

IN THE HIGH COURT OF SOUTH AFRICA

(CAPE OF GOOD HOPE PROVINCIAL DIVISION)

REPORTABLE

CASE NO: 12156/05

In the matter between

TREATMENT ACTION CAMPAIGN First Applicant
SOUTH AFRICAN MEDICAL ASSOCIATION Second Applicant

and

MATTHIAS RATH First Respondent
DR RATH HEALTH FOUNDATION AFRICA Second Respondent
SAM MHLONGO Third Respondent
DAVID RASNICK Fourth Respondent
ALEXANDRA NIEWIECKI Fifth Respondent
ANTHONY BRINK Sixth Respondent
TREATMENT INFORMATION GROUP Seventh Respondent
GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA Eighth Respondent
DIRECTOR GENERAL, DEPARTMENT OF HEALTH Ninth Respondent
CHAIRPERSON MEDICINES CONTROL COUNCIL Tenth Respondent
REGISTRAR OF MEDICINES Eleventh Respondent

MEMBERS OF THE EXECUTIVE COUNCIL FOR HEALTH

WESTERN CAPE PROVINCE Twelfth Respondent

JUDGMENT DELIVERED ON 13 JUNE 2008

ZONDI, J

INTRODUCTION

[1] In this matter the applicants launched an application against the respondents seeking three forms of relief, namely declaratory, mandatory and prohibitory.

[2] The first applicant is the Treatment Action Campaign (“TAC”), a company incorporated in terms of section 21 of the Companies Act, 61 of 1973. The second applicant is the South African Medical Association (“SAMA”) a representative body for medical doctors in South Africa.

[3] The applicants’ principal complaint against the first to seventh respondents (“Rath respondents”) is that they have been systematically contravening various provisions of the Medicines and Related Substances Act 101 of 1965 (“the Medicines Act”) and they seek an order declaring that their conduct is unlawful and an interdict preventing the first to seventh respondents from carrying out the unlawful activities in violation of the Medicines Act. The applicants contend that if the activities of the first to seventh respondents are unlawful then the eighth to ninth respondents (“Government respondents”) are under a duty to take reasonable measures to prevent the aforesaid unlawful conduct and the applicants maintain that the eighth to ninth respondents have failed in their duties to investigate the matter properly and to take reasonable measures to prevent them.

[4] As against the first to seventh respondents the applicants in the amended notice of motion seek the following relief:

1. an order declaring that the distribution and/or sale by the first and second respondents and any of their agents of the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell in South Africa is unlawful, and

2. an order declaring that the clinical trials conducted in South Africa by and/or under the direction of first, second, third, fourth, and fifth respondents are unlawful.

3. an order interdicting the first and second respondents from either directly or through agents distributing and/or selling the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell in South Africa except in accordance with provisions of the Medicines and Related Substances Act 101 of 1965;

4. an order interdicting the first to fifth respondents from conducting unauthorised clinical trials in South Africa; and

5. an order interdicting the first to seventh respondents from publishing false or misleading advertisements concerning vitamins, multivitamins and the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and Vita Cell.

[5] As against the eighth to ninth respondents the applicants seek the following relief:

“5. It is declared that the Eighth and Ninth Respondents are under a duty to take reasonable measures to:

5.1 prevent the sale or distribution of medicines contrary to the provisions of the Medicines and Related substances Act 101 of 1965;

5.2 prevent persons from conducting unauthorized clinical trials;

5.3 prevent persons from publishing false or misleading advertisements concerning medicines.

6. It is declared that the Eighth and Ninth Respondents have failed to carry out their duty referred to in paragraph 5 above, in that they have failed properly to investigate;

6.1 The legality of the distribution and/or sale by the First and Second Respondents of the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell in South Africa;

6.2 The alleged conduct of unauthorized clinical trials in South Africa by the First, Second, Third, Fourth, and Fifth Respondents;

6.3 The alleged publishing by the First, Second, Third, Fourth, Fifth, Sixth, and Seventh Respondents of false or misleading advertisements concerning vitamins, multivitamins, and the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell in South Africa.

7. The Eighth and Ninth Respondents are ordered to take reasonable measures to investigate the matters referred to in paragraph 6 hereof and, in the light of the facts revealed by such investigation, to take further reasonable action in accordance with their duty referred to in paragraph 5.

8. The Eighth and Ninth Respondents are ordered to take reasonable measures to:

8.1 prevent the First and Second Respondents from selling or distributing the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell in South Africa contrary to the provisions of the Medicines and Related Substances Act 101 of 1965;

8.2 prevent the First, Second, Third, Fourth and Fifth Respondents from conducting unauthorized clinical trials in South Africa.

8.3 prevent the First, Second, Third, Fourth, Fifth, Sixth and Seventh Respondents

from publishing false or misleading advertisements concerning the products Vitacor Plus, Epican Forte, Lysin C Drink Mix and VitaCell.

9. The Eighth and Ninth Respondents are ordered within four weeks to present a report under oath to this honourable court alternatively to the Applicants as to what they have done to give effect to the orders set out in paragraphs 6 and 7, what further steps they will take in this regard, and when they will take such further steps.

10. The applicants shall have a period of four weeks after service on them of the said report to deliver their commentary under oath on such report.

11. The Respondents shall have a further period to two weeks after service upon them of the Applicants' commentary to deliver their reply under oath to such commentary.

12. The Applicants shall be entitled, if so advised, to enroll the matter for hearing thereafter for a determination of whether there has been compliance with paragraph 6 and 7 above and for such consequential relief as they may seek."

[6] *Mr Budlender* appearing for the applicants indicated that the applicants no longer seek relief against the third, sixth and seventh respondents. The third respondent passed away while these proceedings were pending and the matter had become settled as between the applicants and the sixth and seventh respondents.

[7] With regard to tenth to twelfth respondents *Mr Budlender* indicated that the applicants are not seeking an order against any of them, save for an order for costs in the event of opposing the application.

[8] As the applicants are seeking relief which is final in nature and the parties have not requested that any factual disputes be referred for trial or oral evidence, such disputes must be resolved by applying the test enunciated in **Plascon-Evans Paints Ltd v Van Riebeeck Paints (Pty) Ltd** 1984(3) SA 623 (A) 634e-g, namely that the final interdict sought can be granted only if the facts as stated by the respondents, together with the admitted facts in the applicants' affidavits justify the granting thereof.

Citation of the Government of the Republic of South Africa

[9] *Mr Moerane*, who appeared together with *Mr Coppin* and *Mr Vally* for the eighth and ninth respondents, contended that the Government of the RSA is not correctly before the Court. The applicants allege that they bring this application against the Government of the Republic of South Africa represented by Dr Tshabalala-Msimang in her capacity as the Minister of Health in the National Government. Referring to various provisions of the Constitution, *Mr Moerane* argued that the Minister of Health cannot represent the government. It is the President who can do so. He submitted that in terms of section 2(1) of the State Liability Act 20 of 1957, the Minister of the department concerned must be cited as a nominal defendant.

[10] In support of his contention, *Mr Moerane* referred to the SCA decision in **Jayiya v MEC for Welfare, EASTERN CAPE** 2004(2) SA 611 at para 5:

“A litigant brings a national or provincial department before Court by citing the political head of the department in a representative capacity. In the case of the department of the National Government, this would be the

responsible Minister. In the case of a provincial department it is the responsible member of the executive council. That is what section 2 of the State Liability Act 20 of 1957 provides. The first respondent should have been the only one. If this had been borne in mind at the outset, some of the procedural mishaps might have been avoided.”

