

# MEDICINES CONTROL COUNCIL



**PUBLICATION OF COMPLEMENTARY MEDICINES (CATEGORY D)  
SUBMITTED FOR REGISTRATION IN TERMS OF SECTION 14(3) OF THE MEDICINES  
AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)**

## To all Stakeholders and Complementary Medicine Applicants

Government Gazette Notice R. 870 of 15 November 2013 calls for the legislative oversight of all complementary or alternative medicines. In terms of the said Notice all medicines falling in Category D shall comply with the regulatory requirements as per the notice.

At the Medicines Control Council meeting of April 2012 (MCC52), the Council resolved that, based on a risk assessment, complementary medicines making claims for and purporting to treat, diagnose and modify conditions associated with high risk conditions associated with the pharmacological classifications stipulated hereunder should submit an application for evaluation to the Council in accordance with the requirements of the General Guideline on *Complementary Medicines- Quality, Safety and Efficacy*.

Therefore, in terms of Government Gazette Notice R. 870, medicines falling in Category D (Complementary Medicines) that were available for sale in the Republic of South Africa before 15 November 2013 and in the pharmacological classifications 20.2.8 (Antiviral agents), 21.2 (Oral hypoglycaemics), 6 (Cardiac medicines), 26 (Cytostatic agents) are subject to registration from the date of the said publication and should have submitted an application for registration by 15 May 2014. No complementary medicine as defined by the Regulations is permitted entry to the market after 15 November 2013 without prior registration by the Council.

All stakeholders are hereby notified in terms of the provisions of Section 15(11) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) [hereinafter referred to as "the Act"], of the list of medicines attached hereto submitted to the Medicines Control Council for consideration of registration and that have the right of sale relating to the pharmacological classifications called up as per the said notice.

Stakeholders are advised that only these Complementary Medicines are permitted rights of continued sale subject to compliance with Regulation 48C(1) and (2)(a) of the General Regulations made in terms of the Act, any further condition by Council made in terms of Section 15 of the Act and any final outcome of such registration process being communicated to the applicants by the Council.

It is further advised that in terms of Section 14(1) of the Act, no other unregistered medicines available for sale prior to 15 November 2013 and not submitted to Council in terms of Regulation 48C(2)(a)(ii) may be allowed continued sale with indications that relate to the aforementioned pharmacological classifications and must therefore be removed from the market.

Yours faithfully

**DR J GOUWS**  
**REGISTRAR OF MEDICINES**

**Category D medicine applications submitted to the Medicines Control Council in terms of Government Gazette Notice R. 870 allowed right of sale in terms of Section 15(11) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)**

<b>Proprietary Name of Medicine</b>	<b>Name of the Applicant and Final Product Release Responsibility</b>	<b>Application Number</b>	<b>Name and address of the Manufacturer</b>	<b>Name and quantity of Active Ingredients</b>	<b>Dosage Form</b>	<b>Name of the Final Product Release Control</b>
Cralonin oral drops	Modhomco (Pty) Ltd	D490318	Biologische Heilmittel Heel GmbH Dr Reckeweg Street 2-4 D-76532 Baden-Baden Germany	<i>Crataegus laevigata</i> MT, <i>Spigelia anthelmia</i> D1, <i>Kalium carbonicum</i> D1	Oral drops	Modhomco (Pty) Ltd 96 Amsterdam Str Clubview Centurion, 1057
Crataegus Oxy Liquid	Bioforce SA (Pty) Ltd	D490323	Bioforce AG CH-9325 Roggwil, Switzerland	<i>Crataegus oxyacantha</i> tincture 47 % alcohol v/v	Oral drops	Bioforce AG CH-9325 Roggwil, Switzerland
Cardio Health	Bell Lifestyle Products SA (Pty) Ltd	D500174	Nutra North Inc. 1370 Argyle Road Windsor, Ontario N8Y 3K7	Each capsule contains 575 mg of a proprietary blend of: Betaine HCl 150 mg <i>Allium sativum</i> extract 100 mg <i>Avena sativa</i> extract 100 mg <i>Saccharomyces cerevisiae</i> extract 100 mg <i>Bromelia ananas</i> 50 mg <i>Rosmarinus officinalis</i> extract 50 mg <i>Carica papaya</i> 25 mg Pyridoxine HCl 85 mg Folic acid 560 µg Cyanocobalamin 560 µg Biotin 140 µg	Capsule	Nutra North Inc. 1370 Argyle Road Windsor, Ontario N8Y 3K7

Proprietary Name of Medicine	Name of the Applicant and Final Product Release Responsibility	Application Number	Name and address of the Manufacturer	Name and quantity of Active Ingredients	Dosage Form	Name of the Final Product Release Control
Antagolin	Medical Nutritional Institute (Pty) Ltd	D490319	Hersol Manufacturing Laboratories (Pty) Ltd. Hersol House, 36 Maddison Street, Jeppestown, 2094	Each tablet contains: Barberry root extract 60 % equivalent to <i>Berberis vulgaris</i> 21,0 mg Banaba leaf extract 1 % equivalent to <i>Lagerstroemia speciosa</i> 4,0 mg Chromium aminocheilate 2 % equivalent to chromium 7 µg Inositol 40 mg	Film-coated tablets	Hersol Manufacturing Laboratories (Pty) Ltd Hersol House 36 Maddison Street, Jeppestown, 2094
Patrick Holford Cinnamon	Brunel Laboratoria (Pty) Ltd	D490321	Nutrpharm Manufacturing industries (Pty) Ltd, 9-11 Coconut Grove, Shaka's Head Industrial Park, Ballito	Each capsule contains Cinnulin PF extract (20:1) 75 mg equivalent to <i>Cinnamomum burmannil</i> 1 500 mg	Film-coated tablets	Nutrpharm Manufacturing industries (Pty) Ltd, 9-11 Coconut Grove, Shaka's Head Industrial Park, Ballito
Bioharmony Cinnabalance	Avid Brands (Pty) Ltd	D490322	Herbal Homeopathic (Pty) Ltd, 12 Pickwick Road, Salt River, Cape Town, 7925	Each capsule contains: Cinnulin PF extract 13,0 mg equivalent to Cinnamon 260,0 mg <i>Sutherlandia frutescens</i> 250,0 mg Cinnulin PF extract (20:1) 13,0 mg	Capsules	Herbal Homeopathic (Pty) Ltd, 12 Pickwick Road, Salt River, Cape Town, 7925