IN THE HIGH COURT OF SOUTH AFRICA
(GAUTENG DIVISION, PRETORIA)

CASE NO: 32570/2015

In the matter between:

OMEGALABS (PTY) LTD Applicant

and

DELETE WHICHEVER IS NOT APPLICABLE
(1) REPORTABLE: YES/~~NO~~
(2) OF INTEREST TO OTHERS JUDGES: YES/~~NO~~
(3) REVISED

7/12/2016 .....
DATE SIGNATURE

THE MEDICINES CONTROL COUNCIL First Respondent

DIRECTOR-GENERAL: DEPT OF HEALTH Second Respondent

MINISTER OF HEALTH Third Respondent

MEC FOR HEALTH: GAUTENG PROVINCE Fourth Respondent

JUDGMENT

NGALWANA AJ

A. The Issue

[1] The Medicines and Related Substances Act, 101 of 1965 (*"the Medicines Act"*) defines *"medicine"* as

> *"any substance or mixture of substances 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"*

[2] The term *"medical device"* is defined in the same Medicines Act as

> *"any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent-*
>
> *(a) used or purporting to be suitable for use or manufactured or sold for use in-*

(i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function; or

(iii) the diagnosis or prevention of pregnancy,

and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or

(b) declared by the Minister by notice in the Gazette to be a medical device,

and includes any part or an accessory of a medical device"

(my emphasis)

[3] It seems clear from these definitions that *"medicine"* is a substance classified as *"medicine"* by reference to the use to which it is put, while a *"medical device"* is an instrument classified as *"medical device"* by reference to the means by which it achieves its purpose. The significance of this distinguishing feature will become clear later in this judgment when I explain what the classification process entails.

[4] The issue before Court is a complex one. The applicant approaches this Court for an order

"1. [urgency].

2. Declaring that:

2.1 the products identified in annexure "FA1" to the founding affidavit ("the Dermalex products") are medical devices as defined in section 1 of the Medicines [and Related Substances] Act No. 101 of 1965, as amended ("the Medicines Act");

2.2 in absence of the promulgation of appropriate regulations in terms of section 35(1)(xxvii) and/or (xxviii) of the Medicines Act the first respondent and/or the second respondent are not empowered to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of the Dermalex range of products in respect of its safety, quality and efficacy in the Republic;

2.3 the Dermalex products are not subject to:

2.3.1 registration in terms of section 14(2) of the Medicines Act;

2.3.2 Government Notice R424 in Government Gazette No 3815 of 23 March 1973 in terms of which various "medicines" under pharmacological classification 13 "Dermatological Preparations"

. . . have been called up for registration in terms of section 14(2) of the Medicines Act;

3. . . .

4. *Directing any party who opposes this application, jointly and severally the one paying the other to be absolved, to pay the costs of this application, including the costs of two counsel where engaged"*

[5] The Dermalex products in question (described by Counsel as some sort of *"cream"* that serves a purpose not dissimilar to a band-aid) are either *"medicines"* as contended by the respondents, or *"medical devices"* as contended by the applicant.

[6] But that is a subordinate question. The pre-eminent and more complex question is whether classification or categorization or documentation of the Dermalex products either as *"medicines"* or *"medical devices"* is a function or competency of a Court of law, or that of a statutory functionary (the Medicines Control Council or MCC) established by the Medicines Act to, among other things, regulate the licensing of medicines and medical devices. Put differently, the pre-eminent question is, in my view, whether this Court is invited by the applicant to, as its Counsel would have it, make a decision that entails simply the interpretation of a statute as regards whether the Dermalex products fit the

"medicine" definition or the *"medical device"* definition, or whether this Court is, as Counsel for the Respondents would have it, invited to make a decision that involves a highly technical and evidence-laden evaluation of deeply contested medical and scientific matters. For convenience let us term this *the Jurisdiction Question*. It relates to prayer 2.1 of the notice of motion.

[7] A separate and self-standing question which relates to prayer 2.2 of the notice of motion is whether the promulgation of appropriate regulations is an absolute condition-precedent to the exercise by the MCC of the power *"to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of the Dermalex range of products in respect of its safety, quality and efficacy in the Republic"*. I call this *the Regulations Question*.

[8] A third question which relates to prayer 2.3 of the notice of motion is whether section 14(2) of the Medicines Act applies to the Dermalex products. I label this *the Section 14(2) Question*.

