PHARMAPACT

SAYS NO! To The Tyranny Of Monopolistic PHARMACEUTICAL EXPROPRIATION Of Natural Health Substances.

Peoples Health Alliance Rejecting Medical Authoritarianism, Prejudice And Conspiratorial Tyranny.
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An open formal letter served on:

26 February 1999

Dr Ayanda Ntsaluba, Director-General, Dept. of Health; Dr Helen Rees, Chairperson, Medicines Control Council; Mrs Precious Matsoso, Registrar, Medicines Control Council; Dr Peter Makhambene, Chairman, Compementary Medicine Committee, MCC. Dr Abe Nkomo, Chairman, Parliamentary Portfolio Committee on Health

Dear Sir/Madam

PROPOSED REGULATION OF ALL NATURAL HEALTH SUBSTANCES AS MEDICINES: Obey the law! If it's unconstitutional, it's not law. SAMMDRA & its regulations are unconstitutional.

At the outset, let us congratulate the organisers of this meeting on having <u>for the first time actually called a legal democratic meeting</u> by virtue of heeding our ongoing criticism and pleas that meetings destined to so significantly affect the health of so many of our citizens, be called **by public notice**. That you have taken two years to do so, and expect to use this occasion to present or to <u>rubber stamp</u> the result of two years of unrepresentative, undemocratic, financially vested interest, autocratic, unconstitutional and hence illegal trash, is an insult to PHARMAPACT and to the Health Freedom South Africa alliance partners.

We also protest the fact that **the public announcement affords** us <u>only six days notice</u>, whereas supporters of the process had advanced notice. Furthermore, the actual **date of the meeting** could not have been more **deliberately <u>ill-chosen</u>**, coming as it does at <u>month end</u>, but also the <u>end of the financial year</u>, and further, at a time when many **small concerns**, which are our primary **constituency** and are **often owner-managed**, are **stock-taking and some even upgrading to Y2K compliant accounting software on the actual day.**

You are referred to the position of **PHARMAPACT** and its <u>Health Freedom South Africa</u> alliance partners as set out in correspondence to the honourable **Minister of Health** dated <u>19 June 1998</u>, and referred to the **Director-General** for further attention by the Minister on <u>3 July 1998</u>; to our letter to the **Registrar**, **Medicines Control Council** dated <u>7 October 1998</u> and to **Health Freedom SA**'s letter of <u>24 February 1999</u>.

All of the above-mentioned, but in particular <u>Dr Makhambene</u> are referred to <u>public lies</u> perpetrated by him and audio-recorded at the recent <u>9 October 1998</u> so-called **Broad Based Reference Group** meeting in reponse to a comment by **Hillary Shannon** as follows: "Dr. Makhambeni, Dr Rees. I have said what I have been through. I really feel I am a member of **PHARMAPACT**. It was the only organization from which I got clarity and help in the struggle I had. I feel that **Anthony Rees would not have** got up here and **stood up today if we had a forum of real democracy in the past** where he could say what is needed to be said".

Dr Makhambene: "I will respond to that Two years ago, we had a meeting held by the Director General. At that meeting we took a look at the problem of how do we register complimentary medicines. Various stakeholders attended that meeting. At that meeting it was decided to resurrect the Complimentary Medicines Committee, which had previously became dysfunctional. From that meeting a workshop was called. All the role-players were asked to be present, so that we could look at the way forward. That meeting was held at the end of November. At that meeting people were then elected to a smaller group that met on the sixth of December, where a Complimentary Medicines Committee was chosen. Now, that committee was an interim committee to try and deal with the situation, the crisis situation. It was also made quite clear that the committee had to act under Act 101. That is the legal position. We also suggested that another group be established called the Broad Based Reference Group. These two groups would work parallel to address issues around complimentary medicines. I remember the Director General saying that the establishment of the other group is to lobby, and ask for changes to legislation so that at the end of the day, we can have new legislation to address the problems.) At that first meeting, on 1 November 1996, PHARMAPACT was represented. If subsequently PHARMAPACT have not participated in all the follow-up meetings, I cannot see how PHARMAPACT can blame other people".

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Anthony Rees: "PHARMAPACT protested from the first day about vested interests and nothing was ever done. (Audience clap) Nothing, Admit it!"

