

REPUBLIC OF NAMIBIA



HIGH COURT OF NAMIBIA MAIN DIVISION, WINDHOEK

JUDGMENT

Case no: HC-MD-CIV-MOT-GEN-2022/00031

In the matter between:

NOVECY PHARMACY CC

APPLICANT

and

MINISTER OF HEALTH AND SOCIAL SERVICES

1st RESPONDENT

NAMIBIA MEDICINES REGULATORY COUNCIL

2nd RESPONDENT

REGISTRAR OF MEDICINES

3rd RESPONDENT

METHEALTH NAMIBIA ADMINISTRATORS (PTY) LTD

4th RESPONDENT

Neutral citation: *Novecy Pharmacy CC v Minister of Health and Social Services* (HC-MD-CIV-MOT-GEN-2022/00031) [2024] NAHCMD 81 (04 March 2024)

Coram: UEITELE J

Heard 24 August 2023

Delivered: 04 March 2024

Flynote: Motion proceedings — Medicines and Related Substances Control Act 13 of 2003 — Pharmacy Act 9 of 2004 — Medicines and Related Substances Control Act 101 of 1965 — Right to compound and sell any specific medicine — Regulations relating to medicines and related substances — Regulation 19(2).

Summary: The dispute between the parties in this matter relates to the interpretation of some of the provisions of the Medicines and Related Substances Control Act 13 of 2003 (the Act). The applicant, a registered pharmacy, approached this court by way of notice of motion seeking three declaratory orders. The applicant decided to approach this court after the second respondent received complaints regarding the applicant's compounding of drugs practices. The second respondent's inspectors conducted a routine inspection at the applicant's premises and found that medicines compounded by the applicant is illegal. This finding was communicated to Methealth, the fourth respondent, who administers the medical aid claims of a few medical aid funds and who rejected all the medical aid claims for medicines compounded by the applicant. The applicant contends that as a result of the second respondent's communication to the fourth respondent, it suffered reputational damage and financial losses and the health and wellbeing of its clients suffers as well.

Held that: where the Council, by resolution approved by the Minister, has determined that a medicine or a category of medicines is subject to registration or is dependent on being registered such medicine may not be sold before it is registered or as provided in s 18 or s 27 of the Act. Section 25 of the Act prohibits the sale of medicine that does not comply with the prescribed requirements.

Held further that: taking into account the stated purpose of the Act, namely, to control medicines and scheduled substances intended for human and for animal use and the prohibition set out in s 25 of the Act, the applicant's right to sell medicine, which it has compounded, is subject to the restrictions imposed by s 18(5).

Held that: the purpose served by regulations is to make an Act of Parliament work. The Act itself sets the norm or provides the framework on the subject matter legislated upon. Regulations provide the sort of detail that is best left by Parliament to a functionary, usually the Minister responsible for the administration of the Act, to look beyond the framework and – in minute detail – to ascertain what is necessary to achieve the object of the Act or to make the Act work.

Held further that: it is a well-established principle of our law that subordinate legislation must be created within the limits of the empowering statute. If they are not, the exercise of the power is unlawful and may be set aside like an unlawful act of any other functionary who has acted outside the powers conferred upon her by the legislature. This means that any regulations promulgated by the Minister under the Act, including the impugned regulation, must be consistent with the Act. If they are not, the Minister acted beyond the scope of the powers conferred upon him by the legislature.

Held that: the Minister cannot by regulation take away what is granted by the Act and regulation 19(2) is, in so far as it attempts take away the applicant's right of anticipatory compounding, *ultra vires* s 18(5)(b) of the Act.

ORDER

1. The application to declare that: 'the applicant's right to compound and sell any specific medicine, is limited as envisaged in section 18(5)(a) and (b) of the Act, and Regulation 19 published in terms of the Act, only in circumstances where, and for such period as, that specific medicine is and remains subject to the provisions of section 18(1) of the Act', is dismissed.
2. Regulation 19(2) of the 'Regulations Relating to Medicines and Related Substances' published under Government Notice No. 178 in Government Gazette No.

4088 dated 25 July 2008 in terms of section 44 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) is *ultra vires* s 18(5)(b) of the Act and is reviewed and set aside.