[11] I agree with *Mr Moerane’s* contention. The applicants should have amended their notice of motion to cite properly the Government of the Republic of South Africa. Similarly the Director-General cannot represent the government. He does not and cannot speak on behalf of the Government of the Republic of South Africa. In their replying heads of argument the applicants expressed their preparedness to accept an order that would be directed against the Minister of Health. In the light of the applicants’ concession I will proceed to deal with the matter on the basis that it is the Minister of Health who is before the Court and not the Government of the Republic of South Africa.

Applicants’ Case

[12] In their founding affidavit the applicants aver that the HIV/AIDS pandemic is a major public health crisis in South Africa. They state that AIDS can be effectively treated with medicines which are known generally as Antiretroviral (“ARVs”) which have been registered for this purpose by the Medicines Control Council. (“the MCC”) They make a point that the ARVs are not the only means of dealing with HIV, but are an essential element of any effective treatment.

[13] The applicants’ complaint against the first to seventh respondents is that they carry out activities which the applicants believe are unlawful and place at risk the health and lives of people with AIDS. The applicants allege that the first to seventh respondents sell and distribute medicines which are not registered, sell products containing scheduled substances; make false and unauthorised statements about efficacy of their medicines in treating or preventing AIDS; conduct unauthorised and unethical clinical trials on people with AIDS; and finally they accuse the first to seventh respondents of making false statements that ARVs are ineffective in treating AIDS, and are poisonous and they discourage people with AIDS from taking medicines which are an essential element of an effective treatment programme.

[14] It is alleged by the applicants that the government authorities including the eighth and ninth respondents are under a duty to take reasonable and effective steps to stop the unlawful activities of the first to seventh respondents but they have failed to take such steps despite having

been given evidence of unlawful activities of the first to seventh respondents by the first applicant.

[15] In support of this assertion that the ARVs can effectively treat AIDS, the applicants rely on the expert opinion of Dr Francois Venter, an expert on the science of HIV/AIDS. Dr Venter explains that there is consensus among all generally recognised scientific institutions dealing with the HIV epidemic that ARV treatment is the only current specific treatment for HIV, and the only current health intervention that reverses the course of AIDS. He says it is a lifelong treatment. He does, however, mention that malnutrition and undernutrition have an adverse impact on the health of people with HIV/AIDS. In his opinion there is no scientific evidence that vitamins or micronutrients reverse the course of AIDS although a particular combination in a particular dose does delay the onset of AIDS in a specific group of patients.

[16] Dr Venter further states that the ARVs, when appropriately prescribed and used, reduce morbidity and mortality in the vast majority of patients. He concedes that antiretroviral treatment can have side effects and which can be fatal in some cases. He goes on to say that there is scientific consensus that the benefits of ARVs, when used as a chronic life long treatment for people with advanced HIV-disease, far outweigh the risk associated with ARVs. The ARVs are registered with MCC for treatment of HIV, and which means they are considered sufficiently safe and effective for the purpose of treating HIV. Dr Venter says the MCC has not registered any micronutrients for the treatment of HIV.

[17] In support of the claims that the first and second respondents had been selling medicines in contravention of the provisions of the Medicines Act, the applicants refer to various affidavits deposed to by the persons who obtained medicines from health facilities allegedly run by the first and second respondents. The applicants aver that the products which various deponents obtained from health facilities run by the first and second respondents are all medicines by virtue of their contents and the claims which are made by the second respondent.

[18] The products which were allegedly obtained from the health facilities run by the first and second respondents are a bottle, branded as "Dr Rath's" Vitacor Plus, a bottle, branded as "Dr Rath's" Epican Forte, a bottle, branded as "Dr Rath's" Lysin C Drink Mix, a bottle of Vitacell. The applicants sent a bottle of Vitacell for analysis to Andrew Loft Gray, a pharmacist. Gray, after analysing the product, concluded that it was liable to registration. Gray says Vitacell contains N-aceylesteine which is a Schedule 2 substance in terms of the Medicines Act and it can only be sold by a pharmacist or a person listed in section 22A(5) of the Medicines Act.

[19] It is further averred by the applicants that the first to seventh respondents have placed advertisements in newspaper and distributed advertisements as pamphlets and posters through out the country in which they make false claims about the treatment of AIDS using multivitamins and micronutrients. The applicants state that these advertisements are in breach of the Medicines Act. They refer to various newspapers and publications in which the first to seventh respondents made these false claims.

[20] The claims in the advertisements include the following:

- Micronutrients reverse the course of AIDS.
- Evidence from a pilot study that micronutrients alone dramatically improve clinical conditions and immune function of HIV/AIDS patients, increasing white blood cells, lymphocytes, monocytes, T-cells and CD4 counts.

- Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body and particularly to the blood cells of our immune system.
- Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death.

[21] The applicants further aver that the first to seventh respondents conduct unauthorised clinical trials in contravention of Regulations made under the Medicines Act. In this regard they refer to advertisements in various newspapers and other publications in which the respondents admit to have been conducting clinical trials. In particular the applicants refer to an advertisement which appeared in The Mercury newspaper dated 15 April 2005 stating:

“we conducted a clinical pilot study in HIV-positive patients with advanced AIDS. The goal of the study was to show that vitamins and other micronutrients alone reverse the course of AIDS, even in its advanced stage... Thus, it was essential that none of the parties had received any ARV drugs before or during this nutritional programme. The nutrient programme consisted of vitamins, minerals amino acids and certain other essential nutrients. Blood tests and clinical evaluations were performed at the start and after four weeks on the nutrient programme. The results of this pilot study were so profound that only one month that we decided to publish the data of the first 15 patients without delay. After the completion of the study a comprehensive report will follow”

[22] The applicants also aver that the first and second respondents operate health facilities in the Western Cape and one of these is in Khayelitsha. They state that the first and second respondents have not been granted permission by the Medicines Control Council (“MCC”) to operate these health facilities at which they conduct clinical trials. The applicants allege that the first to seventh respondents’ advertisements are intended to persuade people with AIDS not to take ARVs and in some instances they have succeeded in doing so.

[23] The applicants further aver that the government authorities are aware of the illegal activities of the first to seventh respondents but have failed to act against them. The applicants allege that on various occasions they brought the illegal activities of the first to seventh respondents to the attention of the government authorities but they failed to act against the first to seventh respondents.

Respondents Responses

[24] The Rath respondents deny that they have carried out activities which are violative of the Medicines Act. They aver that the products complained of are vitamins and nutritional supplements which are not subject to registration in terms of the Medicines Act and which ought not to be classified as drugs or medicines. In particular first and second respondents deny that they have ever sold any nutritional supplements or any other products at all in South Africa. They have, however, donated nutritional substances to community organisations in the country without receiving remuneration and which in turn distribute these products to members of the public as part of a vitamin programme. The Rath respondents deny having conducted clinical trials in South Africa or having published false and misleading advertisements or having made unauthorised claims about vitamins, multi-vitamins, including the nutritional products in question.

[25] The first respondent accuses the first applicant of operating as a front for the pharmaceutical industry. He says the leading members of the second applicant are connected to the pharmaceutical investment interest through their professional careers and positions they hold in organisations heavily sponsored by the drug industry.

[26] He dismisses as false the assertion that the ARVs can prevent the development of AIDS

in HIV infected patients. He characterises these drugs as being highly toxic and highlights their inability to prevent or cure either HIV infections or the development of AIDS. He acknowledges that micronutrients are not a cure for AIDS. But he says in the absence of an effective cure or a vaccine for AIDS – and in the face of the extreme toxicity of ARVs – they are an effective and affordable way to halt progression and even reverse the symptoms of the AIDS disease.

[27] The government respondents deny having failed to take steps against the Rath respondents. The ninth respondent avers that he is not aware that the Rath respondents are acting unlawfully. In particular the ninth respondent in his answering affidavit states:

“47....The first applicant had referred certain of its allegations against some of the first to seventh respondents to the MCC and to my office. The MCC had asked for more information and Mr Andre Du Toit had investigated, inter alia, the specific allegations, i.e. that the second respondent has been selling unregistered medicines and that it has been unlawfully conducting clinical trials for humans. His investigation, thus far, did not confirm the allegations of the first applicant...”

