



16 Ogos 2017
16 August 2017
P.U. (B) 411

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 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 1 Mei 2017 hingga 31 Disember 2020 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 anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia dan dibekalkan dan dijual semata-mata kepada anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia;
- (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

	Nama Keluaran	Kuantiti	Pengeksport
1.	Advocate® (0.4ml) Spot-on Solution (bagi kucing saiz kecil)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
2.	Advocate® (0.8ml) Spot-on Solution (bagi kucing saiz besar)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
3.	Advocate® (0.4ml) Spot-on Solution (bagi anjing saiz kecil)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
4.	Advocate® (1.0ml) Spot-on Solution (bagi anjing saiz sederhana)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
5.	Advocate® (2.5ml) Spot-on Solution (bagi anjing saiz besar)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
6.	Advocate® (4.0ml) Spot-on Solution (bagi anjing saiz lebih besar)	45,000 pipet	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
7.	Profender® Spot-on Solution (bagi kucing saiz sederhana)	12,000 pipet	KVP Pharma + Veterinär Produkte GmbH, Kiel, Germany
8.	Profender® Spot-on Solution (bagi kucing saiz besar)	12,000 pipet	KVP Pharma + Veterinär Produkte GmbH, Kiel, Germany

Bertarikh 27 Julai 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
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 1 May 2017 to 31 December 2020 subject to the following conditions:

- (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 as specified in the Schedule;
- (c) the products shall be imported only for the purposes and use of the members of the Malaysian Small Animal Veterinary Association and supplied and sold solely to the members of the Malaysian Small Animal Veterinary Association;
- (d) a copy of 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

	Product Name	Quantity	Exporter
1.	Advocate® (0.4ml) Spot-on Solution (for small size cats)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
2.	Advocate® (0.8ml) Spot-on Solution (for medium size cats)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
3.	Advocate® (0.4ml) Spot-on Solution (for small size dogs)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
4.	Advocate® (1.0ml) Spot-on Solution (for medium size dogs)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
5.	Advocate® (2.5ml) Spot-on Solution (for large size dogs)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
6.	Advocate® (4.0ml) Spot-on Solution (for extra-large size dogs)	45,000 pipette	Bayer Thai Co. Ltd. Bangrak, Bangkok Thailand
7.	Profender® Spot-on Solution (for medium size cats)	12,000 pipette	KVP Pharma + Veterinär Produkte GmbH, Kiel, Germany
8.	Profender® Spot-on Solution (for large size cats)	12,000 pipette	KVP Pharma + Veterinär Produkte GmbH, Kiel, Germany

Dated 27 July 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
Minister of Health



16 Ogos 2017
16 August 2017
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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 Eli Lilly (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 Mei 2017 hingga 31 Disember 2020 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 anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia dan dibekalkan dan dijual semata-mata kepada anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia;
- (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

	Nama Keluaran	Kuantiti	Pengeksport
1.	Atopica® (25mg)	135,000 biji kapsul	Catalent Germany Eberbach GmbH Eberbach Germany
2.	Atopica® (50mg)	135,000 biji kapsul	Catalent Germany Eberbach GmbH Eberbach Germany
3.	Capstar® (11.4mg)	54,000 biji tablet	Elanco France SAS Huningue France
4.	Capstar® (57mg)	54,000 biji tablet	Elanco France SAS Huningue France
5.	Interceptor® Spectrum (bagi anjing saiz sangat kecil)	54,000 biji tablet	Ex-Lax Inc. Humacao Puerto Rico
6.	Interceptor® Spectrum (bagi anjing saiz kecil)	54,000 biji tablet	Ex-Lax Inc. Humacao Puerto Rico
7.	Interceptor® Spectrum (bagi anjing saiz sederhana)	54,000 biji tablet	Ex-Lax Inc. Humacao Puerto Rico
8.	Interceptor® Spectrum (bagi anjing saiz besar)	54,000 biji tablet	Ex-Lax Inc. Humacao Puerto Rico
9.	Panoramis® (bagi anjing 2.3-4.5kg)	36,000 biji tablet	AbbVie Inc. North Chicago, Illinois, USA
10.	Panoramis® (bagi anjing 4.6-9kg)	36,000 biji tablet	AbbVie Inc. North Chicago, Illinois, USA
11.	Panoramis® (bagi anjing 9.1-18kg)	36,000 biji tablet	AbbVie Inc. North Chicago, Illinois, USA
12.	Panoramis® (bagi anjing 18.1-27kg)	36,000 biji tablet	AbbVie Inc. North Chicago, Illinois, USA

- | | | | |
|-----|---------------------------------------|--------------------|---|
| 13. | Panoramis®
(bagi anjing 27.1-54kg) | 36,000 biji tablet | AbbVie Inc.
North Chicago, Illinois, USA |
|-----|---------------------------------------|--------------------|---|

Bertarikh 27 Julai 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
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 Eli Lilly (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 May 2017 to 31 December 2020 subject to the following conditions:

- (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 as specified in the Schedule;
- (c) the products shall be imported only for the purposes and use of the members of the Malaysian Small Animal Veterinary Association and supplied and sold solely to the members of the Malaysian Small Animal Veterinary Association;
- (d) a copy of 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