Dr Makhambene: "Now, the question of vested interests was raised and I would say at the subsequent meeting when PHARMAPACT did not attend. From then on PHARMAPACT decide to be outside of the process. \leftrightarrow If people are outside the process, I do not see how they can come back after two years and say they are protesting, because vested interests are being addressed as you have heard. \leftrightarrow We are going to address those very issues that are a sore point. I want to say that the work that has been done by the CMC was done by dedicated individuals, all for the safety and good of the public. People have had different opinions and perceptions about what has happened. When the new SAMMDRA Bill comes into being this will show us the integrity of those who have allowed this process to be done. At one stage in Council, when this question came up about the Parliamentary hearings that people said they were not represented, it was brought back to the Medicines Control Council, which again sent out invitations for people to come on board. The Cape Lobby group attended such a meeting, PHARMAPACT again did not respond. Ω So,.... Ahh.... I hear people say that they were not represented, but how do you represent people who stay out of the process? That is a question that we must be all aware of. The process has been going on and they have been aware of the process. They have not taken advantage of being a part of the process".

Anthony Rees: "Sir, the reason we have not been a part of the process from the beginning was because the position was that the CMC, in our opinion was illegal, because of financial interests, there was no public notice and the proceedings were not democratic. Therefore we stayed out the process voluntarily because we would not get involved with a committee which we believe has been illegal".

PHARMAPACT consider the above responses by Dr Makhambene to constitute a lie, not so much by virtue of what was said, as much as what was known, yet deliberately not divulged, which significant omissions constitutes gross misrepresentation of the facts so as to cover-up considerable serious procedural irregularities. We shall elaborate from the official documentational record on the details deliberately excluded and put the record straight and expose Dr Makhambene for the fraud that he is. These accusations apply also to Dr Rees, Mrs Matoso, and the Council, who all are privy to these facts.

Most importantly, the meeting of 1 November 1996 was not called by public notice, nor was any subsequent meeting, with the exception of that of 27 February 1999, which is why PHARMAPACT have now for the first time sent an official delegation to a meeting in this regard, other than the Parliamentary hearings. Invitations were extremely selective, primarily to the Chiropractors, Homoeopaths and Allied Health Professions Interim Council and their constituencies, and to the Health Products Association members. Significantly the title of the agenda was "Natural Health Substances and the Enforcement of Act 101 of 1965", though this was strategically changed to "Complementary Medicines" so as to force pro-active products into a post-active mould, a distinction which only we still maintain to this day. The reason someone outside of the professions and medicines industry like the author of this letter happened to be at the meeting, was that I was implored by one of the "elite" to be present, since I had a reputation of standing up to the MCC, having previously had several personal care products declared illegal medicines.

If one goes back to the official <u>Dept of Health minutes</u>, it is quite clear that <u>this whole thing was a set-up to preferentially favour the homoeopathic pharmaceutical companies who were losing their apartheid spawned monopolies to post sanctions proliferation of imported superior herbal and pro-active nutritional products and who through <u>Rene' Doms</u>, as ex- MCC Inspectorate, used his inside experience and influence to present the Listing Procedure as a means to achieving this advantage for <u>Pharma Natura</u>, whose management he had recently secured. <u>It was Doms who complained to the MCC about the new competition and who fabricated a toxicological storm in a herbal teacup so as to present his solution to <u>his falsely fabricated problem</u>. Significantly the Listing procedure was already at quite an advanced stage of development, Doms and Turner (HPA)(both Pharma Natura) managing to do presentations at the "Symposium on Regulatory Submissions" on <u>20 November 1996</u>. On <u>9 December</u> 1996 **Doms wrote** to us stating: "we are exploring new avenues that could be fruitfully applied internationally".</u></u>

The <u>Health Products Association submission</u> to the 1 November 1996 meeting was already calling for implementation of the Listing Procedure. Dr <u>Stoffberg (Natura)</u>, called for a separate listing committee as part of the CMC to look at technical issues. It is this <u>Technical Committee</u>, dominated by the big three <u>homoeopathic pharmaceutical companies</u>, which later <u>drove the process in the pharmaceutical direction</u> where it stands today, and contrary to the claimed bottom-up nature of the BBRG-CMC interface, this <u>Technical Committee</u> outranked even the CMC itself. The lies had started, the <u>HPA</u> submission confirming our fears and <u>fraudulently claiming that "With the Listing Procedure all the approximately 90 member companies are prepared to become registered pharmaceutical companies". <u>Professor Folb</u> at the 1 November meeting <u>concluded that "the ideas of the listing need to receive careful attention from the Committee" but qualified this, stating that "other ways should also be investigated".</u></u>