[28] Mr D Potgieter , who appeared together with Ms Kusevitsky on behalf of the twelfth respondent, submitted that the suggestion that the twelfth respondent as well as the Western Cape Provincial government have not fully complied with the duty to take reasonable steps to stop the alleged unlawful activities of the Rath respondent, was incorrect. He argued that the twelfth respondent immediately took necessary steps to refer the allegations by the Western Cape Clinicians concerning the first respondent to the MCC for attention.

Statement of Issues

[29] This application concerns the following questions:

1. whether the Rath respondents are distributing medicines in contravention of the Medicines Act;
2. whether the Rath respondents are conducting unauthorised clinical trials in contravention of the Medicines Act;

3. whether the Rath respondents are publishing unauthorised, false and misleading advertisements concerning vitamins, multivitamins, and certain products produced by Dr Rath and the entities associated with him; and
4. Whether the Government has taken reasonable measures to investigate and put an end to such activities.

The question of lawfulness of the Rath respondents' conduct must be determined with reference to the applicable law, and in particular, the Medicines Act.

Applicable Law

Meaning of "Medicine"

[30] The word "medicine" is defined in section 1 of the Medicines Act as:

"any substance or mixture of substance used or purporting to be suitable for use or manufactured or sold for use in -

- a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
- b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine."

[31] *Mr Budlender*, appearing for the applicants, submitted that first, there is no power vested in anybody other than a Court to determine whether a substance is a medicine. A substance either is

or is not a medicine in terms of the definition. He argued that it is not registration which determines whether a substance is a medicine. If the substance as a matter of objective fact falls within the definition then it is a medicine. Secondly he submitted that in certain circumstances a substance will be a medicine if it is used for the defined purpose or if it purports to be suitable for use, for instance for-treating people or if it is manufactured or sold for the purpose of treating people. He argued that the present substance sold or distributed by the first and second respondents is a medicine because they say the substance is good for the purpose of treating or preventing HIV/AIDS. In support of his contentions he referred the Court to the case of **Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines and Another** 1998(4) SA 660 (T). I agree with *Mr Budlender's* submissions. The question whether or not any particular substance is a medicine must be determined with reference to the provisions of the Act and when its identity is being questioned. The attributes of the substance and the claims made in respect of the substance will determine if it is a medicine within the meaning of the Medicines Act.

[32] *Mr Ntsebeza*, who appeared together with *Mr Walther* for the first, second, third, fourth and fifth respondents, submitted that the definition of "medicine" contended for by the applicants is wider than that contained in section 1 of the Medicines Act. He argued that on the applicants' construction even Rooiboos Tea or "Boereraad" remedies and other traditional remedies would fall within the definition of a "medicine". He submitted that the construction contended for by the applicants could never have been the intention of the legislature. He contended for a more circumspect, practical and common sense approach.

[33] *Mr Moerane* submitted that the interpretation suggested by the applicant makes the definition of "medicine" overbroad. He argued that such an interpretation would not allow for discriminating between water or a soft drink that is claimed quenches "any thirst". He pointed out that the meaning of "medicine" contended for by the applicants would result in the word "medicine" losing its meaning and could lead to absurd result. In support of his contention, *Mr Moerane* referred to **Reitzer Pharmaceuticals** case, supra at 683 E-F:

" But to return to applicant's argument: water may be used for restoring, correcting or modifying any somatic or organic function in man namely to quench thirst..."

Does that mean that the Council may in terms of section 30 of the Act lay down "prescribed requirements" in relation to water used for drinking purposes? Obviously that would be absurd. Parliament could never have

intended the Council to have authority to prescribe requirements in relation to water used merely for drinking purposes”

[34] Mr Moerane submitted that to avoid the glaring absurdity which could result if the literal meaning of “medicine” was applied, a definition of “medicine” has to be qualified.

[35] The question to be determined is the meaning of the word “medicine” as used in the Medicines Act. The matter is essentially one of interpretation. The intention of the Legislature should be ascertained from a study of the provisions of the Medicines Act and that the language of the Legislature should be read in its ordinary sense.

[36] If the meaning of the words using this approach is clear then such meaning represented the intention of Parliament, the object of statutory interpretation always being to stamp a particular meaning with the Legislature’s *imprimatur* by means of the fiction of Parliament intent. (*Judicis est ius dicere sed non dare.*)

[37] It was, however, pointed out by Schreiner JA that:

“what seems a clear meaning to one man may not seem clear to another. This consideration must also, I think, be borne in mind when one refers to the literal, ordinary, natural or primary meaning of words or expressions. The ‘literal’ meaning is not something revealed to judges by a sort of authentic dictionary; it is only what individual judges think is the literal meaning, if they employ that term.”

(Savage v Commissioner for Inland Revenue 1951 (4) SA 400 (A) at 410 F-G).

[38] It was recently held by Hurt AJA, delivering a majority judgment in the Supreme Court of Appeal on 26 November 2007 that:

“In recent years courts have placed emphasis on the purpose with which the Legislature has enacted the relevant provisions. The interpreter must endeavour to arrive at an interpretation which gives

effect to such purpose. The purpose (*which is usually clear or easily discernible*) is used, in conjunction with the appropriate meaning of the language of the provision, as a guide in order to ascertain the legislator's intention (the so-called method of 'purposive construction')."

(**Commissioner for South African Revenue Service v Airworld CC and Another** Case no 672/06, Supreme Court of Appeal, at para [25]).

[39] In the Concise Oxford English Dictionary "medicine" is described as "a drug or other preparation for the treatment or prevention of disease."

[40] It is clear to me that the dictionary meaning of "medicine" is limited to the drug for treatment or prevention of diseases. It only includes two functions of the drug, namely treatment and prevention and does not include other functions as set out in section 1 of the Medicines Act, such, as the "diagnosis, mitigation, or modification of disease" (section 1(a)) or "restoring, correcting or modifying any somatic or psychic or organic function in man..." (Section 1(b)). In the present matter the dictionary meaning of "medicine" seems to have some limitations and therefore may not be used as a tool to ascertain the intention of the Legislature. It is therefore clear that the Legislature intended the word "medicine" to have a wider than a dictionary meaning in order to achieve the object of Medicines Act namely to control and regulate dissemination of medicines either inherently harmful or potentially so when misused. The definition of "medicine" in the Act places more emphasis on the "use" of substance or mixture of substances. A substance or a mixture of substances must be "used or purporting to be suitable for use or manufactured or sold for "use" in performing various functions set out in the Act.

[41] It is correct, as *Mr Ntsebeza* argued, that if one adopts a literal interpretation of the word "medicine" Rooibos Tea or water used to quench thirst could fall within the definition of "medicine".

That interpretation, would, however, in my view be repugnant to the intention of the Legislature.

It was pointed by Corbett AJ (as he then was) in **S v Burger** 1963 (4) SA (C) 304 at 308 A-C that:

"...where the language of a statute is unambiguous and its meaning is clear, the Court may only depart from such meaning if it leads to absurdity so glaring that it could never have been contemplated by the Legislature or if it leads to a result contrary to the intention

of Parliament as shown by the context or such other considerations as the Court is justified in taking into account...”

