



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/  
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 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 |
|-----|---|------------|-------------------------------------|

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*



6 Mei 2019  
6 May 2019  
P.U. (B) 238

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 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 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>                       |
|----------------------------------|-----------------|--|
| Osrnia, gel telinga untuk anjing | 280,000 tiub    | Argenta Dundee Limited, United Kingdom |

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 Elanco 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 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>                    |
|--------------------------|-----------------|--|
| Osrnia, ear gel for dogs | 280,000 tubes   | Argenta Dundee Limited, United Kingdom |

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

DATUK SERI DR. DZULKEFLY BIN AHMAD  
*Minister of Health*



6 Mei 2019  
6 May 2019  
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WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT  
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN  
DI BAWAH PERATURAN 31

*NOTIFICATION OF EXEMPTION  
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DISIARKAN OLEH/  
PUBLISHED BY  
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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 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 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. | Frecardyl                      | 2,300 vial         | Vetoquinol SA,<br>Perancis |
| 2. | UpCard 3mg tablet untuk anjing | 63,000 biji tablet | Vetoquinol SA,<br>Perancis |

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 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 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. | Frecardyl                   | 2,300 vials     | Vetoquinol SA,<br>France |
| 2. | UpCard 3mg tablets for dogs | 63,000 tablets  | Vetoquinol SA,<br>France |

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*



6 Mei 2019  
6 May 2019  
P.U. (B) 240

WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT  
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN  
DI BAWAH PERATURAN 31

*NOTIFICATION OF EXEMPTION  
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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, mengeccualikan Ritma Prestasi 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. | Vetmedin 1.25mg tablet kunyah untuk anjing                          | 255,000 biji tablet | Boehringer Ingelheim, Mexico    |
| 2. | Vetmedin 5mg tablet kunyah untuk anjing                             | 99,000 biji tablet  | Boehringer Ingelheim, Mexico    |
| 3. | Pexion 100mg tablet untuk anjing                                    | 174,000 biji tablet | Boehringer Ingelheim, Mexico    |
| 4. | Pexion 400mg tablet untuk anjing                                    | 36,000 biji tablet  | Boehringer Ingelheim, Mexico    |
| 5. | Metacam 5mg/ml (10ml) larutan bagi suntikan untuk anjing dan kucing | 1,310 botol         | Labiana Life Sciences, 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 Ritma Prestasi 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. | Vetmedin 1.25mg chewable tablets for dogs                      | 255,000 tablets | Boehringer<br>Ingelheim, Mexico |
| 2. | Vetmedin 5mg chewable tablets for dogs                         | 99,000 tablets  | Boehringer<br>Ingelheim, Mexico |
| 3. | Pexion 100mg tablets for dogs                                  | 174,000 tablets | Boehringer<br>Ingelheim, Mexico |
| 4. | Pexion 400mg tablets for dogs                                  | 36,000 tablets  | Boehringer<br>Ingelheim, Mexico |
| 5. | Metacam 5mg/ml (10ml) solution for injection for dogs and cats | 1,310 bottles   | Labiana Life<br>Sciences, 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*





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WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT  
GAZETTE*

PEMBERITAHUAN PENGEQUALIAN  
DI BAWAH PERATURAN 31

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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 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)<br>larutan bagi suntikan untuk<br>anjing dan kucing | 20,000 vial         | Produlab Pharma<br>B.V., Belanda |
| 10. | Prevomax 10mg/ml (20ml)<br>larutan bagi suntikan untuk<br>anjing dan kucing | 20,000 vial         | Produlab Pharma<br>B.V., Belanda |
| 11. | Prevomax 10mg/ml (25ml)<br>larutan bagi suntikan untuk<br>anjing dan kucing | 20,000 vial         | Produlab Pharma<br>B.V., Belanda |
| 12. | Prevomax 10mg/ml (50ml)<br>larutan bagi suntikan untuk<br>anjing dan kucing | 20,000 vial         | Produlab Pharma<br>B.V., Belanda |
| 13. | Phenoleptil 12.5mg tablet<br>untuk anjing                                   | 160,000 biji tablet | Produlab Pharma<br>B.V., Belanda |
| 14. | Phenoleptil 25mg tablet<br>untuk anjing                                     | 160,000 biji tablet | Produlab Pharma<br>B.V., Belanda |
| 15. | Phenoleptil 50mg tablet<br>untuk anjing                                     | 160,000 biji tablet | Produlab Pharma<br>B.V., Belanda |
| 16. | Phenoleptil 100mg tablet<br>untuk anjing                                    | 160,000 biji tablet | Produlab Pharma<br>B.V., Belanda |
| 17. | Isoflurin 1000mg/g (250ml)<br>wap sedutan, cecair                           | 12,000 botol        | Chemical Iberica PV,<br>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)<br>solution for injection for dogs<br>and cats | 20,000 vials    | Produlab Pharma<br>B.V., The<br>Netherlands |
| 10. | Prevomax 10mg/ml (20ml)<br>solution for injection for dogs<br>and cats | 20,000 vials    | Produlab Pharma<br>B.V., The<br>Netherlands |
| 11. | Prevomax 10mg/ml (25ml)<br>solution for injection for dogs<br>and cats | 20,000 vials    | Produlab Pharma<br>B.V., The<br>Netherlands |
| 12. | Prevomax 10mg/ml (50ml)<br>solution for injection for dogs<br>and cats | 20,000 vials    | Produlab Pharma<br>B.V., The<br>Netherlands |
| 13. | Phenoleptil 12.5mg tablets<br>for dogs                                 | 160,000 tablets | Produlab Pharma<br>B.V., The<br>Netherlands |
| 14. | Phenoleptil 25mg tablets<br>for dogs                                   | 160,000 tablets | Produlab Pharma<br>B.V., The<br>Netherlands |
| 15. | Phenoleptil 50mg tablets<br>for dogs                                   | 160,000 tablets | Produlab Pharma<br>B.V., The<br>Netherlands |
| 16. | Phenoleptil 100mg tablets<br>for dogs                                  | 160,000 tablets | Produlab Pharma<br>B.V., The<br>Netherlands |
| 17. | Isoflurin 1000mg/g (250ml)<br>inhalation vapour, liquid                | 12,000 bottles  | Chemical Iberica PV,<br>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*



6 Mei 2019  
6 May 2019  
P.U. (B) 242

WARTA KERAJAAN PERSEKUTUAN

*FEDERAL GOVERNMENT  
GAZETTE*

PEMBERITAHUAN PENGECCUALIAN  
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 PENGECEUALIAN 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 Bayer Co. (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 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>                                   |
|--|-----------------|--|
| Veraflox 25mg/ml (15ml)<br>suspensi mulut untuk kucing | 4,000 botol     | KVP Pharma +<br>Veterinar Produkte<br>GmbH, Jerman |

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 Bayer Co. (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 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>                                 |
|--|-----------------|---|
| Veraflox 25mg/ml (15ml) oral suspension for cats | 4,000 bottles   | KVP Pharma +<br>Veterinar Produkte<br>GmbH, Germany |

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

DATUK SERI DR. DZULKEFLY BIN AHMAD  
*Minister of Health*