

GENERAL NOTICE

NOTICE 637 OF 2014

DEPARTMENT OF HEALTH

NO C64, 67 and 66.....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, 6 June and 1 August 2014** respectively so called Complementary medicines submitted in terms of the Government Gazette No 23128 Notice R205, dated 22 February 2002 and subjected to compliance with the provisions of Government Gazette No 37032 Notice R807, dated 15 November 2013 from the information to appear on:

the label and outer carton of the product

- o Regulation 8(1): labeling of medicines intended for human administration in so far as bilingualism
- o Regulation 8(1)(a) the inclusion of the scheduling status
- o Regulation 8(1)(c) registration number on the immediate container label and the outer container label (carton)
- o Regulation 8(1)(z) the category of medicine
- o Regulation 8(1)(cc) the pharmacological classification
- o Regulation 8 (1)(dd) in the case of a complementary medicine-
 - (i) the discipline of the medicine; and
 - (ii) if the medicine has not received registration with the Medicines Control Council the disclaimer "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease."
- o Regulation 9 inclusion of a South African Package Insert
- o Regulation 10 inclusion of a Patient Information Leaflet

For a period up to 15 August 2014 provided that the Applicants submit to the Registrar a two (2) monthly report on the status of the labelling implementation.

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MANDISA HELA
REGISTRAR OF MEDICINES