[42] The purpose of the Act is to protect the public against quackery through assessing and controlling the quality, efficacy of the medicines. It is not the intention of the Legislature to control substances which are ordinarily drunk by man such as Rooibos Tea as long as such substances are ordinarily used and there are no claims of their medicinal efficacy. In my view the use of a particular substance is the determining factor in deciding whether or not it is a medicine. If one adopts this approach one is able to limit the seemingly overbroad definition of “medicine”. To use *Mr Ntsebeza’s* Rooibos Tea example in order to emphasise the purpose of the Act, if a person were to sell Rooibos Tea and to hold out to the public that it could cure arthritis Rooibos Tea could fall under the definition of “medicine”. The reason for such finding would not be difficult to fathom: a number of people are likely to start using Rooibos Tea in the hope that it would treat or prevent or cure arthritis. The only logical way to protect the public against such claims would be to bring Rooibos Tea within the definition of “medicine” so that its quality, safety and efficacy could be controlled and regulated.

[43] With this legal background I now turn to consider whether the substance donated by the first and second respondents to South African National Civic Organisation (SANCO) for distribution to the community members is a medicine. In their answering affidavit the first and second respondents do not deny that they distribute vitamins and nutritional supplements. However, what is denied is that these substances are medicines or that they sell any of these substances. They say they donate these substances to community organisations in the country without receiving any remuneration and the only product they donated in large quantities is VitaCell which was registered with the Department of Health on 18 March 2004 as food supplement in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 54 of 1972.

[44] They deny that they are still donating Vitacor Plus, Epican Forte and Lysin C Drink Mix. They aver that they ceased donating these substances many months ago, well before the launch of this application. The applicants, in their replying affidavit, do not seriously challenge the respondents’ averment in this regard. In the circumstances in so far as there is a dispute of facts on the question whether or not the first and second respondents are still distributing these three substances I will resolve it in favour of the first and second respondents and find that the first and second respondents ceased distributing these three substances long before the launch of these proceedings. As the applicants are seeking an interdictory relief there will be no need for such remedy once the alleged unlawful conduct complained of has ceased to exist. In other words I find that the first and second respondents still donate VitaCell to Sanco.

[45] I have already held that in determining whether or not a particular substance is “medicine” for the purpose of the Medicines Act one must have regard to the use of a substance. Is it used for medicinal purpose? In this case it is alleged by the applicants that the first respondent made claims in various media that the substances he distributes cure or reverse the course of AIDS. The substances are medicines in that the first and second respondents distribute them for use for medicinal purposes. It is therefore necessary to bring them under the ambit of the definition of “medicines” in order to control and regulate their use. Members of the public, because of statements about their medicinal efficacy, will start using the substances on the basis that, when taken, they will cure or reverse the course of AIDS. The control and regulation of these substances is necessary in order to prevent confusing messages being sent out to the public about the treatment of AIDS. In the circumstances I find that VitaCell is a medicine within the meaning of the Medicines Act.

[46] Having found that VitaCell is a medicine, the next question for determination is whether the first and second respondents “sell” VitaCell within the meaning of the Medicines Act. The determination of this question is important because in terms of the Medicines Act certain medicines may not be sold unless they are registered.

Definition of “Sell”

[47] In terms of section 1 of the Medicines Act “Sell” means “sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct for sale or authorise, direct or allow a sale or prepare or possess for purpose of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise”.

[48] It is clear from this definition that the Act defines “sell” very broadly. The consequence is that a person who offers or advertises a medicine or distributes it to other persons even without a charge runs the risk of exposing himself to the application of the Act. In other words once the MCC has made a determination by way of resolution that a particular medicine be registered, one cannot “sell” that particular medicine unless it is registered. The definition of “sell” is very broad but has a narrow consequence.

[49] However, Kriegler AJA (as he then was) in **Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd** 1992(1) SA 245 (A) found that the meaning of “sell” was not as wide as it appears to be. At 258 A-B he pointed out:

“Notwithstanding the wide ambit of *the words and the ostensibly diverse range of acts enumerated, there is an identifiable common denominator characterising the whole. That is some transaction or action of a commercial or quasi-commercial nature related, albeit remotely, to selling-or delivery pursuant thereto- with a view to consumption. That the word ‘supply’ was not intended to apply – to the administration of an injection by a nurse at the bedside of the hospital or to a mother cajoling her offspring to gulp a proffered spoonful of cough syrup.”*

[50] It was argued by *Mr Ntsebeza* on behalf of the Rath respondents that the word “sell” ought to be given a narrow meaning and should not be construed to include the conduct of the first and second respondents. He submitted that the donation of vitamins by the first and second

respondents to a community organisation cannot be construed as “selling”

[51] I disagree with *Mr Ntsebeza’s* contention. It is clear from the Act that the meaning of “sell” includes donation and the first and second respondents’ supply of VitaCell to Sanco constitutes a sale for the purpose of the Act. The supply of substance does not have to be for consideration. There is a compelling reason for finding that the supply of VitaCell by the first and second respondents constitutes a sale for the purpose of the Act. In this case not only do they donate VitaCell to Sanco but they also actively promote its use by persons with AIDS and monitor its performance.

Whether Rath’s products should be registered

[52] The next question is whether VitaCell should be registered. The fact that a substance is found to be a medicine does not automatically render it liable for registration. A requirement to register a medicine in terms of the Medicines Act is based on the fact whether it has been called up for registration in terms of section 14 of the Medicines Act. In other words the fact that a substance is a medicine does not, without having been called up for registration, make it an offence to sell that substance without having it registered.

[53] The Medicines Act makes provisions for the registration of medicines:
Section 14(1) and (2) provides:

“(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.

(2) (a) The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.

(b) Any such resolution may also relate only to medicines which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.

(c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.”

Section 15(1) deals with the registration process and submission of the application for the registration of medicines. In terms of section 15(3) the MCC must approve the application if, after considering the application and after investigating, it is satisfied that the medicine, in respect of which an application for registration is made, is suitable for the purpose for which it is intended and complies with the prescribed requirement and is in the public interest.

[54] It is clear that the MCC performs an administrative function when it considers applications for registration of medicines. Its decision must comply with the provisions of section 33 of the Constitution which provides that everyone has the right to administrative action that is reasonable and procedurally fair. The decision of the MCC must be reasonable within the meaning of the Promotion of Administrative Justice Act No.3 of 2000 (“PAJA”). What that means is that during the registration process the manufacturers, distributors or wholesalers must have a hearing.

Section 19(1) provides:

“no person shall sell any medicine unless it complies with the prescribed requirements.”

[55] It is clear from the provisions of the Medicines Act that if the MCC has by notice determined that a medicine or class or category of medicine is subject to registration then it is an offence to sell that medicine or class or category of medicine unless it has been registered.

[56] The Rath respondents aver that VitaCell does not need to be registered as it is currently registered as a “food supplement for distribution and importation into South Africa in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (“the Foodstuffs Act”)”. They accordingly contend that the call up notice issued and published by the MCC in 2002 does not apply to VitaCell.

[57] I agree with *Mr Budlender* that a substance which is a medicine under the Medicines Act is not governed by the Foodstuffs Act. In the light of the fact that I have already found that VitaCell is a medicine within the definition of the Medicines Act, the Rath respondents may not rely on the provisions of the Foodstuffs Act as a basis for their argument that VitaCell is not covered by the provisions of the Medicines Act. The provisions of the Medicines Act apply to VitaCell and not the Foodstuffs Act.

[58] It is the applicants’ contention that VitaCell is subject to registration in terms of the Medicines Act pursuant to the call up Notice 204 of 2002. The Rath respondents and government respondents argue that the applicants’ reliance on the Notice 204 of 2002 is misplaced. They submit that Notice 204 of 2002 does not contain a resolution in terms of section 14(2) to the effect that products containing vitamins, multivitamins and micronutrients are required to be registered under the Medicines Act.

[59] In terms of the Medicines Act, the Department of Health issued Government Notice R 204 in the Government Gazette dated 20 February 2002. (“the 2002 Notice”). The 2002 Notice superseded all previous call up notices including the 1985 call up notice.