[9] Each of these three questions requires a different approach. The *Regulations Question* and *the Section 14(2) Question* entail an exercise in statutory interpretation. Not so, however, the *Jurisdiction Question* which,

because the applicant places its Dermalex products in the *"medical device"* camp, entails an inquiry not only into whether these are instruments (in contra-distinction to substances) but also an assessment of the means by which they achieve their purpose. I address each of these questions in turn.

B. The Jurisdiction Question

[10] As indicated earlier, the question under this rubric is whether this Court is invited to make a decision that entails simply the interpretation of the Medicines Act as regards whether the Dermalex products fit the *"medicine"* definition or the *"medical device"* mould, or whether this Court is invited to make a decision that involves a highly technical and evidence-laden evaluation of deeply contested medical and scientific matters.

[11] Which of these two approaches is an appropriate one to follow must be determined by the definition of the box in which the applicant claims that its Dermalex products belong – the *"medical device"* definition. The reason for this is that the subordinate question that this Court is called upon to answer is not so much whether the Dermalex products fit the *"medicine"* definition but rather whether they fit the *"medical device"* definition. The significance of this distinction lies in the fact that, on a proper construction of both definitions, an answer to the inquiry whether the products are or are not *"medicines"* will not

tell us whether or not they are *"medical devices"*. In this regard, I incline more towards the test proposed by the applicant's Counsel – namely, whether in achieving their purpose the Dermalex products do so *"through chemical, pharmacological, immunological or metabolic means in or on the human body [although they] may be assisted in [their] function by such means"* – than the test contended for by Counsel for the respondents, namely, whether the products are not *"medicines"*.

[12] In a sense (to use an antiquated analogy in this age of Global Positioning System or GPS) the respondents' Counsel is inviting the Court to locate Marrakesh using the map of South America. However diligently one may pore over the labyrinth that is the map of South America, one will never locate Marrakesh there. The same is true of trying to ascertain whether the Dermalex products are *"medical devices"* by asking whether or not they are *"medicines"*. By their very definition, *"medicines"* are substances that owe their classification as *"medicines"* to the use to which they are put; *"medical devices"* are instruments classified as devices by reason of the means by which they achieve their purpose. That is why asking the question whether or not a substance is a *"medicine"* cannot tell one whether or not an instrument is a *"medical device"*.

[13] Thus, it seems to me the subordinate question must be whether the Dermalex products achieve their diagnostic, mitigation, monitoring, modification and prevention purpose *"through chemical, pharmacological, immunological or metabolic means in or on the human body [or are] assisted in [their] function by such means"*. In my view, such an assessment entails making a decision that involves a highly technical and evidence-laden evaluation of deeply contested medical and scientific matters, as is demonstrated by the differing views propounded by the parties' respective experts. A Court of law is not equipped or has no particular proficiency to make that assessment. The Medicines Control Council is.

[14] In *Minister of Environmental Affairs and Tourism and Others v Phambili Fisheries (Pty) Ltd; Minister of Environmental Affairs and Tourism and Others v Bato Star Fishing (Pty) Ltd* 2003 (6) SA 407 (SCA) the Court, in a review setting, made the need for judicial deference on matters outside judicial proficiency quite clear when it said:

> *"Judicial deference is particularly appropriate where the subject-matter of an administrative action is very technical or of a kind in which a Court has no particular proficiency."*[1]

---

1 At paragraph [53]

[15] On appeal to the Constitutional Court, in *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism and Others* 2004 (4) SA 290 (CC), the principle of judicial deference was endorsed in these words:

> *"The use of the word 'deference' may give rise to misunderstanding as to the true function of a review Court. This can be avoided if it is realised that the need for Courts to treat decision-makers with appropriate deference or respect flows not from judicial courtesy or etiquette but from the fundamental constitutional principle of the separation of powers itself."*[2]

[16] The Constitutional Court continued:

> *"In treating the decisions of administrative agencies with the appropriate respect, a Court is recognising the proper role of the Executive within the Constitution. In doing so a Court should be careful not to attribute to itself superior wisdom in relation to matters entrusted to other branches of government. A Court should thus give due weight to findings of fact and policy decisions made by those with special expertise and experience in the field. The extent to which a Court should give weight to these considerations will depend upon the character of the decision itself, as*

---

2 At paragraph [46]

well as on the identity of the decision-maker. A decision that requires an equilibrium to be struck between a range of competing interests or considerations and which is to be taken by a person or institution with specific expertise in that area must be shown respect by the Courts . . . "[3]

[17] Before this Court is an application not for the review of a decision of the Medicines Control Council but for a raft of declaratory orders. Even so, I can conceive of no reasonable basis why judicial deference should not be observed in equal measure in a collateral challenge as it is in a review application.

