Onsior (6mg) untuk kucing	6,725,000 biji tablet	Elanco, Perancis
8.	Onsior (20mg/ml) larutan bagi suntikan untuk kucing dan anjing	70,000 vial	Bela-Pharm GmbH & Co. KG, Jerman
9.	Fortekor Plus (1.25mg/2.5mg) untuk anjing	1,130,000 biji tablet	Lek Pharmaceuticals, Slovenia

10.	Fortekor Plus (5mg/10mg) untuk anjing	1,340,000 biji tablet	Lek Pharmaceuticals, Slovenia
11.	Galliprant (20mg)	208,000 biji tablet	Argenta Limited, New Zealand
12.	Galliprant (60mg)	155,000 biji tablet	Argenta Limited, New Zealand
13.	Galliprant (100mg)	155,000 biji tablet	Argenta Limited, New Zealand

Bertarikh 28 Januari 2019
[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
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SALE OF DRUGS ACT 1952

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- (a) the products shall be imported only from the exporter 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 solely 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>Exporter</i>
1.	Milbemax (4/10mg) film coated tablets for small cats and kittens	1,355,000 tablets	Elanco, France
2.	Milbemax (16/40mg) film coated tablets for small cats and kittens	1,355,000 tablets	Elanco, France
3.	Onsior (5mg) for dogs	2,310,000 tablets	Elanco, France
4.	Onsior (10mg) for dogs	1,750,000 tablets	Elanco, France
5.	Onsior (20mg) for dogs	1,750,000 tablets	Elanco, France
6.	Onsior (40mg) for dogs	1,165,000 tablets	Elanco, France
7.	Onsior (6mg) for cats	6,725,000 tablets	Elanco, France
8.	Onsior (20mg/ml) solution for injection for cats and dogs	70,000 vials	Bela-Pharm GmbH & Co. KG, Germany
9.	Fortekor Plus (1.25mg/2.5mg) for dogs	1,130,000 tablets	Lek Pharmaceuticals, Slovenia

10.	Fortekor Plus (5mg/10mg) for dogs	1,340,000 tablets	Lek Pharmaceuticals, Slovenia
11.	Galliprant (20mg)	208,000 tablets	Argenta Limited, New Zealand
12.	Galliprant (60mg)	155,000 tablets	Argenta Limited, New Zealand
13.	Galliprant (100mg)	155,000 tablets	Argenta Limited, New Zealand

Dated 28 January 2019
[KKM.R.600-1/3/72]ld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health



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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, mengeccualikan Delfi Marketing Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 1 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada syarikat Troy Laboratories Pty. Ltd., Australia;
- (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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; 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>
Ilium Xylazil-100 (100mg/ml) suntikan untuk analgesik, sedatif dan merehatkan otot	21,600 vial

Bertarikh 28 Januari 2019

[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD

Menteri Kesihatan

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- (a) the products shall be imported only from the company of Troy Laboratories Pty. Ltd., Australia;
- (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 solely 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>
Ilum Xylazil-100 (100mg/ml) injection for analgesic, sedative and muscle relaxant	21,600 vials

Dated 28 January 2019
[KKM.R.600-1/3/72]ld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
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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, mengeccualikan Gladron Chemicals Sdn. Bhd. daripada pemakaian subperaturan 7(1) berhubung dengan penjualan, pembekalan, pengimportan dan pemilikan keluaran veterinar sebagaimana yang diperihalkan dalam Jadual berkuat kuasa mulai 1 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada syarikat Vetoquinol, Perancis;
- (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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; 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>
1.	Calmivet (12.5mg)	161,000 biji tablet
2.	Calmivet (0.5% w/v) larutan bagi suntikan	3,700 vial
3.	Vetacortyl (4% w/v) suntikan	6,550 vial

Bertarikh 28 Januari 2019
[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

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 Gladron Chemicals 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 1 March 2019 to 31 December 2021 subject to the following conditions:

- (a) the products shall be imported only from the company of Vetoquinol, France;
- (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 solely 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>
1.	Calmivet (12.5mg)	161,000 tablets
2.	Calmivet (0.5% w/v) injectable solution	3,700 vials
3.	Vetacortyl (4% w/v) injectable	6,550 vials

