GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 1478 **29 DECEMBER 2017**

C87 **2017**

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCE ACT, 1965 (ACT 101 OF 1965)

I, **Joey Gouws Registrar of Medicines**, acting by virtue of a delegation in terms of section 34A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), hereby exclude in terms of Section 36 of Act 101 of 1965, on the unanimous recommendation of the members present at a meeting of the Medicines Control Council held on **23 November 2017** the medicines and medical devices listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No R510 of 10 April 2003.

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Joey Gouws

REGISTRAR OF MEDICINES

C87 **2017**

UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKER BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE MIDDELS 1965 (WET 101 VAN 1965)

Ek, **Joey Gouws, Registrateur van Medisyne**, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Middels, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op **23 November 2017**, sluit hierby uit, kragtens Artikel 36 van die Wet 101 van 1965, die medisyne en medisese toestelle in die bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing Nr. R.510 van10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.

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Joey Gouws

REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
42/21.5.1/0895	Innuvair 120 & 180 metered doses	inhaler	**Regulation 10:** labelling of medicines intended for human administration in so far as on the immediate container label: Bilingualism on the immediate label, English only [Regulation 10(1)].		Safeline Pharmaceuticals
48/26/0433	Adcetris 50 mg/ml vial	vial	**Regulation 10:** labelling of medicines intended for human administration in so far as on the outer container label: Bilingualism [Regulation 10(1)]: Inclusion of the scheduling status [Regulation 10(1)(a)] Registration number [Regulation 10(1) (c)]. Name of holder of certificate of registration [Regulation 10(1) (q)].	**Provided that** the exemption is only valid for exemption to import 600 units EU(UK) (English/Danish) approved labelling of the of Adcetris vials to the South African market. The exemption is valid until 30 April 2018.	Takeda (Pty) Ltd
29/30.1/0637	Tetavax injection	vial	**Regulation 10:** labelling of medicines intended for human administration in so far as on the outer container label:	**Provided that** the exemption is only valid for exemption to import	Sanofi Pasteur

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
			Bilingualism [Regulation 10(1)]. Inclusion of the scheduling status [Regulation 10(1)(a)] Registration number [Regulation 10(1) (c)]. Name of holder of certificate of registration [Regulation 10(1) (q)].	the following batches: • M7462, 18252, expiring on 31 August 2018, English and Arabic (Tetavax mono dose); • M7260,246800, expiring on 30 November 2018; English, French and Portuguese (Tetavax multidose) The total quantity to be imported is 429752 vials. The exemption is valid until 31 December 2018.	
50/30.1/097	Keytruda Solution for Infusion	Infusion solution	**Regulation 10:** labelling of medicines intended for human administration in so far as on the outer container label: Bilingualism [Regulation 10(1)]. Inclusion of the scheduling status [Regulation 10(1)(a)]. Registration number [Regulation 10(1) (c)]. Name of holder of certificate of registration [Regulation 10(1) (q)].	**Provided that** the exemption is only valid for exemption to import 50 units of USA approved labelling of the of Adcetris vials to the South African market. The exemption is valid until 28 of February 2018	MSD (Pty) Ltd
49/30.2/1042	Boostrix vaccine	vial	**Regulation 10:** labelling of medicines intended for human administration in so far as on the immediate container label: Bilingualism on the immediate label, English only [Regulation 10(1)].	The exemption is consistent with regulation 10(3)(a)(i)	GlaxoSmithKline South Africa (Pty) Ltd
N/A	Medical Devices and IVD's	Various	**Section 18A and 18B** relating to the sampling and the bonusing of medical devices and IVD's for a period of one (1) year from the date of publication of this gazette.	**Provided that** the exemption is valid for a period of one (1) year from the date of publication	Various