[18] The Medicines Control Council is the body that is specifically set up under the Medicines Act to issue licenses for the manufacture, import, export, distribution and wholesale of not only *"medicines"* but also *"medical devices"*.[4] In order to do that, it must surely also have the competence to determine whether the Dermalex products achieve their diagnostic, mitigation, monitoring, modification and prevention purpose *"through chemical, pharmacological, immunological or metabolic means in or on the human body [or are] assisted in [their] function by such means"*. That is an exercise that self-evidently calls for

---

3 At paragraph [48]

4 For example, section 22C(1)(b) reads:
"Subject to the provisions of this section-
(a) . . .
(b) *the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a* medicine or *medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine."*

(emphasis supplied)

technical assessment steeped in the medico-scientific discipline. A Court of law – except perhaps for a few omniscient sages who may have stumbled into law as a discipline purely out of intellectual curiosity after finding practice in the disciplines of medicine and science unfulfilling and dull – has no particular proficiency in such matters.

[19] Thus, in my view this is an exercise best performed by the Medicines Control Council.

[20] On this finding, it is not necessary to consider and pronounce upon the parties' expert evidence (and the question of a possible dispute of facts arising as a corollary of that exercise) and other points raised by the respondents' Counsel as regards prematurity of the application, failure to exhaust internal remedies, the application to strike out, the application of the Promotion of Administrative Justice Act, 3 of 2000 (PAJA), delay in launching this application, and all the authorities invoked by Counsel in aid of pressing those points home. It is also not necessary to pronounce upon a point which, in its articulation though not labelled as such, sounded like a peremption point.[5] I thus expressly decline to deal with those points.

---

[5] It was suggested that the applicant had made a *"comprehensive submission"* to the Medicines Control Council for a determination of this very issue (what I term the subordinate question) that this Court is now called upon to determine, thereby indicating a contrary intention to launching these proceedings as a collateral challenge. A decision of the Medicines Control Council was pending still at the time of the launching of this application.

[21] In finding as I do, I part company with two judgments of this Court on which Counsel for the applicant places considerable reliance. In my view, both judgments are with respect either distinguishable or quite wrong.

[22] The first of these, *Gelderma Laboratories SA (Pty) Ltd v Medicines Control Council and Others* (54281/2013) [2014] ZAGPPHC 360 (12 June 2014), comprises, without much more, a summary of Counsel's submissions, quotations from the record and excerpts from judgments referred to by Counsel, and rounds off by granting the orders sought by the applicant, ostensibly *"[f]or the reasons set out above"*[6]. Absent, regrettably, is a proper assessment of Counsel's respective submissions, an interrogation of the judgments referred to by Counsel and, all told, a healthy dose of what Justice BR Southwood, in his book titled Essential Judicial Reasoning, calls *"the reasoning process relevant to the situation which has been laid down in the case law"*[7].

[23] At best, the *ratio decidendi* in the judgment is implied in one paragraph in which the Learned Judge seems to suggest that the reason for granting the orders[8] sought was failure by the Minister to promulgate regulations for the regulation of *"medical devices"*[9]. The Learned Judge says:

---

6 At paragraph [32]

7 LexisNexis ©2015

8 *". . . declaring that:*

(1.1) Medical devices as defined in section 1 of the Medicines and Related Substance Act 101 of 1965 ("The Medicines Act") are not subject to registration in terms of section 14(2) of the Medicines Act

(1.2) in absence of the promulgation of appropriate regulations in terms of section 35(1) xxvii)

"The Act in terms of section 35 has a built in procedure for making regulations in terms of section 35. It was submitted that if the intention was to promulgate regulations restricting or controlling a device it should regulate it as such in terms of the section. This procedure has not been followed."[10]

[24] But this was not even the issue that the Learned Judge identified as *"the question which needs to be determined"*. The issue identified by the Learned Judge for determination was *"whether the dermal fillers containing lidocaine is a medical device as the applicant contends or whether it should be registered because it contains a substance which is registrable"*[11] (sic). So, the Learned Judge appears to have posited one question for determination but in fact determined the case on a quite different question.

