DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. 643 **22 August 2014**

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

I, **Mandisa Hela, 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 **7 March 2014, 10 April 2014, 6 June 2014, 1 August 2014** the medicines 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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MANDISA HELA
REGISTRAR OF MEDICINES

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
D/7.5/39	Questran Lite	Powder	**Regulation 8: Labelling of medicines:** Regulation 8 (1) Bilingualism Regulation 8 (1) (a) Scheduling status Regulation 8 (1) (b) Proprietary name: use of the na Questran Light® [UK] instead of Questran Lite® [RSA] Regulation 8(1) (c) Registration number **Regulation 9 South African Package Insert** **Regulation 10 Patient Information Leaflet:** Regulation 10(1): Bilingualism Regulation 10(1)(a):inclusion of Scheduling number Regulation 10(1)(b): Proprietary name: use of the name Questran Light® [UK] instead of Questran Lite® [RSA] Regulation 10(1)(k):Registration number Regulation 10(1)(l):Name of the holder of the certificate of registration Bristol Myers Squibb Holdings Ltd, Sanderson Ropad, Uxbridge, England [UK] instead of Bristol Myers Squibb Holdings Ltd, 47 Van Buuren Road, Bedfordview [RSA]	**Provided that** the exemption is only valid for 12 months until 7 March 2015	Bristol Myers Squibb
42/11.10/0263	Gaviscon Plus tablets – Handy Pack	Tablets	**Regulation 8: Labelling of medicines:** Regulation 8(1): Bilingualism	None	Reckitt Benckiser
30/5.1/0395 31/5.4/0206 31/5.4/0207 32/21.5.1/0338 32/21.5.1/0512	Pharma-Q: Adrenaline inject 1mg/1ml Atropine injection 0,5mg/1ml Atropine injection 1mg/1ml Betamethazone injection 4mg/1ml Dexamethasone Phosphate	Injection	**Regulation 8: Labelling of medicines:** Regulation 8(1): Bilingualism on the immediate container label	None	Pharma-Q

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	injection 4mg/1ml				
31/20.1.1/0442	Gentamicin injection 40mg/1ml				
32/11.2/0242	Hyoscine Butylbromide injection 20mg/1ml				
33/2.1/0423	Ketamine injection 10mg/1ml				
33/2.1/0424	Ketamine injection 50mg/1ml				
33/2.1/0425	Ketamine injection 100mg/1ml				
29/2.7/0475	Morphine injection 10mg/1ml				
29/2.7/0476	Morphine injection 15mg/1ml				
31/2.9/0083	Pethidine injection 25ml/1ml				
31/2.9/0084	Pethidine injection 50ml/1ml				
31/5.3/0393	Neostigmine Methyl Sulphate injection 2,5mg/1ml (A/A)				
31/5.3/0394	Neostigmine Methyl Sulphate injection 2,5mg/1ml (5ml A/V)				
Unregistered	Solal Dehydroepiandrosterone (DHEA)	Tablet	**Section 14(1):** Prohibition of sale of a medicine that is subject to registration and are not registered **Regulation 22:** Application for registration	**Provided that** the exemption is only valid for 3 months until 26 June 2014 to allow withdrawal of the product from the market	Solal Technologies
Unregistered	Solal Melatonin 3mg	Tablet	**Section 14(1):** Prohibition of sale of a medicine that is subject to registration and are not registered **Regulation 22:** Application for registration	**Provided that** the exemption is only valid for 3 months until 26 June 2014 to allow withdrawal of the product from the market	Solal Technologies