Both Shisana and Folb pointed out that the only way the Act could be changed is by a Parliamentary Committee, Folb stating that "the people have the power to change the law", and that "a special Parliamentary Committee should be asked to examine suggestions". When matters deteriorated along the lines to be explained hereafter, PHARMAPACT, unprepared to be subject to the bullying of the Overwhelming financially and power-play vested interests illegally permitted by the MCC to dominate the deliberations, had no option but to boycott, all the while calling on the MCC to rectify matters by democratising the system. When the three rounds of Parliamentary hearings came about, we tried not only to suggest alternative regulatory models, but also to draw the above-mentioned unacceptable circumstances to the Committee's attention. At each hearing, we were further treated with scorn, the first denying us proportionate time, the second cutting us off before our time was up and the third, expelling us and striking our submission from the Parliamentary Record. This matter is now subject to a Human Rights Commission investigation and will shortly be subject to further investigation by the Public Protector, as are all prejudicial developments at the hands of State officials to date, including the above listed respondents.

Let us return more directly to the circumstances which **<u>Dr Makhambene</u>** has mischievously misrepresented.

→ Dr Makhambene talks about the "vested interests being raised at the subsequent meeting when PHARMAPACT did not attend". However the vested interests were looming but were not entrenched until the following "elections". We did not attend the subsequent meeting because Michael O'Brien had set out similar sentiments to ours in a letter to the Director-General dated 4 November 1996 and after some discussion with O'Brien, we mandated him to present our views at the 28 November 1996 meeting. Our proposed candidate for the CMC was Prof. C F van der Merwe, Head of Gastroenterology at Medunsa, appropriately, since he had boldly defied attempts to suppress his research into evening primrose as an anticancer therapeutic, and also since most orally ingested toxic products have their primary impact on the gastrointestinal tract. Similarly, after O'Brien's 6 December 1996 letter to Folb, we again, after discussions, mandated him to represent us at the 10 December 1996 election. However, when O'Brien indirectly, via his 18 December 1996 letter to the D-G, related that he had "agreed to keep the whole process within the MCC, instead of outside it, as outlined in my (his) letter of 6 December", we had been seriously betrayed.

How deep has this creep sunk? At three Parliamentary hearings he fraudulently described the process as representing all role-players and being democratic. He is either ignorant of the meaning of the word, or is a habitual liar. O'Brien also wrote a letter to Dr Nkomo dated 25 May 1998 stating: "in reading the list of witnesses wishing to make presentations, I would like you to confirm what we have asked you previously, namely that the presentations will be limited to those pertaining to our legislation only. I am referring here specifically to the applications of: Mr S Thomsom, Pharmapact; Mr A Rees, Natal Nat Health Alliance".

Moreover, the manner in which the "election" was conducted by simple choice from the nominations list, with Folb and O'Brien taking turns, made a total mockery of subsequent lip-service to the 'democratic' nature of the process. The last straw for us was the totally unacceptable allopathically biased (Folb, Makhambene, Moloi, Gericke, Coopan, Brom, and O'Brien) and especially the financially vested interest composition of the CMC, namely, Gericke (SA Druggists - traditional African), Coopan (Natura, Sportron, Bioforce), Brom (Chinese herbs), Stoffberg (Natura) and Tsotsetsi (Schwabe). When we realised the level of expertise, or rather the absence thereof in the field of complementary medicines, we were appalled at the incompetent composition of the Complementary Medicines Committee. Not a single member, with the possible exception of Gericke had any formal education or training in any of the nominated disciplines. The allopaths were just that, with some dabbling in complementary modalities, O'Brien, a psychologist, and of the non-allopaths, Stoffberg (education), Tsotsetsi (allegedly some bogus homoeopath qualifications) and Webber (O'Brien pawn) (8-month correspondence course in micsellaneous natural healing which is not even a nominated category).

I is interesting to note that only by <u>April 1998</u>, was a letter by <u>Brom</u> circulating <u>lamenting</u> "the lack of power", "the lack of the Chairman's expertise" and "his non-democratic appointment". Is it any wonder that PHARMAPACT from the outset rejected this totally unprofessional Committee with contempt? The financially vested interests and lack of credible formal education and training pertaining to the nominated categories within the so-called "Expert Committees", not to mention the gross financially vested interests on the "Technical (read industry) Committee" actually driving the process into an inappropriate pharmaceutical model favouring these Committee members is a scandal. A survey of the registered <u>PHARMAPACT</u> documents will prove that we <u>made every possible effort to halt and reform the process from the moment that this state of affairs came to our attention.</u>

The <u>first correspondence</u> of <u>16 January 1997</u> was addressed <u>to Dr Makhambene</u>, who correctly tabled it as a <u>late motion at Council's meeting</u> of <u>17 January</u>. The previous two paragraphs summarise the contents of this letter which began and ended as follows: "Of immediate urgency is our vehement rejection of the undemocratic structures put in place via the reconstituted Complementary Medicine Committee (CMC) and its sub-committees. ------ <u>All of the foregoing seriously throws this whole process into question and hence I am calling for the non-ratification by Council of the pseudo-structures currently in place".</u>