Its heading reads as follows:

“CALL UP NOTICE FOR MEDICINES FREQUENTLY REFERRED TO AS
COMPLEMENTARY MEDICINES IN TERMS OF THE MEDICINES AND RELATED
SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965)”.

[60] The Preamble reads:

The Medicines Control Council (MCC) has noted that there are increasing numbers of medicines frequently called complementary medicines being sold in South Africa for which claims of safety, quality and efficacy are being made without the approval of the MCC. The Complementary Medicines Working Group of the MCC, after consultation with stakeholders recommended to Council that a call up of the following categories of medical products be undertaken, for purposes of which certain specified exemptions in the application for registration of a medicine (MBRI) form will be allowed.

The categories of the medicines frequently referred to as complementary medicines should

include:

“ 7 Nutritional substances that purport to have therapeutic or medicinal effects”.

The submission of an application in response to this call up would not constitute product registration but should be considered a primary step in the registration process.

The data compiled from this call up will enable Council to compile an audit of all products currently available in the market place. Council will review the claims of safety, quality and efficacy for all identified products and will determine whether any such claims constitute a public health hazard and act accordingly.

For all products, Council will at a later stage determine which additional Annexures of the MBR1 form will be required for registration purposes.

Any person who contravenes this call up notice shall be subjected to the provisions of Section 14 read with Section 29 (b) and (h) and Section 30 of Act 101, 1965.

Council also noted that similar unsubstantiated claims of safety, quality and efficacy are being made with respect to African traditional medicines that are widely available in the market place. The MCC's African Traditional Medicines Working Group will be asked to consider whether a similar approach to a call up for the purposes of preparing an audit of these products could be gainfully undertaken at this time.

(b) the Medicines Control Council established in terms of Section 2 of

the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) by virtue of the powers vested in it by section 14(2) of the Act has by resolution approved by the Minister of Health, determined that, with effect from the date of publication of this notice-

All preparations or mixtures of substances that fall under the definition of a medicine, including all dilutions, mixtures or derivations of any substances that are anthroposophical medicines, aromatherapeutic medicines, ayurvedic medicines, Chinese traditional medicines, energy substances, homeopathic medicines, nutritional substances that purport to have therapeutic or medicinal effects, western herbal medicines, Unani-Tibb medicines, combination homoeopathic/ flower essences, and combination complementary medicines,

shall be subject to a call-up process instituted as a primary step towards registration of such as medicines and shall be submitted to the MCC within six(6) months of the date of publication of this notice.

It is further notified that under section 14(2)(b) of Act 101 of 1965, the abovementioned resolution shall relate to medicines available for sale or distribution in the Republic on the date on which it comes into operation and shall relate also to medicines that become available after the said date.”

[61] The ninth respondent (the Director General) explains how in his understanding the call up notice was intended to apply. He says:

“28.3 I am informed by the tenth respondent that the 2002 notice was designed to ensure that all complementary medicines, nutritional substances that purport to have therapeutic or medicinal effects and other scheduled substances are brought to the attention of the MCC, which would then decide which of the above products would be subject to registration in order to enable the MCC to devise an appropriate system for their registration. The 2002 notice is not, and was never intended to determine what is and is not a medicine and furthermore, which medicine is subject to registration and which not. The MCC envisaged that the data collected from the call-up would enable it to compile an audit of all products currently available on the market, and review the claims of safety, quality and efficacy for all identified products and determine whether any claims in connection therewith constitute a public health hazard and act accordingly.

28.6 The fact that the product contains a schedule 2 substance does not necessarily make it a medicine. It is necessary for the MCC to resolve, and not for the Court to declare, that it is a medicine, as envisaged in the Medicines Act, especially if the product could also be regarded as a *foodstuff or food supplement*. *Furthermore, it is for the MCC to resolve that any particular product requires to be registered and the MCC has to have in place a system for its registration and regulation. It has not been established, let alone beyond a reasonable doubt, that the products containing the schedule 2 substance have been dispensed by persons not competent and qualified to do so and that there has accordingly been a transgression of section 22A(5) of the Medicines Act.”*

[62] The question for determination is whether VitaCell is subject to registration as a medicine.

The answer to this question will turn on the interpretation of the 2002 call up notice. I agree with *Mr Budlender’s* submission that it is not for the MCC to decide whether the substance is a medicine. It is for the Courts to decide that question. But it is correct that it is for the MCC to resolve that any particular substance requires to be registered. The term “medicine” is defined in the Medicines Act and if there is a dispute about the nature of a substance it is for the Courts to make a determination whether or not a particular substance is a medicine as defined in the Medicines Act.

[63] The 2002 call up notice is said to have superseded all call up notices previously issued including the 1985 call up notice. There is a marked difference between the 1985 call up notice and the 2002 call up notice. In terms of the 1985 call up notice all oral preparations which

contained a vitamin or vitamins but excluding foodstuffs and if they contained or exceeded per recommended total daily dose any of the respective doses stated in the notice, would be subject to registration as medicines whether or not medicinal claims were made. The 1985 call up notice identified the criteria which had to be used in determining whether oral preparations had to be registered. To be registered all oral preparations had to have attributes mentioned in paras 1 and 2 of the notice. Claims about the medicinal effect of the oral preparations were irrelevant in determining whether they were subject to registration. The 2002 call up notice, unlike the 1985 call up notice, is inelegantly worded and appears to be self contradictory in terms.

[64] The 2002 call up notice, however, emphasises the therapeutic or medicinal effect as a criteria for the registration of a nutritional substance as a medicine. The object of the call up notice as expressed in its preamble is to address problems associated with complementary medicines which are being sold in the country for which claims of safety, quality and efficacy are being made. In my view it is not the purpose of the 2002 call up notice to subject to registration the nutritional substances mentioned in the notice. Its primary purpose is to bring the substances about which medicinal claims are made to the attention of the MCC for it in order to determine the correctness of the claims and whether the claims constitute a public health hazard. The notice states categorically that submission of an application in its response would not constitute product registration but would be considered a primary step in the registration process. The 2002 notice does not render the substances it identifies subject to registration as medicines. It renders them "subject to a call-up process instituted as a primary step towards registration of such as medicines." In other words the substances identified in the 2002 notice do not automatically become registrable.

[65] In my view, the 2002 call up notice does not subject VitaCell to registration even though medicinal claims are being made about it. I therefore hold that VitaCell is not subject to registration as a medicine. The MCC must still determine the correctness of its medicinal claims and whether the claims constitute a public health hazard. The purpose of the 2002 call up notice is to allow the MCC to determine whether the complementary medicines are registrable and their scheduled status. This is necessary in order to subject them to the provisions of the pricing regulations. Pricing regulations may not be applied to complementary medicines such as VitaCell until their scheduled status is established. What it means then is that the Rath respondents should stop making claims about efficacy of VitaCell until it has been submitted to the MCC to review claims about its safety, quality and efficacy.

Sale of Scheduled Substances

[66] The next question to determine is whether the Rath respondents sell scheduled substances. The Rath respondents admit that they are donating VitaCell to Sanco. It is common cause that VitaCell contains N-acetylcysteine which is a Schedule 2 substance under the Medicines Act. The Act defines scheduled substances to mean any medicine or other substance prescribed by the Minister under section 22A.