3. The application to declare that: 'Section 31(5) (b) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) is not applicable to Novocy Pharmacy CC, while it does not manufacture, but only compounds the medicine which it packs and sells' is refused.

4. Each party must pay its own costs.

5. The matter is regarded as finalised and is removed from the roll.

JUDGMENT

UEITELE J:

Introduction

[1] The dispute between the parties in this matter relates to the interpretation of some of the provisions of the Medicines and Related Substances Control Act 13 of 2003¹ (the Act). The applicant seeks an order declaring that:

(a) its right to compound and sell any specific medicine, is limited as envisaged in s 18(5)(1)(a) and (b) of the Act and Regulation 19 published in terms of the Act, only in circumstances where, and for such period as, that specific medicine is and remains subject to the provisions of s 18(1) of the Act;

¹ Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003).

(b) Regulation 19(2) is *ultra vires* the provisions of section 18(5)(b) of the Act; and

(c) Section 31(5) (b) of the Act is not applicable to Novecy Pharmacy CC, while it does not manufacture, but only compounds the medicine which it packs and sells.

[2] The applicant is Novecy Pharmacy CC, a close corporation incorporated in terms of the laws applicable in Namibia. Novecy Pharmacy CC is a pharmacy registered as a community pharmacy in terms of the Pharmacy Act 9 of 2004.² Novecy Pharmacy CC has two members who are both registered and practising pharmacists, they are Riana Potgieter, who deposed to the founding affidavit, and Lodewikus Hendrik Jacobus van Zyl.

[3] The first respondent is the Minister responsible for Health and Social Services (the Minister), the second respondent is the Namibia Medicines Regulatory Council, established as the Medicines Control Council in terms of the Medicines and Related Substances Control Act 101 of 1965³, continued under its new name as provided under s 2(1) of the Act. I will for the sake of convenience refer to the second respondent as the Council. The third respondent is the Registrar of Medicines, appointed by the Minister in terms of s 16 of the Act, who will for the sake of convenience be referred to as the Registrar. The fourth respondent is Methealth Namibia Administrators (Pty) Ltd, a private company with limited liability registered in terms of the company laws of Namibia. I will for the sake of convenience refer to the fourth respondent as Methealth.

[4] As I have indicated earlier, the applicant is a registered pharmacy; it thus conducts the business of a pharmacy, the bulk of which is the selling of manufactured medicine. Section 18 of the Act prohibits the sale of medicines, which are subject to registration and are not registered.

[5] The applicant, however, contends that although it conducts the business of a pharmacy (that is, the selling, subject to the Act, of manufactured medicines) what

² Pharmacy Act, 2004 (Act No 9 of 2004).

³ Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).

distinguishes it from every other pharmacies in Namibia is that it is primarily a compounding pharmacy which mainly sells medicine compounded by it. It states that about 92% of its business is drug/medicine compounding. On 19 April 2021, the Council, in terms of s 31(5)(c) the Act, issued Ms Potgieter, of the applicant, a licence to import or export medicine or scheduled substances. The licence was valid for a period of one year, that is, from 29 April 2021 to 28 April 2022.

[6] The deponent to the applicant's founding affidavit contends that the applicant compounds drugs/medicine for its own patients and also compounds drugs/medicine upon request from other pharmacies for their patients and furthermore compounds medicine for medical doctors and veterinarians.

[7] Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Invariably compounded medicine is not registered as contemplated in the Act.

[8] The deponent to the Council's answering affidavit deposed that during the year 2020 and during August 2021, the Council received complaints regarding the applicant's compounding of drugs practices. She continued and stated that as a result of the complaints received, the Council instigated an investigation into the applicant's compounding activities/practices. She further deposed that the Council's inspectors also conducted a routine inspection, at Namib Pharmacy, on 11 September 2020. The investigation and inspections allegedly revealed that the applicant was irregularly 'compounding' medical products and engaging in small-scale manufacturing of medicines under the guise of 'compounding' medicines. The applicant's 'compounded' products that were found at Namib Pharmacy were therefore confiscated by the Council's inspectors.