Dated 28 January 2019
[KKM.R.600-1/3/72 Jld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health



22 Februari 2019
22 February 2019
P.U. (B) 108

WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN
DI BAWAH PERATURAN 31

*NOTIFICATION OF EXEMPTION
UNDER REGULATION 31*

DISIARKAN OLEH/
PUBLISHED BY
JABATAN PEGUAM NEGARA/
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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 1 Mac 2019 hingga 31 Disember 2021 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 semata-mata kepada doktor veterinar berdaftar;
- (d) suatu salinan borang import Kastam mengenai keluaran itu hendaklah dihantar dalam masa tiga puluh hari dari tarikh pengimportan kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan bagi tiap-tiap pengimportan; 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.	Thyforon (200mcg) tablet berperisa untuk anjing	2,500,000 biji tablet	Eurovet Animal Health BV, Belanda
2.	Thyforon (400mcg) tablet berperisa untuk anjing	2,500,000 biji tablet	Eurovet Animal Health BV, Belanda
3.	Cardisure (1.25mg) tablet berperisa untuk anjing	700,000 biji tablet	Eurovet Animal Health BV, Belanda
4.	Cardisure (2.5mg) tablet berperisa untuk anjing	700,000 biji tablet	Eurovet Animal Health BV, Belanda
5.	Cardisure (5mg) tablet berperisa untuk anjing	700,000 biji tablet	Eurovet Animal Health BV, Belanda
6.	Cardisure (10mg) tablet berperisa untuk anjing	700,000 biji tablet	Eurovet Animal Health BV, Belanda
7.	Vetoryl (10mg) kapsul keras untuk anjing	432,000 biji kapsul	Dechra Limited, United Kingdom
8.	Vetoryl (30mg) kapsul keras untuk anjing	432,000 biji kapsul	Dechra Limited, United Kingdom
9.	Vetoryl (60mg) kapsul keras untuk anjing	432,000 biji kapsul	Dechra Limited, United Kingdom
10.	Felimazole (2.5mg) tablet salut untuk kucing	1,000,000 biji tablet	Dechra Limited, United Kingdom

11.	Felimazole (5mg) tablet salut untuk kucing	1,000,000 biji tablet	Dechra Limited, United Kingdom
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DATUK SERI DR. DZULKEFLY BIN AHMAD
Menteri Kesihatan

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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 1 March 2019 to 31 December 2021 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 solely 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.	Thyforon (200mcg) flavoured tablets for dogs	2,500,000 tablets	Eurovet Animal Health BV, The Netherlands
2.	Thyforon (400mcg) flavoured tablets for dogs	2,500,000 tablets	Eurovet Animal Health BV, The Netherlands
3.	Cardisure (1.25mg) flavoured tablets for dogs	700,000 tablets	Eurovet Animal Health BV, The Netherlands
4.	Cardisure (2.5mg) flavoured tablets for dogs	700,000 tablets	Eurovet Animal Health BV, The Netherlands
5.	Cardisure (5mg) flavoured tablets for dogs	700,000 tablets	Eurovet Animal Health BV, The Netherlands
6.	Cardisure (10mg) flavoured tablets for dogs	700,000 tablets	Eurovet Animal Health BV, The Netherlands
7.	Vetoryl (10mg) hard capsules for dogs	432,000 capsules	Dechra Limited, United Kingdom
8.	Vetoryl (30mg) hard capsules for dogs	432,000 capsules	Dechra Limited, United Kingdom
9.	Vetoryl (60mg) hard capsules for dogs	432,000 capsules	Dechra Limited, United Kingdom
10.	Felimazole (2.5mg) coated tablets for cats	1,000,000 tablets	Dechra Limited, United Kingdom

11.	Felimazole (5mg) coated tablets for cats	1,000,000 tablets	Dechra Limited, United Kingdom
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Dated 28 January 2019
[KKM.R.600-1/3/72]ld. 2 (6); PN(PU2)269A/V]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health