---

of the Medicines Act the first respondent and / or the second respondent are not empowered to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation exportation, storage, transportation, sale or use of any medical device or class of medical devices in respect of its safety, quality and efficacy in the Republic;

(1.3) The product identified in annexure "FA1" to the founding affidavit ("the Restylane products") as emanating from the applicant are medical devices as defined in section 1 of the Medicines Act;

(1.4) The Restylane products are accordingly not subject to registration in terms of section 14 (2) of the Medicines Act.

(2) Such parties who oppose this application are ordered to pay the costs of this application, including the costs of two counsel"

9 A topic dealt with later in this judgment under the rubric *"the Regulations Question"*.

10 At paragraph [31]

11 At paragraph [9]

[25] In any event, even on the question posited but not quite answered by the Learned Judge by way of didactic reasoning, whether or not a product containing one or other chemical or substance is to be classified as a *"medical device"* is, for reasons already discussed earlier, in my view not a question that falls within the proficiency of a Court of law. It is thus not surprising that the Learned Judge simply declares, without more, that the products in question are *"medical devices"* and are, for that reason, not subject to registration in terms of section 14(2) of the Medicines Act. In order to answer that question proficiently, the Learned Judge would have had to embark upon a medico-scientific assessment of the products in question, something at which the MCC is adept, but not so a Court of law.

[26] But even the *ratio decidendi* is in my view with respect not correct. There is nothing in the Medicines Act that is reasonably capable of the construction placed by the Learned Judge on section 35(1)(xxvii), namely, that absent a set of regulations the MCC is denuded of any power to authorize, regulate, control, restrict or prohibit the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any *"medical device"* or class of *"medical devices"* or *"medicines"* in respect of its safety, quality and efficacy. I deal with this issue in greater detail under *the Regulations Question* rubric below.

[27] The second judgment, *Allergan Pharmaceuticals (Pty) Ltd v Medicines Control Council and Others* [2015] 3 All SA 173 (GP), starts off with an endorsement of the *Gelderma ratio decidendi* described earlier in this judgment.[12]

[28] Then, after trawling the evidence of expert witnesses to discover that similar products are classified and documented as *"medical devices"* elsewhere in some parts of the world, and citing a Cape High Court judgment in *Treatment Action Campaign and Another v Rath and Others* [2008] 4 All SA 380 (C) (*"the Rath case"*) for the proposition that *"it is not for the Medicines Control Council to decide whether a substance is a medicine, but that it is a question to be decided by a court"*[13], the Learned Judge concluded that *"the Optive range of products*[14] *are (sic) medical devices and not subject to registration, absent any regulations to do so"*[15], and granted the orders sought by the applicant which are similar to those sought here and in the *Gelderma* case.

[29] The approach of the Court in the *Allergan judgment* is in my view with respect an unhappy one for a number of reasons.

---

12 The endorsement appears in paragraph [7] of the *Allergan judgment*
13 At paragraph [50]
14 Dubbed ophthalmic lubricants in that case
15 At paragraph [53]

29.1 First, the *Gelderma* judgment is not authority for the proposition that it is for a Court and not the Medicines Control Council to decide whether a substance is a *"medicine"* or a *"medical device"*. In an un-numbered paragraph lodged between paragraphs [22] and [23] of that judgment, the Learned Judge merely recorded that Counsel for the applicant *"relied upon the [Rath case]"* for that proposition. The Learned Judge himself did not so find.

29.2 Second, the fact that similar products are registered or classified as *"medical devices"* elsewhere in the world, with no discernible appreciation of what process was followed in those countries to so classify those products there, is in my view not a helpful form of assessment in order to conclude that South Africa should simply follow those countries' example.

29.3 Third, there is no indication that classification of similar products as *"medical devices"* in those other countries was made by Courts of law.

29.4 Fourth, the significance, if any, of classification of similar products as *"medical devices"* in other so-called *"benchmark"* countries is a matter for debate among experts at the Medicines Control Council,

and if the applicant should be unhappy with the outcome there it may then appeal internally under section 24 of the Medicines Act and, if still aggrieved by the outcome of the appeal, approach the Courts on review if there should be grounds for such relief. There is nothing in section 24 that suggests that appeals are confined to decisions made in respect only of *"medicines"*. The section says, *"[a]ny person aggrieved by a decision of the council may . . . appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned"*.

29.5 Fifth, the judgment of the Cape High Court in *Rath* cannot, on a proper construction, mean that a body such as the MCC has no power to classify products either as *"medicines"* or *"medical devices"* when it was set up to regulate *"medicines"* and other related substances. It seems to me the import of that judgment must be that the Court is the final arbiter in these matters on the ordinary grounds of review of the MCC's decision. That is not to second-guess the decision of the MCC as regards the correctness of its classification. If the decision is not taken on review, then it is final.