This matter was referred to the following: Minister of Health (20 Jan; 25 Mar; 13 Nov 97; 16 Jul; 19 Jul 98); Director-General Health (22 Jan; 6 Nov; 13 Nov 97; 12 Jan 98); Parliamentary Portfolio Committee on Health (12 May; 6 June; 3 Sept 97; Nkomo-6 Oct 97; Baloyi-23 Oct & 13 Nov 97; 26 Oct 98) and repeatedly with the MCC (25 Mar; 23 Oct; 13 Nov 97; 7 Oct 98). Public Protector - ongoing. Media: M&G 22-28 Nov 96; 10 Dec 96; Health Counter News. Updates: Mar; May; Oct 97; Jan 98; Reports: Jan; Mar; Jun; Aug 98; The Natural Health Directory 1997 & 1998; & PE Express 21 Jan 98.

Responses as follows: <u>D-G</u>: <u>18 Feb 97</u>: "no locus standi to intervene"; <u>Registrar</u>: <u>25 Mar 97</u>: "Some of the documents you refer to and which need to be studied by me in order to respond to you, are in the posession of our legal counsel as well as the Public Protector"; 6 May 97; "The letter was discussed and it was decided that the matter be referred to the State Attorneys. Legal advice is sought on the libellous nature of the letter as well as possible action to be taken in this regard". NB. Nothing came of this intimidation.

Ω <u>Dr Makhambene</u> states that "<u>at one stage in Council, when this question came up about the Parliamentary hearings that people said they were not represented, it was brought back to the Medicines <u>Control Council,</u> which again <u>sent out invitations for people to come on board</u>. The Cape Lobby group attended such a meeting, <u>PHARMAPACT again did not respond</u>".</u>

What the MCC had written was as follows: "At a recent Medicines Control Council meeting, during the discussion of the 'final draft of the proposed listing system, it was decided by Council that members of the Health Products Industry not actively involved in the process be invited to form part of the process".

"It was noted by Council that a gap in communication existed between this sector of industry and the MCC. Council decided to invite members interested in meeting persons from the MCC to discuss perceived differences and to examine possibilities of working together".

PHARMAPACT, insulted that this "working together" offer should be forthcoming only after the "final draft" has been discussed, responded on 13 November 1997 as follows:

"Whilst we appreciate an invitation to meet with the Council, the circumstances at hand render such an invitation insulting in the extreme".

"PHARMAPACT has over this year lodged numerous serious objections to MCC activities and aspects of the proposed listing systems, in particular our letters of 16 January, 25 March and most recently 23 October 1997, all of which have been consistently ignored without consideration of our constitutional rights to adequate written responses and access to information required for the exercise of our legal and constitutional rights".

"We are insulted by the expectation that false smiles, a cup of tea and a few Marie biscuits could possibly bridge the communication gap which the MCC has allowed to develop. We would minimally require legally and constitutionally acceptable replies to said correspondence as a starting point to bridge said gaps. Re-submitting our questions to which we demand answers would alone take at least the scheduled hour and the requisite replies several hours more, and in any event, we require written responses for the legal record".

Having introduced our motion, Makhambene procedurally bears responsibility for its final resolution.

After this debacle had dragged on for a year, PHARMAPACT were still trying to enter the process and on 12 January 1998 communicated the following appeal to the Director-General: "With reference to this ongoing matter, largely initiated by your November 1996 Pretoria meeting, we feel strongly that a truly representative public meeting to reflect on developments this past year, is now imperative, before this matter proceeds further and fixes us in unnecessary battle rather than in constructive co-operation which until now has not been possible due to our boycotting the BBRG meetings of the CMC because of their non-representative, undemocratic, unconstitutional

and illegal activities, to which we have refused to lend credibility via our participation, on moral grounds".

Ten months later, just prior to the last BBRG meeting, PHARMAPACT wrote to Mrs Matoso, the Registrar: "It is with deep concern that PHARMAPACT note the continued unconstitutional and hence illegal official collaboration between the MCC and the BBRG during this transitional stage of the MCC/MRA".

"Our initial concerns were outlined in registered correspondence dating back to 16 January 1997 and have yet to be formally addressed by Council. Since then the situation has progressively deteriorated to the extent that PHARMAPACT have been unable to liase further with the authorities (see our letter of 13 November, 1997) and hence your 30 September, 1998 notice is but one example of this disregard for the constitutional rights of others, in particular the small operators who do not have the resources to play the listings procedure game and those who oppose developments on procedural and constitutional grounds".