[9] The deponent to the Council's answering affidavit further stated that, in addition to the alleged discovery, that the applicant, instead of compounding medicine within the

legal framework, was conducting 'small scale manufacturing of medicine', Council had a major concern as to quality-wise, due to the fact that the shelf-life of compounded medicine is limited to 30 days. The investigations/inspections allegedly revealed that the applicant's compounded medicine was kept longer than the prescribed period of 30 days on the shelf. This was a risk to patients and the public, so the averral goes.

[10] As a result of the inspectors' findings, the applicant was invited to show cause why its licence to import raw materials for the 'compounding' must not be revoked. The Council furthermore instructed the applicant to discontinue their 'compounding' operations.

[11] The applicant in response to the Council's invitation and contentions denied the allegations that it was conducting small scale manufacturing of medicine under the guise of compounding. The applicant, through its legal practitioners, addressed a letter dated 17 September 2021 to the Council stating that in terms of s 29 of the Act, the applicant is entitled to sell registered medicine subject to the requirements set out in that section, and that in terms of s 18 it may sell unregistered medicine which is subject to registration by virtue of a resolution published by the Registrar in the government gazette.

[12] The applicant in the same letter of 17 September 2021 continued and stated that;

(a) it may compound and sell medicine, which is not registered and which the registrar does not require to be registered, without restriction to patients and other pharmacies or registered health care facilities subject to the regulatory regime of the Act, but excluding the limitations in s 18(5)(a) and (b);

(b) it may compound and sell medicine which is not registered and which the registrar requires to be registered, but then it must do so subject to the limitations in s 18(5)(a) and (b).

[13] The applicant continued and stated that when it compounds and sells medicine to other pharmacies it has at all times complied with the Act, in particular and when it has compounded medicine subject to a prescription, such medicine has never been sold or on-sold to a member of the public without a valid prescription. It stated that despite this fact, the Council has communicated its view that medicines compounded by the applicant is illegal to Methealth, who administers the medical aid claims of the following medical aid funds: Namibia Medical Care (NMC), BankMed Namibia (BankMed), and Public Service Employees Medical Aid Scheme ("PSEMAS). As a result of the Council's communication to Methealth, Methealth rejected all the medical aid claims for medicines compounded by Novecy.

[14] The applicant thus contends that as a result of the Council's communication to Methealth, it (applicant) suffers reputational damage and financial losses and the health and wellbeing of its clients suffers as well. The applicant, accordingly, demanded that the Council must, by not later than 28 September 2021, retract its allegations that the medicine compounded by the applicant is illegal and undertake that it will not confiscate any medicine compounded by the applicant without first affording the applicant and the pharmacies involved a reasonable opportunity to show that they complied with the Act. The applicant threatened to approach this Court for an appropriate relief if its demand was not met.

[15] The Council did not respond by 28 September 2021, as demanded by the applicant, it only responded during October 2021. In its response it refused to give the undertakings demanded by the applicant and recorded its version of the interpretation of the Act. The parties as a result exchanged communications with respect to the interpretation of the Act. The Council, furthermore, continued with its confiscation of medicines which it alleged and believed were compounded in contravention of the Act. As a result of the correspondence exchanges between the Council and the applicant, and the Council's actions, the applicant ultimately instituted this application, seeking the relief that I referred to in the opening paragraph of this judgment.

[16] Having briefly set out the background to the dispute in this matter, I now proceed to outline the legislative framework that is applicable to the dispute in this matter.

Interpretation of the legislative framework

[17] The Supreme Court⁴ quoting with approval from *Natal Joint Municipal Pension Fund v Endumeni Municipality*⁵ expressed itself as follows regarding the current legal position in respect of the interpretation of statutes:

'The present state of the law can be expressed as follows: Interpretation is the process of attributing meaning to words used in a document, be it legislation, some other statutory instrument, or contract, having regard to the context provided by reading the particular provision or provisions in the light of the document as a whole and the circumstances attendant upon its coming into existence. Whatever the nature of the document, consideration must be given to the language used in the light of the ordinary rules of grammar and syntax; the context in which the provision appears; the apparent purpose to which it is directed and the material known to those responsible for its production.'

....

