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WARTA KERAJAAN PERSEKUTUAN

FEDERAL GOVERNMENT GAZETTE

PEMBERITAHUAN PENGECUALIAN DI BAWAH PERATURAN 31

NOTIFICATION OF EXEMPTION UNDER REGULATION 31

DISIARKAN OLEH/
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AKTA JUALAN DADAH 1952

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

PEMBERITAHUAN PENGECUALIAN 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 Mac 2019 hingga 31 Disember 2021 tertakluk kepada syarat yang berikut:

(a) keluaran itu hendaklah diimport hanya daripada syarikat KVP Pharma + Veterinar Produkte GmbH, Jerman;

(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.

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JADUAL

Keluaran Yang Dikecualikan

Nama Keluaran	*Kuantiti*
Rompun (2% w/v) larutan bagi suntikan	19,000 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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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 March 2019 to 31 December 2021 subject to the following conditions:

(a) the products shall be imported only from the company KVP Pharma + Veterinar Produkte GmbH, Germany;

(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.

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SCHEDULE

Exempted Products

Product Name	*Quantity*
Rompun (2% w/v) solution for injection	19,000 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

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