29.6 Sixth, in any event, the context of the *Rath judgment* must not be lost. The case had to do with a request for multifarious orders, against numerous and disparate respondents, including alleged failure of organs of state to perform their duties and so the Court being called upon to intervene and compel them to do so.

29.7 Seventh, if the *Rath* judgment, properly construed, meant to convey that only the Courts have the power to decide whether a substance is a *"medicine"* or not, then I disagree with the correctness of that decision. A Court of law has no particular proficiency in matters such as these that entail a medico-scientific assessment of highly technical matters that are deeply contested among experts. In any event, even if it were correct, a Cape High Court judgment of a single Judge does not bind this division.

29.8 Eighth, as in the *Gelderma judgment* the Learned Judge in the *Allergan judgment* posits two questions for determination but decides the case on a third. The first question identified by the Learned Judge was *"whether the Optive products constitute medicines or medical devices"*[16]; the second was *"whether the Optive range of products was called up for registration . . . as*

16 At paragraph [9]

medicines in terms of section 14(2) of the Medicines Act"[17]. But the case appears to have been decided on the absence of regulations as the Learned Judge concludes, *"Given what has been set out above, the Optive range of products are medical devices and not subject to registration, absent any regulations to do so"* (my emphasis).

29.9 Ninth, this finding can in my respectful view not be correct because it is the Medicines Act and not the absent regulations that confer upon the MCC the power to regulate medicines and other related substances. For example, section 22C(1)(b) confers upon the MCC the power to license, among other things, the import, export, manufacture, distribution and wholesale of *"medical devices"*. In order to do that it must have the competency and power to classify a product either as a *"medicine"* or a *"medical device"*. The applicant describes itself as *"the sole importer and distributor of various non-prescription or over-the-counter products"*. I deal with this issue immediately below under the rubric *"the Regulations Question"*.

17 At paragraph [46]

[30] For all these reasons, the declaratory order sought in paragraph 2.1 of the notice of motion cannot be granted.

C. The Regulations Question

[31] As already indicated above, section 22C(1)(b) of the Medicines Act confers upon the Medicines Control Council the power to issue licenses for the manufacture, import, export, distribution and wholesale of not only *"medicines"* but also *"medical devices"*.[18] It thus seems to me that if the Medicines Control Council has the power to license the manufacture, import, export and distribution of medical devices, it must of necessity also have the power and competence to classify and register *"medical devices"* and does not require the Minister first to make regulations in order to do so. After all, it is the Medicines Act, not the regulations, that confers on the Medicines Control Council the power to license the manufacture, import, export and distribution of *"medical devices"*.

---

18 The section reads:
"Subject to the provisions of this section-
(c) . . .
(d) *the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine."*

(emphasis supplied)

[32] In this regard, I with respect associate myself with the *dictum* of this division, in a judgment delivered after both the *Gelderma* and *Allegan* judgments, in *Telkom SA Soc Limited v Mncube NO and Others; Mobile Telephone Networks (Pty) Ltd v Pillay NO and Others; Cell C (Pty) Limited v The Chairperson of ICASA and Others; Dimension Data Middle East & Africa (Pty) Ltd t/a Internet Solutions v ICASA and Others (55311/2015; 77029/2015; 82287/2015) [2016] ZAGPPHC 93 (26 February 2016)* where the Learned Judge said:[19]:

> *"[31] The fact that there were no regulations in place which governed the application, does not mean the application could not properly be considered. In the absence of regulations contemplated in sections 13(2)[20] and 31(3)(c)[21] of the EC Act at the time the application was lodged, Neotel and Vodacom nevertheless provided information in terms of the Regulations in respect of the Limitation of Ownership and Control of Telecommunication Services. . .*

---

19 Cell-C sought to have a decision of ICASA set aside on review on the ground that ICASA exercised a power before applicable regulations has been promulgated,

20 The section, which deals with the transfer of transfer of individual licenses and or change of ownership, reads:
"(2) An application for permission to let, sub-let, assign, cede or in any way transfer an individual licence, or assign, cede or transfer control of an individual licence may be made to the Authority in the prescribed manner." (my emphasis)