'An interpretation will not be given that leads to impractical, unbusinesslike or oppressive consequences or that will stultify the broader operation of the legislation or contract under consideration.' (Underlined for emphasis).

Purpose of the Act

[18] It is against the background of what I stated in the preceding paragraph that I start off the discussion relating to the legislative framework by referring to the long title of the Act. The long title of the Act is relatively straightforward. It states that the purpose of the Act is:

⁴ *Total Namibia (Pty) Ltd v OBM Engineering and Petroleum Distribution CC* 2015 (3) NR 733 (SC) at paras 17-20.

⁵ *Natal Joint Municipal Pension Fund v Endumeni Municipality* 2012 (4) SA 593 (SCA) para 18.

'To provide for the establishment of a Namibia Medicines Regulatory Council; for the registration of medicines intended for human and for animal use; for the control of medicines and scheduled substances; and to provide for incidental matters.'

[19] Kriegler AJA in *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd*⁶ explained the purpose of the predecessor of the Medicine Act as follows:

'... it would be advisable to pause for reflection lest the wood become obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensible to most. The man in the street - and indeed many medical practitioners - could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasizes, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts'

Trading in or selling of medicines

[20] There are a few sections that deal with the sale of medicine. The first is s 18 of the Act which provides as follows:

'18. (1) Except as provided in this section or section 27, a person may not sell a medicine, which is subject to registration by virtue of a resolution published in terms of subsection (3), unless that medicine is registered.

⁶ *Administrator, Cape v Raats Röntgen and Vermeulen (Pty) Ltd* 1992 (1) SA 245 (A) at 254.

(2) The Council, by resolution approved by the Minister, may from time to time determine that a medicine or a category of medicines is subject to registration in terms of this Act.

(3) A resolution referred to in subsection (2) –

(a) may relate only to medicines, which were available for sale in Namibia immediately prior to the date of publication of such resolution or only to medicines which were not so available then; and

(b) must be published by the Registrar in the *Gazette*.

(4) In the case of a medicine, which was available for sale in Namibia immediately before the date of publication in the *Gazette* of a resolution subjecting that medicine to registration, the sale of that medicine becomes prohibited –

(a) after six months from the date of publication of the resolution, if the registration of that medicine is not applied for before the expiry of that period; or

(b) one month after the date of publication in the *Gazette* of a notice in respect of that medicine in terms of section 19(13), if the registration of the medicine is applied for under section 19 within six months after the date of publication of the resolution and the application is rejected.

(5) Subsection (1) does not apply in respect of the sale of a medicine –

(a) compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional, in the course of carrying on his or her professional activities for a particular person or animal in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, the pharmacist, the practitioner, the registered nurse, the veterinarian or the para-veterinary professional; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed under this Act for sale in the retail trade, subject to the conditions prescribed, or in a quantity for a

particular person or animal as prescribed by a medical practitioner, a dentist, a practitioner, a veterinarian or a para-veterinary professional, as the case may be, if that medicine does not contain any component the sale of which is prohibited by this Act, or any component in respect of which an application has been rejected, and if that medicine has not been advertised.'

[21] The next section that governs trading in medicines is s 19, which requires a person, who wishes to have a particular medicine registered, to submit an application to the registrar in the prescribed form. Section 24 provides that a person may not-

- (a) sell a medicine or a scheduled substance, unless the immediate container and the package, if any, in which that medicine or scheduled substance is sold, bear a label stating the prescribed particulars; or
- (b) advertise a medicine or a scheduled substance for sale, unless the advertisement complies with the prescribed requirements.

[22] The section, however, grants the Council the authority to deviate from the prescribed label format if, in its opinion, the circumstances of a particular case warrant a deviation.

[23] Section 25 prohibits the sale of medicine which has been registered in terms of the Act or in respect of which the Council has authorised the sale as contemplated in section 27, unless that medicine complies with the prescribed requirements. Section 27 empowers the Council to authorise the sale of unregistered medicine for certain purposes. Section 29 empowers the Minister to, on the recommendation of the Council and for the purpose of the control of medicines and other substances classify medicines and other substances, by notice in the Gazette, as Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substances.