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B/2.7/1014	Sublimaze 2 ml	Injection	**Regulation 8: Labelling of medicines:** Bilingualism [Regulation 8(1)]. Inclusion of the scheduling status [Regulation 8(1)(a)] Inclusion of the Proprietary name use of the name Fentanyl-Janssen® instead of Sublimaze® [Regulation 8(1)(b)] Inclusion of registration number [Regulation 8(1)(c)] Address of the holder of the certificate of registration Janssen instead of Janssen Pharmaceutica (Pty) Ltd, Building 6, Country club Estate, 21 Woodlands Drive, Woodmead. [Regulation 8(1)(p)] **Regulation 9: Information to appear on the Package Inse** Regulation 9(1): Bilingualism Regulation 9(1)(a):inclusion of Scheduling number Regulation 9(1)(b): Proprietary name: use of the name Fentanyl-Janssen® instead of Sublimaze® 2 ml Regulation 9(1)(q):Registration number Regulation 9(1)(q):Address of the holder of the certificate of registration Janssen instead of Janssen Pharmaceutica (Pty) Ltd, Building 6, Country club Estate, 21 Woodlands Drive, Woodmead. **Regulation 10: The inclusion of a Patient Information Leaflet**	**Provided that** the exemption is only valid for 5 500 packs containing 10 ampoules	Janssen Pharmaceutica (Pty) Ltd
Q/2.7/327	Rapifen® 2 ml	Injection	**Regulation 8: Labelling of medicines:** Bilingualism [Regulation 8(1)]. Inclusion of the scheduling status [Regulation 8(1)(a)] Inclusion of the registration number [Regulation 8(1)(c)] Address of the holder of the certificate of registration Janssen instead of Janssen Pharmaceutica (Pty) Ltd, Building 6, Country club Estate, 21 Woodlands Drive, Woodmead.	**Provided that the exemption is only valid for** 4 000 packs containing 10 ampoules	Janssen Pharmaceutica (Pty) Ltd

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			[Regulation 8(1)(p)] Address of the holder of the certificate of registration Janssen instead of Janssen Pharmaceutica (Pty) Ltd, Building 6, Country club Estate, 21 Woodlands Drive, Woodmead. [Regulation 8(1)(p)] **Regulation 9: Information to appear on the Package Inse** Regulation 9(1): Bilingualism Regulation 9(1)(a):inclusion of Scheduling number Regulation 9(1)(q):Registration number Regulation 9(1)(r):Address of the holder of the certificate of registration Janssen instead of Janssen Pharmaceutica (Pty) Ltd, Building 6, Country club Estate, 21 Woodlands Drive, Woodmead. **Regulation 10:** The inclusion of a Patient Information Leaflet		
NX/15.4/151	BBS Sterile Irrigation Solution®	Solution	**Regulation 8: Labelling of medicines:** Regulation 8 (1) (a) Scheduling status Regulation 8(1) (c) Registration number	Provided that the exemption is only for a quantity of 2 batches consisting of about 7 500 units	Alcon Laboratories SA (Pty) Ltd
44/2.6.5/003 44/2.6.5/004	Perida 0,5 mg Perida 1 mg®	Tablets	**Regulation 8:Labelling of medicines:** Regulation 8(1)(p): Name of the holder of the certificate of registration **Regulation 9: Information to appear on the Package Insert** Regulation 9(1)(h): Warnings to include the general safety update for all *risperidone* containing products. Regulation 9(1)(r):Address of the holder of the certificate of registration **Regulation 10: Information to appear on a Patient Information Leaflet** Regulation 1(e)(iii) Instructions before taking the medicine	Provided that the exemption is only applicable to 4 batches: Perinda 0,5mg Batch G403595, 2736 Perinda 0,5mg Batch G403596, 2616 Perinda 0,5mg Batch G403597, 1766 Perinda 1mg Batch G401155, 4599	Unicorn Pharmaceuticals (Pty) Ltd

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			which include the general safety update required for all *risperidone* containing products. Regulation 10(1)(l):Address of the holder of the certificate of registration		
Various	Mebendazole containing medicine	Tablets and Suspension	**Section 22A (4) and (5)** to allow for prescribing and administrating of deworming medicines to children aged 1 year and older.	Provided that the exemption is only for the deployment of the Department of Health ***Ward based PHC outreach teams*** to allow Community Health Workers and School teachers to treat and administer deworming medication to children aged 1 year and older under the supervision of a professional nurse and that the prescribing information be recorded.	Department of Health

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