	Product Name	Quantity	Exporter
1.	Atopica® (25mg)	135,000 capsules	Catalent Germany Eberbach GmbH Eberbach Germany
2.	Atopica® (50mg)	135,000 capsules	Catalent Germany Eberbach GmbH Eberbach Germany
3.	Capstar® (11.4mg)	54,000 tablets	Elanco France SAS Huningue France
4.	Capstar® (57mg)	54,000 tablets	Elanco France SAS Huningue France
5.	Interceptor® Spectrum (for very small size dogs)	54,000 tablets	Ex-Lax Inc. Humacao Puerto Rico
6.	Interceptor® Spectrum (for small size dogs)	54,000 tablets	Ex-Lax Inc. Humacao Puerto Rico
7.	Interceptor® Spectrum (for medium size dogs)	54,000 tablets	Ex-Lax Inc. Humacao Puerto Rico
8.	Interceptor® Spectrum (for large size dogs)	54,000 tablets	Ex-Lax Inc. Humacao Puerto Rico
9.	Panoramis® (for dogs 2.3-4.5kg)	36,000 tablets	AbbVie Inc. North Chicago, Illinois, USA
10.	Panoramis® (for dogs 4.6-9kg)	36,000 tablets	AbbVie Inc. North Chicago, Illinois, USA
11.	Panoramis® (for dogs 9.1-18kg)	36,000 tablets	AbbVie Inc. North Chicago, Illinois, USA
12.	Panoramis® (for dogs 18.1-27kg)	36,000 tablets	AbbVie Inc. North Chicago, Illinois, USA
13.	Panoramis® (for dogs 27.1-54kg)	36,000 tablets	AbbVie Inc. North Chicago, Illinois, USA

Dated 27 July 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
Minister of Health



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PEMBERITAHUAN PENGEQUALIAN
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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 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 Mei 2017 hingga 31 Disember 2020 tertakluk kepada syarat yang berikut:

- (a) keluaran itu hendaklah diimport hanya daripada syarikat Merial, Lyon, France;
- (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 anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia dan dibekalkan dan dijual semata-mata kepada anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia;
- (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

	Nama Keluaran	Kuantiti
1.	NexGard® (11mg)	54,000 biji tablet
2.	NexGard® (28mg)	126,000 biji tablet
3.	NexGard® (68mg)	144,000 biji tablet
4.	NexGard® (136mg)	243,000 biji tablet
5.	Broadline® (0.3ml) Spot-on Solution untuk kucing	81,000 unit
6.	Broadline® (0.9ml) Spot-on Solution untuk kucing	121,500 unit
7.	Biodyl®(50ml)	21,000 botol

Bertarikh 27 Julai 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
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 May 2017 to 31 December 2020 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 as specified in the Schedule;
- (c) the products shall be imported only for the purposes and use of the members of the Malaysian Small Animal Veterinary Association and supplied and sold solely to the members of the Malaysian Small Animal Veterinary Association;
- (d) a copy of 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

	Product Name	Quantity
1.	NexGard® (11mg)	54,000 tablets
2.	NexGard® (28mg)	126,000 tablets
3.	NexGard® (68mg)	144,000 tablets
4.	NexGard® (136mg)	243,000 tablets
5.	Broadline® (0.3ml) Spot-on Solution for cats	81,000 units
6.	Broadline® (0.9ml) Spot-on Solution for cats	121,500 units
7.	Biodyl®(50ml)	21,000 bottles

Dated 27 July 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
Minister of Health



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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 Mei 2017 hingga 31 Disember 2020 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 anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia dan dibekalkan dan dijual semata-mata kepada anggota Persatuan Doktor Veterinar Haiwan Kesayangan Malaysia;
- (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

	Nama Keluaran	Kuantiti	Pengeksport
1.	Apoquel® (3.6mg)	300,000 biji tablet	Zoetis Belgium SA Belgium
2.	Apoquel® (5.4mg)	600,000 biji tablet	Zoetis Belgium SA Belgium
3.	Apoquel® (16mg)	300,000 biji tablet	Zoetis Belgium SA Belgium
4.	Cerenia® (20ml)	6,000 vial	Zoetis Belgium SA Belgium
5.	Convenia® (4ml)	9,000 vial	Zoetis LLC Kalamazoo Michigan USA
6.	Convenia® (10ml)	3,000 vial	Zoetis LLC Kalamazoo Michigan USA
7.	ProHeart® SR-12	9,000 vial	Zoetis Australia Research and Manufacturing Pty Ltd, Victoria Australia

Bertarikh 27 Julai 2017
[KKM.600-11/2/22; PN(PU2)269A/IV]

DATUK SERI DR. S.SUBRAMANIAM
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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 Zoetis 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 May 2017 to 31 December 2020 subject to the following conditions:

- (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 as specified in the Schedule;
- (c) the products shall be imported only for the purposes and use of the members of the Malaysian Small Animal Veterinary Association and supplied and sold solely to the members of the Malaysian Small Animal Veterinary Association;
- (d) a copy of 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

	Product Name	Quantity	Exporter
1.	Apoquel® (3.6mg)	300,000 tablets	Zoetis Belgium SA Belgium
2.	Apoquel® (5.4mg)	600,000 tablets	Zoetis Belgium SA Belgium
3.	Apoquel® (16mg)	300,000 tablets	Zoetis Belgium SA Belgium
4.	Cerenia® (20ml)	6,000 vials	Zoetis Belgium SA Belgium
5.	Convenia® (4ml)	9,000 vials	Zoetis LLC Kalamazoo Michigan USA
6.	Convenia® (10ml)	3,000 vials	Zoetis LLC Kalamazoo Michigan USA
7.	ProHeart® SR-12	9,000 vials	Zoetis Australia Research and Manufacturing Pty Ltd, Victoria Australia

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DATUK SERI DR. S.SUBRAMANIAM
Minister of Health