21 This section deals with radio frequency spectrum licenses and reads as follows:
"(3) The Authority may, taking into account the objects of the Act, prescribe procedures and criteria for-
(a) . . .
(b) . . .
(c) *permission to assign, cede, share or in any way transfer a radio frequency spectrum licence, or assign, cede or transfer control of a radio frequency spectrum licence as contemplated in subsection (2A)."*

[32] In Verstappen v Port Edward Town Board & Others 1994 (3) SA 569 (D&CLD) it was held that the Minister's failure to promulgate regulations foreshadowed in section 20(2) of the Environment Conservation Act No 73 of 1989 did not render lawful the conduct of the local authority in operating a waste disposal site without a permit. In view of the fact that no regulations dealing with waste management have been promulgated under that Act, Magid J said the following at 537 E-G:

> *"If some person desires to 'establish, provide or operate' a waste disposal site he requires a permit from the Minister to do so. And if the Minister has failed to prescribe the form on which such application is made or the information which must accompany it, such person may make an application to the Minister in whatever reasonable form he desires, furnishing all such information as the Minister might reasonably be likely to need. If the Minister were to decline to deal with the application because it was not on the appropriate form or did not contain sufficient information, I have no doubt at all that any Court would hold such a decision by the Minister to be so grossly unreasonable as to justify review. That is not to say, of course, that the Minister would not be entitled to require that such an applicant furnish such further information as might reasonably be*

required to enable the Minister properly to assess the merits of the application."

[33] I associate myself with this approach. The absence of applicable regulations does not render the application submitted, or the procedure followed thereafter, unlawful. The EC Act itself provides a statutory framework and ICASA was therefore entitled, in my view, to exercise its statutory powers in terms of sections 13(1) and 31(2A) of the EC Act (the transfer of control of an individual licence and the transfer of control of a radio frequency spectrum licence respectively) with regard to the application. I therefore conclude that this ground of review falls to be dismissed."

[33] Thus, there is no impediment to the applicant making submissions to the Medicines Control Council (a body that is statutorily mandated to perform that function and is better equipped to do so) for classification of its Dermalex products as *"medical devices"* by reason only of the Minister not yet having promulgated the regulations contemplated in section 35(1)(xxvii) of the Medicines Act.

[34] Thus, the prayer for a declaratory order in paragraph 2.2 of the notice of motion cannot be granted.

D. The Section 14(2) Question

[35] The section reads:

> *"**14 Prohibition on the sale of medicines which are subject to registration and are not registered***
>
> *(1)* . . .
>
> *(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."*

[36] There can be no dispute that on a plain reading of this provision only *"medicines"* can be called up for registration. All that is required is a resolution of the Medicines Control Council published in the Government Gazette and the

Minister's approval. But the applicant cannot resort to self-help by declaring unilaterally that its Dermalex products are *"medical devices"* and then say they are therefore not subject to a call-up under section 14(2). As I have already discussed earlier in this judgment, that similar products are classified as *"medical devices"* elsewhere in the world is not decisive. The Medicines Control Council must be given space to do its job and determine whether the Dermalex products are *"medicines"* or *"medical devices"*. If it should determine that they are *"medical devices"*, then the section would find no application. But if it should determine that they are *"medicines"* then it can call them up for registration as such.

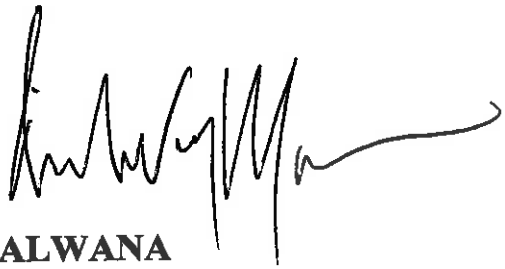
[37] Thus, the prayer for the declaratory orders in 2.3 of the notice of motion cannot be granted.

E. Discretion

[38] Declaratory relief is granted on the exercise of the Court's discretion.

[39] For all the reasons discussed in this judgment, I can conceive of no compelling factors that would sway me to exercise discretion in favour of granting the declaratory orders sought. To do so would, in fact, be to encourage a resort to self-help.

[40] In the result, the application is dismissed with costs.



V NGALWANA

ACTING JUDGE OF THE HIGH COURT

Date Heard:	24 November 2016
For the Applicant:	B Leech SC; AC Botha
Instructed by:	Werksmans Attorneys
For the Respondents:	G Marcus SC; Rajab-Budlender
Instructed by:	State Attorney (Pretoria)
Date of Judgment:	06 December 2016