[24] In addition, the Minister has in terms of s 44 made regulations relating to the sale and compounding of medicine. One such regulation is Regulation 19 which provides that:

'19. (1) A pharmacist compounding a medicine for sale in the retail trade as contemplated in section 18(5)(b) of the Act may only compound a medicine that is –

- (a) related to a treatment regimen of a particular patient; and
 - (b) sufficient to be used by the patient for not more than 30 consecutive days from the date of dispensing.
- (2) Any medicine referred to in subregulation (1) must be compounded extemporaneously.'

Discussion

[25] I have indicated earlier in this judgment that the applicant seeks three declaratory orders. The first order that the applicant seeks is an order to the effect that its right to compound and sell any specific medicine, is limited as envisaged in s 18(5) (a) and (b) of the Act, and Regulation 19 only in circumstances where, and for such period as, that specific medicine is and remains subject to s 18(1) of the Act.

[26] My understanding of the declaratory order sought by the applicant is that, the Court must declare that, once a specific kind of medicine is registered, the applicant may compound and sell the compounded medicine without the restrictions imposed by s 18(5) of the Act or Regulation 19 on the basis that s 18 no longer applies. The question to be answered is then whether the applicant is correct on its assertion that once it compounds registered medicine, that medicine is no longer required to be registered, it can thus sell the medicine so compounded without the restrictions imposed by s 18(5).

[27] My reading of s 18 of the Act is that where the Council, by resolution approved by the Minister, has determined that a medicine or a category of medicines is subject to registration or is dependent on being registered such medicine may not be sold before it is registered or as provided in s 18 or s 27. Section 25 of the Act prohibits the sale of medicine that does not comply with the prescribed requirements.

[28] Subsection 5 of s 18 of the Act states that s 18(1) does not apply in respect of the sale of a compounded medicine, in one of two scenarios. My further reading of the Act is that the first scenario, in respect of which compounded medicine is not required to be registered, is medicine which:

(a) is compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional;

(b) is compounded by the medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional in the course of carrying on his or her professional activities; or

(c) is compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional in the course of carrying on his or her professional activities for a particular person or animal in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, the pharmacist, the practitioner, the registered nurse, the veterinarian or the para-veterinary professional.

[29] The second scenario, in respect of which compounded medicine is not required to be registered, is medicine which:

(a) is compounded by a pharmacist in a quantity not greater than that prescribed under the Act for sale in the retail trade, subject to the conditions prescribed, if that medicine does not contain any component the sale of which is prohibited by this Act, or

any component in respect of which an application has been rejected, and if that medicine has not been advertised, or

(b) is compounded by a pharmacist in a quantity for a particular person or animal as prescribed by a medical practitioner, a dentist, a practitioner, a veterinarian or a para-veterinary professional, as the case may be if that medicine does not contain any component the sale of which is prohibited by the Act, or any component in respect of which an application has been rejected, and if that medicine has not been advertised.’

[30] I have therefore reached the conclusion that taking into account the stated purpose of the Act, namely to control medicines and scheduled substances intended for human and for animal use and the prohibition set out in s 25 of the Act, the applicant’s right to sell medicine it has compounded is subject to the restrictions imposed by s 18(5). The first declaratory order must therefore fail.

Is Regulation 19(2) *ultra vires* s 18(5) of the Act?

[31] The second declaratory order which the applicant seeks is an order declaring regulation 19(2) to be *ultra vires* the provisions of s 18(5)(b) of the Act. This declaratory order is sought on the basis that Regulation 19 detracts from the scope of the right to compound as it exists under s 18(5)(a) and (b). The applicant’s complaint is that its right to compound medicine, as it exists under s 18(5)(a) and (b), includes what is called anticipatory compounding, which is ousted by the requirement in regulation 19(2) that compounding must be done ‘extemporaneously’.

[32] Counsel for the respondents argued that the applicant seems to be ignoring the wording in s 18(5)(b) namely ‘... subject to the conditions prescribed....’. He continued and argued that s 44(1)(hh) of the Act mandate the Minister to, after consultation with the Council, make regulations –

'prescribing the quantities of unregistered medicine, which may be compounded and sold in the pharmaceutical trade and the conditions under which that medicine may be sold'.