[67] Section 22A of the Medicines Act provides for the control of the distribution of any product that contains scheduled substances. In terms of section 22A (5) of the Act any substance containing a schedule 2, 3, 4, 5 or 6 can only be sold or dispensed by a particular class of persons. It is the Rath respondents' contention that they donate VitaCell to Sanco which in turn distributes it to people with AIDS who are attended to and examined by a community physician, a

registered medical practitioner. There is a factual dispute between the applicants and the Rath respondents on the status of the people who dispense VitaCell to persons who visit the SANCO “clinics”. The people who obtained VitaCell from Sanco “clinics” do however confirm that they were seen by a doctor. In the circumstances I will accept that VitaCell was dispensed properly and in accordance with the provisions of section 22 (A) of the Act. In any event even if I may be wrong in my reasoning there is another basis which supports my view and it is the following: the fact that VitaCell contains a schedule 2 substance does not necessarily make it a scheduled substance in the absence of its registration and scheduling. It has not been called up for registration. The 2002 Call Up Notice does not call it for registration. It renders it “subject to a call-up process instituted as a primary step” towards its registration. Ordinarily pricing regulations do not apply to complementary medicines. If VitaCell was a scheduled substance pricing regulations would apply to it. The fact that the pricing regulations do not apply to VitaCell is indicative of the fact that it should not be regarded as a scheduled substance. The pricing regulations do not apply to unscheduled substances. It is therefore difficult to determine the Scheduled status of VitaCell while it remains an unregistrable complementary medicine.

Clinical Trials

[68] I now turn to consider the question whether the Rath respondents conduct unauthorised clinical trials. In support of the allegations that the Rath respondents conduct unauthorised clinical trials, the applicants refer to copies of advertisements placed on behalf of some of the Rath respondents in various newspapers, a copy of a pamphlet, alleged quotations of statements downloaded from the website of the Rath Foundation, a transcript of an interview conducted between Radio 786 and the first respondent as well as a transcript of an interview which the first respondent conducted on P4 Radio. The applicants also rely on affidavits of various persons who participated in the “clinical trials” conducted by the first and second respondents. It is common cause that the Rath respondents whether rightly or wrongly did not have permission to conduct clinical trials.

[69] Clinical trials are regulated by the Regulations promulgated under the Act. They are contained in Government Notice R510 in Government Gazette 24727 of 10 April 2003. Regulation 1 defines “clinical trial” as follows:

“ An investigation in respect of a medicine for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy.”

[70] Regulation 34 regulates the conduct of clinical trials for humans. Regulation 34(1) provides as follows:

“A person desiring to initiate or conduct a clinical trial in respect of an unregistered medicine, a new indication or new dosage regimen of a registered medicine or substance, shall apply to a Council on a form determine by the Council for authority to conduct such a clinical trial”

[71] Regulation 34(2) to (4) deals with the content of the application, the trial protocol, and the information which is required to be provided. Clinical trials must be conducted in accordance with guidelines for good clinical practice as determined from time to time by the Council. Regulation 34(6) requires the person conducting the trials to submit regular progress reports to the Council. Regulation 34(7) empowers the Council to request information, inspect a clinical trial, or withdraw the authorisation.

Regulation 34(5) contains a prohibition:

“No person shall conduct clinical trials referred to in subregulation (1) without the authorisation of the Council.”

[72] It is correct that the term “clinical trial” has never been judicially considered in South Africa. In *Health Professions Council v Turner* [2002] JOL 9499 (ZS) the Supreme Court of Zimbabwe dealt with the matter concerning the contravention of the provisions of section 15A of the Drugs and Allied Substances Control Act which defines “clinical trial” as:

“ a systematic study in human beings or animals to establish the efficacy of, or to discover or verify the effects or adverse reactions of drugs...”

[73] The court pointed out that the definition in the Act is largely a subjective one. It held that a series of experimental treatments with a drug becomes a “*clinical trial*” when the person conducting them does so “*in order to establish the efficacy of ... or to discover or verify the effects or adverse reactions of ... drugs...*” The court found that the doctor in that matter had two objectives in mind when he carried out the experimental treatments. The Court went on to say at page 12: “*Primarily... he was concerned with helping his patients. But inevitably, given that he was and is a man with an enquiring mind, he was equally intent on establishing the efficacy of or discovering the effects or adverse reactions of ‘povidone iodine’. To that extent, it seems to me, it could be said that he was carrying out a clinical trial.*”

[74] Counsel for the applicants argued that the activity of the Rath respondents constituted clinical trials. The purpose of the activities should be looked at in order to determine the intention of the Rath respondents. *In casu* the purpose was to establish the efficacy of VitaCell on people with AIDS. That is what in fact the first respondent has been saying. He admitted that they “*conducted a clinical pilot study in HIV-positive patients with advanced AIDS. The goal of the study was to show that vitamins and other micronutrients alone reverse the course of AIDS, even in its advanced stage. Thus it was essential that none of the patients had received any ARV drugs before or during this nutritional programme... Blood tests and clinical evaluations were performed at the start and after 4 weeks on the nutrient programme. The results of this pilot study were so profound after only one month that we decided to publish the data of the first 15 patients without delay.*”

[75] There is no doubt in my mind that the activity of the Rath respondents, though they prefer to characterise it as a clinical pilot study, was an investigation in respect of micronutrients for use in human beings with AIDS and was intended to discover or verify the clinical effects of the

micronutrients. It seems to me they were carrying out a clinical trial. Although they deny that they conducted clinical trials, that denial, in my view, is, however, entirely inconsistent with their own repeated statements none of which they denied having made. It appears to be an attempt to escape liability for their widely proclaimed conduct now that its legality is being challenged. In my view, the Rath respondents' activity, (conducting a clinical pilot study) viewed subjectively constituted a clinical trial as defined in the Regulation. Their conduct was unlawful in that they did not have a permission to run clinical trials.

Making False or Misleading Advertisements

[76] The next question is whether the Rath respondents published false or misleading advertisements. The applicants allege that the Rath respondents have contravened the provisions of section 20(1) (a) and (b) of the Medicines Act. Section 20 of the Act prohibits the publication or distribution of false or misleading advertisements or unauthorised claims concerning any medicine. It provides:

“ 20 (1) No person shall-

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of subparagraph (ii) of paragraph (a) of section twenty-two or state or suggest that any medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of subparagraph (iii) or paragraph (a) of that section.

[77] Section 1 of the Act defines “advertisement” as follows:

“Any written, pictorial, visual or other descriptive matter or verbal statement or reference -

- a) appearing in any newspaper, magazine, pamphlet or other publication; or
- b) distributed to members of the public; or
- c) brought to the notice of members of the public in any manner whatsoever which is intended to promote the sale of that medicine or scheduled substance”.

[78] The applicants allege that the Rath respondents have made numerous claims that vitamins and micronutrients in general, and the Rath products, in particular, can reverse the course of AIDS. The applicants, in support of their averment, refer to an advertisement placed by the first respondent in the Business Day, on 18 February 2005, an advertisement published in the New York Times and a pamphlet which was distributed in the Western Cape.

[79] It is the applicants’ contention that the claims made by the Rath respondents are false and to prove falsity of the claims, the applicants rely on the expert opinion of Dr Venter, an expert on HIV/AIDS science. According to Dr Venter, although there is some evidence that a specific combination of multivitamin supplements in specific doses slows down the progression of HIV to AIDS, there is no evidence that vitamins or micronutrients reverse the course of AIDS. He states that the available scientific evidence shows only that the particular combination in a particular dose delays the onset of AIDS in a specific group of patients. He says the MCC has not registered micronutrients for the treatment of HIV. He accordingly concludes that the claims made by the Rath respondents about micronutrients are false and misleading.

[80] In response to the applicants' claims, some of the Rath respondents filed their answering affidavits. The first respondent, while admitting having made placements in newspapers and other media, denies that he and the second respondent placed a single product advertisement in the South African media. He alleges that the public health information they published, provided scientific facts about the role of vitamins and other micronutrients in relation to health. They say this knowledge has been documented in the textbooks of biology for years. They allege that their micronutrients have health benefits for people living with AIDS. They deny that the only proven therapy for AIDS patients are ARVs. They say nowhere in the world have ARVs been registered to be sold as a cure for AIDS. They aver that ARVs are extremely toxic especially to the cells of the immune systems. They make the point that, while not being a cure, micronutrients can reverse the disease-defining symptoms of AIDS and significantly improve the quality of life people living with AIDS.

