

26 March, 2009

An open letter to the Medicines Control Council from concerned academics and others

Professor Peter Eagles – Chairperson  
Professor Tshimbi Mathivha – Vice Chairperson  
Mrs Mandisa Hela – Registrar  
Members of Council

Sunday 22<sup>nd</sup> February 2009 marked the 7<sup>th</sup> anniversary of the call up of “medicines frequently referred to as complementary medicines” [Notice No R204, Regulation Gazette No 7282, Gazette No 23128, Date 20020222] in terms of Section 14(2) of the Medicines and Related Substances Act (Act 101 of 1965). As stated in Notice No R204, this well-intentioned “call up” was primarily for the purposes of auditing the complementary medicines market over six months. The notice expired on 22 August 2002.

However, as you would well be aware, manufacturers and marketers of these products continue to submit their information in terms of the expired call up. This information continues to be accepted by the Medicines Regulatory Affairs Cluster of the Department of Health. As a consequence the products are freely marketed without any regulatory oversight. This is an unfortunate and regrettable failure of the MCC’s statutory obligation to ensure that the availability of medicines and related substances are in the public interest.

The MCC’s failure to regulate these products undermines the Constitution of our country. The Bill of Rights, [Chapter 2 of The Constitution of the Republic of South Africa, 1996 (Act 108 of 1996), Section 12 “Freedom and Security of the person” subsection 2(b)] states: “Everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body.” The free availability of these unregulated products to largely ill-informed consumers and citizens from all strata of society is a direct attack on their bodily integrity (as there is no guarantee of the quality of the products, and hence no valid safety or efficacy claims are possible) and on their psychological integrity (as the advertising creates and sustains false beliefs in the non-validated claims for quality, safety and efficacy of the products).

The fundamental issue of there being no independent assessment of the quality of these products means that:

- We do not know whether products contain no active ingredients at all and possibly contain only inactive excipients.
- We do not know whether products possibly contain toxic heavy metals and how much.
- We do not know whether products are possibly contaminated with bacteria or what the concentrations of these are.
- We do not know whether products may be adulterated with banned substances.
- We do not know which products contain Scheduled substances according to the Schedules to the Medicines Act.
- We do not know which products may contain conventional, registered medicines or other synthesised ingredients.
- We do not know whether the combinations or amounts of individual ingredients contained within various formulations are rational or safe.

We would point out that the public statements made by the then spokesperson for the Department of Health in September 2006 and July 2007 were inaccurate in that he claimed that 14,000 of the 20,000 submissions received as a result of the Complementary Medicines call-up had been “assessed” by the MCC. As you know, no assessment was done, and only administrative details were entered into a database. One of the signatories to this open letter, Professor Jobson, submitted to the Inspectorate a list of some 150 products containing prohibited substances. None of these had been detected in the so-called “assessment” of these medicines.

In June 2008, in his High Court judgment against Matthias Rath and others, Judge Zondi clearly indicated that the primary purpose of the 2002 Complementary Medicines call up was to bring to the attention of the MCC the substances about which medicinal claims were being made, in order to determine the correctness of the claims, and whether the claims constitute a public health hazard.

The MCC has however failed to determine the correctness of the claims made for the myriad products which have been submitted in the last seven years. We would re-emphasise the argument that because no independent assessment of quality is being carried out on these products by the MCC, the products must be considered to constitute a public health hazard.

Another aspect of the Zondi judgment relates to advertising claims, and he indicates that: “. . . in view of the provisions of the 2002 call up notice the . . . respondents must stop making claims about the medicinal effect of their products until their products in respect of which medicinal claims are made have been submitted to the MCC to review the efficacy, quality and safety of those

claims.”

Judge Zondi further ruled that the publishing of advertisements concerning the efficacy of VitaCell on persons with AIDS was unlawful in that the respondents had not submitted VitaCell to the MCC to review its medicinal claims.

In our understanding this would mean that no advertising claims can be made for *any product* called up in terms of the 2002 call up notice, until every product’s medicinal claims have been submitted to the MCC for review. This has clearly not been done.

In our view, the advertising claims of any medicine which has been submitted in terms of the 2002 call up can be considered misleading. This is on the basis that, because the quality of the product is unknown and has not been independently assessed by the MCC or any independent body, no valid claims are possible. Furthermore, virtually every one of these medicines has already been “called up for registration” in terms of Regulation 25 of the Regulations to the Act. This cannot be “overturned” by the 2002 call up.

It should be noted that the Advertising Standards Authority of South Africa (ASA) has no medical or scientific expertise, and it has made this explicit in several of its rulings. It is therefore unable to adequately protect the public from misleading advertising of medicines, including complementary medicines. It could also be considered a dereliction of the MCC's duty for the ASA, without any pharmaceutical, pharmacological or medical expertise, to carry out this function on behalf of the MCC.

We therefore call on the MCC to, with immediate effect, rescind the 22 February 2002 notice (No R204) calling up medicines frequently referred to as complementary medicines. We would respectfully recommend that the MCC simultaneously issue a notice in terms of Section 19(2) of the Act. This states:

“The council may by notice in writing require any person who manufactures or sells or administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his possession or which such person is in a position to obtain regarding such medicine.”

We would respectfully recommend that such a notice be worded to incorporate all unregistered

medicines. We would suggest that an appropriate period for compliance be no more than six months, and that the notice be worded to include the information already required and obtained in terms of the 2002 call up.

We would further respectfully recommend that in addition, every product submit a current certificate of analysis from an independent laboratory, as well as all advertising claims made for the product. All submissions already received as a result of Notice No R204 should be considered as having met the requirements of this new notice apart from the current certificate of analysis, and the advertising claims requirements. In essence, the Section 19(2) directive could replace the 2002 “call up” without too much disruption to the industry. The 1985 call up would be reinstated through the rescinding of the “call up”.

We would like to suggest that it would be opportune to simultaneously begin a process to re-assess the quality, safety and efficacy of the so-called “old medicines.” Although “old medicines” are technically registered, they have not been rigorously assessed in terms of quality, safety and efficacy, but were apparently registered primarily on the basis of monographs.

A mechanism to implement the assessment of the submissions, the certificates of analysis, and the advertising claims would have to be established forthwith.

In summary:

- The Complementary Medicines 2002 call up has resulted in an untenable regulatory hiatus where medicines of unknown quality have flooded the South African market.
- The South African public has been put at risk – not only health-wise but in terms of potentially fruitless expenditure of their disposable income on products which have not been independently assessed.
- This undermines citizens’ rights to bodily and psychological integrity as enshrined in the Constitution of our country.
- It is the Medicines Control Council's responsibility to regulate all medicines available to the public.
- The Medicines Control Council has failed to ensure that as far as complementary medicines are concerned, their availability is in the public interest, and it has failed to consider “only” these products' safety, quality and therapeutic efficacy in relation to their effects on the health of South African persons, because it has not required any evidence for these products' safety, quality and

efficacy.

- Based on the Zondi judgment, the Medicines Control Council must resume its statutory obligation to consider all medicinal claims made in the advertising of medicinal products.
- The 2002 call up should be rescinded, and replaced with a notice in terms of Section 19(2) of the Medicines Act – but with the additional provisos of submitting current certificates of analysis and all advertising claims made. A six month period should be stipulated for fulfilment of these requirements.

Respectfully yours,

Signatories:

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cc. Minister of Health, Ms B. Hogan

Director General of Health, Mr T. Mseleku

Chairperson of the Parliamentary Portfolio Committee on Health, Mr LVJ Ngculu