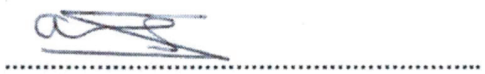
GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 565 **25 MAY 2016**

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 **22 April 2016** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No R. 510 of 10 April 2003.



JOEY GOUWS
REGISTRAR OF MEDICINES

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
45/8.3/0948	Ferinject	injection	**Regulation 8: Labelling of medicines:** Regulation 8 (1) Bilingualism Regulation 8(1)(a) Scheduling status Regulation 8(1)(c) Registration number Regulation 8(1)(p) Name of the Holder of Registration **Regulation 9: Package Insert** Regulation 9(1) Bilingualism Regulation 9(1)(a) Scheduling status Regulation 9(1)(q) Registration number Regulation 9(1)(r) Name of the holder of the certificate of registration **Regulation 10: Patient Information Leaflet** Regulation 10(1) Bilingualism Regulation 10(1)(a) Scheduling status Regulation 10(1)(k) Registration number Regulation 10(1)(l) Name of the holder of the certificate of registration Regulation 10(1)(m) The date of publication of the patient information leaflet	**Provided that the authorization is only for 5000 units of Batch 522011.**	Takeda (Pty) Ltd
43/20.2.8/0226	Aptivus 250 mg	tablet	**Regulation 8: Labelling of medicines:** Regulation 8(1): Bilingualism Regulation 8 (1) (a) Scheduling status Regulation 8(1) (c) Registration number **Regulation 9 Package Insert:** Regulation 9(1) Bilingualism Regulation 9(1)(a) Scheduling Regulation 9(1)(q) Registration number Regulation 9(1)(r)Name of the Holder of the Certificate of Registration. **Regulation 10 Patient Information Leaflet:** Regulation 10(1)(a) Scheduling Regulation 10(1)(k) Registration number Regulation 10(1)(l) Name of the Holder of Certificate of Registration	**A period of twelve months from the date of Government Gazette publication**	Ingelheim Pharmaceuticals

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
			Regulation 10(1)(m) date of publication of the patient information leaflet		
Various	SCHEDULE 0 Human medicines	Various	Section 22G(3) and Section 18A relating to the supply of the medicine according to a bonus system and a transparent pricing system which includes a single exit price	**A period of three years from the date of Government Gazette publication.**	Various