[81] The first respondent dismisses the expert opinions given by the applicants' experts on the basis that they lack any scientific record in the area of micronutrients research or nutritional therapy. He criticises Dr Venter's expertise and dismisses his assertion about the efficacy of micronutrients as a misleading information.

[82] The question is whether the applicants have established the contravention of the provisions of section 20 of the Medicines Act by the first and second respondents. It is clear that the provisions of section 20(1)(b) do not apply to the present case because the MCC has not made any claims about the therapeutic effect of VitaCell or what it can be used for. Section 20(1)(a) therefore applies. It is common cause that the first respondent caused to be published in various newspapers and pamphlets statements about micronutrients and other products of the second respondent. The next question is whether those statements constitute "advertisement" as defined in the Medicines Act. In other words the statements must have been intended to promote the sale of Rath's products. In relation to medicines or scheduled substance an advertisement will be false or misleading if it can be shown that the person who made it was aware that it was incorrect. This finding cannot be made in the present case because there is no consensus amongst the experts upon whom the parties rely for their view on what the micronutrients can and cannot do to persons with AIDS. The dispute cannot be resolved on papers. However, in view of the provisions of the 2002 call up notice the first and second 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.

Conduct of Government Respondents

[83] I have found that the first, second, fourth and fifth respondents' clinical pilot study constitutes clinical trials within the meaning of the Medicines Act and that such clinical trials are unlawful in that they are not conducted in accordance with the provisions of the Act. I accordingly declared the respondents' clinical trials unlawful and to that end I have concluded that the first, second, third, fourth and fifth respondents' should be interdicted from conducting unauthorised clinical trials in South Africa. I have also found that the first to seventh respondents' conduct, in publishing advertisements concerning the efficacy of VitaCell on persons with AIDS, is unlawful in that the first to seventh respondents have not submitted vitaCell to the MCC to review its medicinal

claims. I accordingly concluded that the first to seventh respondents should be interdicted from publishing advertisements concerning the medicinal effects of VitaCell on persons with AIDS pending the submission by the first to seventh respondents of VitaCell to the MCC to review its medicinal claims.

[84] The first question is whether the eighth (Minister of Health who is properly before this Court) and the ninth respondents are under a duty to take reasonable measures to prevent the first to fifth respondents from conducting unauthorised clinical trials and to prevent the first to seventh respondents from publishing advertisements concerning medicinal effects of VitaCell on people with AIDS pending the submission of VitaCell to the MCC to review its medicinal claims. The second question is whether eighth (Minister of Health) and ninth respondents have failed to carry out their duty.

[85] The applicants allege that they have since February 2005 repeatedly brought the unlawful conduct of the Rath respondents to the attention of the government. They say they have provided the government and the MCC with the information at their disposal and have attempted to persuade them to take some action in this regard. They set out details of their attempts. They contend that the Government authorities are under a duty to take reasonable and effective steps to stop the unlawful activities of the Rath respondents. They say the government authorities have failed to take such steps.

[86] It is correct that in terms of the National Health Act 61 of 2003 it is the responsibility of the Minister of Health to endeavour to protect, promote, improve and maintain the health of the population and to determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population (section 3). The Minister of Health is assisted by the Director-General who in terms of the National Health Act is responsible, *inter alia*, to ensure the implementation of the National Health Policy.

[87] The object of the Medicines Act is to control the quality, manufacture and dissemination of medicines. It is the responsibility of the Director-General to enforce the provisions of the Medicines Act. Thus in terms of section 26 of the Act the Director-General may appoint the inspectors for the proper enforcement of the Medicines Act. The powers of the inspectors are contained in section 28 of the Act.

[88] It is clear from the provisions of the National Health Act that the eighth respondent primarily is under a duty to take reasonable measures to ensure that the provisions of the Medicines Act, which she administers, are enforced in order to protect, promote, improve and maintain the health of the population of the country. The ninth respondent assists the eighth respondent in carrying out her primary responsibilities under the National Health Act by ensuring that the provisions of the Medicines Act are enforced. I therefore find that the eighth and the ninth respondents are under a duty to take reasonable measures to prevent the first to fifth respondents from conducting unauthorised clinical trials and to prevent the first to seventh respondents from publishing advertisements concerning medicinal effects of VitaCell on people with AIDS pending the submission of VitaCell to the MCC to review its medicinal claims.

[89] The next question is whether the eighth and the ninth respondents have taken reasonable measures to carry out the identified duty.

[90] In deciding the question whether the eighth and ninth respondents have taken reasonable measures to prevent the unlawful conduct of the first to seventh respondents one should consider the provisions of the Act within which the measures are to be taken. The relevant provisions are sections 26 and 28 of the Medicines Act.

“26. **Inspectors.** – (1) *The Director-General may authorise such persons as inspectors,*

as he may consider necessary for the proper enforcement of this Act.

(2) Every inspector shall be furnished with a certificate signed by the Director- General and stating that he has been authorised as an inspector under this Act.

(3) An inspector shall, before he exercises or performs any power or function under this Act, produce and exhibit to any person affected hereby, the certificate referred to in subsection (2).

28. Powers of inspectors. – (1) *An inspector may, at all reasonable times –*

(a) enter upon –

(i) any place or premises from which –

(aa) a person authorised under the Act to compound or dispense medicines or scheduled substances;

(bb) the holder of a licence as contemplated in section 22C (1) (b);

(cc) the holder of a certificate of registration of a medicine,

conducts business;

ii) any place, premises, vessel or aircraft if he or

she suspects on reasonable grounds that an

offence in terms of this Act has been or is

being committed thereon or therein or that an

attempt has been made or is being made to

commit such an offence thereon or therein; or

a magistrate may issue a warrant authorising the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant”

[91] The eighth and ninth respondents reject the suggestion that they did not act on the complaints received by them from the applicants and other relevant bodies. They say upon receiving the applicant's complaints about the Rath respondents' unlawful activities, they instructed one Andre Du Toit in the Law Enforcement Unit to investigate the claims. He found no independent evidence to support the allegations of unlawful acts of the Rath respondents. They say the Law Enforcement Unit will continue to monitor the activities of the second respondent in order to obtain independent evidence of unlawful conduct.

[92] The ninth respondent admits that he is aware that the applicants had submitted documents to the tenth respondent alleging that some of the first to seventh respondents were acting unlawfully. He says the department through the offices of its Law Enforcement Unit investigated some of these allegations and found that there was insufficient independent evidence to establish that any of the respondents were acting unlawfully.

[93] One of the allegations made against some of the first to seventh respondents was that they were conducting unauthorised clinical trials. In my view Du Toit had powers to investigate this allegation in the light of the fact that the first respondent was publicly announcing that he and other respondents had conducted clinical pilot study and explained what the purpose of their study was. Mr Du Toit should have used the provisions of section 28(1)(a)(ii) of the Act by entering upon the premises at which the clinical pilot study was being carried out in order to investigate the allegations which were being made against some of the first to seventh respondents. This is what Du Toit should have done and in my view at least in so far as the allegation concerning the conduct of unauthorised clinical trials is concerned, Du Toit did not sufficiently investigate the matter.