"I draw your attention to the fact that the BBRG is for all intents and purposes, a private financially vested-interest industry grouping illegally collaborating in a legislation drafting process to preferentially suit their own monopolistic circumstances. Their scheduled 9 October 98 meeting has furthermore been illegally advertised via selective invitations on MCC letter-head and faxed at taxpayers expense. This meeting was not arranged on the request of, but is a BBRG meeting, as per their notice of 27 September 1998 announcing the meeting and that the Director-General has agreed to chair same. I must reiterate that PHARMAPACT do not recognise the BBRG as a legally constituted forum for the legislation of natural health substances, which they and the MCC insist on classifying arbitrarily as complementary medicines".

"PHARMAPACT warns you of serious legal ramifications for the MCC for its continuing to encourage the BBRG to illegally proceed along the present course established by the former dismissed Registrar and disgraced Chairman, and the dismissed and subsequently reinstated Council as well as the long-standing members of the Complementary Medicines Committee and its sub-committees who have also had their attention repeatedly drawn to the controversial nature of their actions in conflict with the constitutional rights of others opposed to the undemocratic and irregular procedural development of the listing system".

"Needless to say the MCC itself will be held legally responsible for any damages sustained by our membership should the listing procedure actually be implemented, and will face public exposure and criminal investigation and proceedings for all illegal activities incidental to any and all procedural irregularities to date, of which there are considerable, and which is most unbecoming of an authority in reform and transition and portraying itself as being reformed, fair and transparent in its public dealings".

"PHARMAPACT have taken a decision, as per our consistent position to date, not to send a delegation to Friday's meeting for the reasons outlined above. We will however send observers delegated the right to defend PHARMAPACT's position if need be, and to inform attendees of the illegality of proceedings and of their constitutional rights in defense of prior and subsequent developments in this serious matter. We also record our disappointment at not receiving the documentational record on the Listing procedure as discussed and agreed between Helen Rees and Anthony Rees, as a goodwill gesture towards the proposed re-establishment of formal communication between the "new" MCC and an aggrieved PHARMAPACT".

"Let me make it quite clear that we do not deduce from the foregoing that you are a fully informed party to current developments, since we know that the BBRG/CMC / industry diplomats have deception, misrepresentation and other forms of persuasion down to a fine art. If you truly wish to do long-term justice to these issues, you will however first deliberate these matters with PHARMAPACT to hear the other side of the story before embarking on a course of action which will throw the regulation of all registered and unregistered medicines alike into the greatest constitutional / legal turmoil imaginable".

There are serious additional issues which we would like to raise, that relate to the MCC/MRA and these illegal structures:

- a) Why are the illegal and especially absolutely useless complex homoeopathic products with disease indications and making medical claims apparently subject to a moratorium, not only now when other effective products without claims are being subjected to suppression, but have illegally, under application for registration, enjoyed MCC 'protection' since 1986, in spite of the fact that no demonstrable efficacy has been forthcoming in the 12 years since these applications were filed?
- b) Why has virtually nothing been done to prevent the thousands of annual mortalities and the hundreds of thousands of morbidities caused by not only MCC approved or registered drugs, but also by a handful of traditional African drugs, which latter deaths are largely avoidable and have been known and legally under the MCC's jurisdiction since 1965, and we believe ignored for evil political expedience during the wicked apartheid era, and ignored by the new regime, certainly since we published our African Traditional Medicine MCC Genocide reports in January, March and June 1998, and which were served on the Minister of Health, Director-General of Health, MCC, Dukes Review Team and the Parliamentary Portfolio Committee on Health and was furthermore televised nation-wide on the Options programme, with a repeat.

Do you people really care, or is the salary king and to hell with the public responsibility that comes with the job? What has been done by the MCC and their illustrious Complementary Medicines Committee, eg in response to the honourable Minister of Health's 23 April 1998 referral of the "Medicines Control Council Genocide Against The African People" report to the MCC/CMC (Ref 3/6/2/2) and what progress has been made even generally in this regard? Why the *#%\$ don't you get on with your primary mandate and leave the honourable natural health care providers alone to assist in improving the health of the people who wish to take responsibility for their health into their own hands?

If you want a war, try to take away the health of those who are awake enough to care. Don't squeal when you suffer the fate of Schlebusch, Bruchner and Folb, or worse, when you stand naked before the judge on Earth or at the pearly gates.

Yours faithfully

Stuart Thomson

National Co-ordinator, PHARMAPACT