[94] The applicants further allege that the investigation conducted by Du Toit was insufficient because Du Toit does not explain the nature and extent of the investigation he conducted. The applicants do have a point here. Neither the ninth respondent nor Mr Du Toit has furnished information as to the nature and extent of the investigation carried out by Mr Du Toit. One of the applicant's complaints was that the first respondent was selling a substance which contains N-acetylcysteine, a schedule 2 substance, in contravention of section 22 A(5) of the Act. The first respondent admits that VitaCell, which it donated to Sanco, contains a N-acetylcysteine. Section 22 A (6) provides that a sale under section 22A (5) must only take place on condition that *“all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner”*. But even if Du Toit had investigated the first and second respondents' conduct to establish a possible section 22A (5) violation, in my view his investigation would not have taken the matter any further given the provisions of the 2002 call-up notice. The 2002 call-up notice does not call up VitaCell for registration. It merely subjects complementary medicines such as VitaCell *“to a call up process instituted as a primary step towards registration of such as medicines”*. In other words VitaCell is not registrable and it is not an offence to sell a medicine which had not been called up for

registration. (**Novartis SA (Pty) Ltd v Ingelheim Pharmaceuticals (Pty) Ltd, Johannesburg High Court** (WLD case no. 11880/03, Appeal case number 337/05). If a medicine has been called up for registration it is an offence to sell it before it is registered unless written authority to sell it is granted in terms of section 21. The fact that VitaCell contains a schedule 2 substance does not necessarily mean that it is a scheduled substance. Once it is rendered registrable by the MCC, the latter will determine its scheduled status. In terms of the Government Notice R510, dated 10 April 2003, schedule 2 substances, unlike schedule O substances, do not include all substances which are subject to registration in terms of the Act.

[95] In the circumstances there is no basis for the suggestion that the investigation conducted by Du Toit, at least in so far as it related to a possible section 22 A(5) violation, was lacking.

[96] The ninth respondent, in justifying the decision not to investigate the conduct of the first and second respondents, says the MCC has not passed a resolution to the effect that the products distributed by the first and second respondents are medicines and that they are subject to registration. He says the department holds the view that the products are food supplements and that there is nothing objectionable to their distribution. This view is incorrect. The MCC may, by resolution approved by the Minister of Health, determine that certain medicines are subject to registration. But it does not have the power to resolve that a particular product is a medicine. The question whether or not a substance is a medicine is determined with reference to the provisions of the Medicines Act dealing with the meaning of a "medicine" and whether the substance makes medicinal claims about itself. A substance which falls within the definition of "medicine" cannot be classified as foodstuff in terms of the Foodstuffs Act.

[97] Even if the Director-General had correctly granted permission to the second respondent to import into the country VitaCell as food supplements in terms of the Foodstuffs, Cosmetics and Disinfectants Act, the second respondent did not, however, comply with the conditions to which the permission was subject. In terms of the letter dated 18 March 2004 the Director-General granted second respondent permission to import and distribute in South Africa as a food supplement VitaCell containing not more than 15 mg of NAC. But the VitaCell, which the second respondent imported into the country, was found to contain 30 mg of NAC. It is therefore clear that by distributing VitaCell, which contained NAC in excess of the permissible levels, the second respondent did not comply with the terms of the permit. In doing so it contravened the provisions of section 2 of the Foodstuffs Act. But the complaint is not about the contravention of the provisions of the Foodstuffs Act. It is about the violation of the Medicines Act.

Relief

[98] I shall not make any order with regard to the relief sought against the third, sixth and seventh respondents as they are now out of the picture. I have found that the supply by the Rath respondents of VitaCell to Sanco constitutes a sale within the meaning of the Medicines Act. Such sale is, however, not prohibited because the MCC has not determined that VitaCell should be registered as a medicine in terms of section 14 (2) of the Act. It is correct that medicinal claims are made about it. It is also correct that it contains a scheduled substance. But the fact that it contains a scheduled substance does not render it registrable in terms of the 2002 notice. In the circumstances the applicants are not entitled to the relief sought in paras 1.1, 2, 5.1, 6.1 and 8.1 of amended the notice of motion.

[99] The applicants seek an order interdicting the first to seventh respondent from publishing false or misleading advertisements concerning vitamins, multivitamins, and other named products including VitaCell. I will grant the relief sought in a modified form and which will be consistent with the provisions of the 2002 call up notice. In the result I will grant an order interdicting the first, second, fourth and fifth respondents from publishing advertisements concerning the efficacy of VitaCell on persons with AIDS pending the submission of VitaCell to the MCC to review medicinal claims made by the respondents.

[100] The applicants are also entitled to the relief sought in paras 5.2, 5.3, 8.2 and 8.3 as modified. The applicants are also seeking an order in which I should put the eighth and ninth respondents on terms to take steps to implement the order. Though such an order is competent I am, however, not persuaded in the circumstances of the present case that it is an appropriate order. There is nothing to suggest that in the light of my finding the eighth and ninth respondents will not take steps to comply with the terms of the order.

[101] With regard to the relief sought as against the twelfth respondent it is clear that there was no legal basis for the applicants to have involved the twelfth respondent in the proceedings. It has complied with its obligations in terms of the Medicines Act. Counsel for the applicants conceded that twelfth respondent has complied with its obligations under the Act. The twelfth respondent was entitled to defend the application in order to set the record straight in the light of the fact that very serious allegations of neglect and misconduct were levelled against it.

Costs

[102] It is clear from what I have said above that with regard to the relief sought by the applicants in these proceedings, the applicants have been substantially successful as regards the first to seventh respondents. The third, sixth and seventh respondents have, however, fallen out of the picture and are no longer before the Court. The applicants are therefore entitled to an order that the first, second, fourth and fifth respondents be held liable jointly and severally, for 90% of the applicants' costs.

[103] The applicants were, however, unsuccessful in their application against the twelfth respondent. As indicated above, the applicants have not satisfied the Court that they are entitled to any of the substantive relief sought as against the twelfth respondent. In the circumstances I shall order the applicants to pay the twelfth respondent's costs such costs to include the costs of two counsel. It is correct that the issues raised in these proceedings are of considerable importance to the litigants and to the public in general and that one should be cautious in awarding costs against litigants who seek to enforce their constitutional right against the State as such orders may have an unduly inhibiting effect on other potential litigants. (**Motsepe v Commissioner for Inland Revenue** 1997 (2) SA 898 (CC) at 911 F- 912 A). But the costs award is justified in this matter as the attack on the twelfth respondent's conduct was unfounded.

[104] As regards the eighth and ninth respondents the applicants have partially succeeded in the relief sought against them. The eighth respondent should pay 10 % of the applicants' costs.

Order

[105] In the circumstances I make the following order:

1. It is declared that the clinical trials conducted in South Africa by and/or under the direction of the first, second, fourth and fifth respondents are unlawful.

2. The first, second, fourth and fifth respondents are interdicted from conducting unauthorised clinical trials in South Africa.

3. The first, second, fourth and fifth respondents are interdicted from publishing advertisements concerning the medicinal effects of VitaCell on persons with AIDS pending the submission by the aforementioned respondents of the VitaCell to the MCC to review its medicinal claims.

4. It is declared that the eighth (Minister of Health) and the ninth respondents are under a duty to take reasonable measures to:

4.1 prevent the first, second, fourth and fifth respondents from conducting unauthorised clinical trials;

4.2. prevent the first, second, fourth and fifth respondents from publishing advertisements concerning the medicinal effects of VitaCell on persons with AIDS pending the submission by the aforesaid respondents of VitaCell to the MCC to review its medicinal claims.

5. The eighth and ninth respondents are ordered to take reasonable measures to investigate the matters referred to in paragraph 4 hereof and, in the light of the facts revealed by such investigation, to take further reasonable action in accordance with their duty.

6. The first, second, fourth and fifth respondents are jointly and severally ordered to pay 90% the costs of the applicants in these proceedings.

7. The eighth and ninth respondents are jointly and severally ordered to pay 10 % of the applicants' costs in these proceedings.

8. The applicants are ordered to pay the costs of the twelfth respondent including costs consequent upon employment of two counsel.

ZONDI, J