[33] He continued and argued that the conditions under which compounded medicine may be sold is prescribed in Regulation 19 which I quoted earlier. He argued that the conditions prescribed in Regulation 19 limits the right to compound and sell medicine in terms of s 18(5)(b) as follows:

- (a) The medicine in question is compounded only by a pharmacist;
- (b) The compounded medicine can only be sold in the retail trade;
- (c) The medicine is only compounded in relation to a treatment regimen of a particular patient;
- (d) The quantity of the compounded medicine is intended to be used by the patient for not more than 30 consecutive days from the date of dispensing; and
- (e) The medicine in question must be compounded extemporaneously.

[34] Counsel for the respondents continued and argued that in terms of the scheme of the Act, the nature of the compounding that the Legislature prescribed is an extemporaneous compounding. That is, compounding undertaken in response to a prescription of a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional, in the course of carrying on his or her professional activities for a particular person or animal based on the idiosyncratic needs of a particular patient. Counsel accordingly contended that such compounding is typically based on an existing relationship between the medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional with the patient.

[35] Counsel further argued that the scheme of the Act clearly shows that the Legislature limited the nature and scope of compounding as set out in the Act and available only in circumstances that conforms to extemporaneous compounding by the designated persons namely, a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional. The practice of extemporaneous compounding is based on an existing relationship between the designated person and the patient, the argument went. He said:

'A simple example of extemporaneous compounding can arise in a situation where there may be a commercially available medicinal product that the designated person has prescribed for a specific patient and the product contain an ingredient to which the patient is allergic to, or it may come in a dose that would be inappropriate for a patient (a child or an older person) and this prompts a need to modify the medicinal product in some way, or to develop the same medicine without the ingredient concerned.'

[36] Counsel concluded that in both situations prescribed in sections 18(5)(a) and 18(5)(b) it is only extemporaneous compounding that is envisaged, and in both situations the compounded medicine cannot and should not be prepared in advance of the relevant medical prescription. Counsel thus concluded that Regulation 19(2) is not *ultra vires* the Act.

[37] The purpose served by Regulations is to make an Act of Parliament work. The Act itself sets the norm or provides the framework on the subject matter legislated upon. Regulations provide the sort of detail that is best left by Parliament to a functionary, usually the Minister responsible for the administration of the Act, to look beyond the framework and – in minute detail – to ascertain what is necessary to achieve the object of the Act or to make the Act work.⁷ In *Engelbrecht*,⁸ the Constitutional Court of South

⁷ *Minister of Finance v Afribusines* NPC 2022 (4) SA 362 (CC).

⁸ *Engelbrecht v Road Accident Fund* [2007] ZACC 1; 2007 (6) SA 96 (CC); 2007 (5) BCLR 457 (CC) para 26.

Africa embraced the following words of Bennion⁹ which were quoted with approval by Ponnau AJA in a minority judgment in *Makwetlane*:

'[U]nderlying the concept of delegated legislation is the basic principle that the Legislature delegates because it cannot directly exert its will in every detail. All it can in practice do is lay down the outline. This means that the intention of the Legislature, as indicated in the outline (that is the enabling Act), must be the prime guide to the meaning of delegated legislation and the extent of the power to make it ...

The true extent of the power governs the legal meaning of the delegated legislation. The delegate is not intended to travel wider than the object of the Legislature. The delegate's function is to serve and promote that object, while at all times remaining true to it.'¹⁰

[38] It is common cause that regulations are subordinate/delegated legislation. It is a well-established principle of our law that subordinate legislation must be created within the limits of the empowering statute. If they are not, the exercise of the power is unlawful and may be set aside like an unlawful act of any other functionary who has acted outside the powers conferred upon her by the legislature. This means any regulations promulgated by the Minister under the Act, including the impugned regulation, must be consistent with the Act. If they are not, the Minister acted beyond the scope of the powers conferred on him by the legislature.

[39] When the vires of subordinate regulations is under consideration, it is necessary to consider the regulations in relation to the empowering provisions under which they have been made. No matter how clear and unequivocal such regulations may purport to be, their interpretation and validity are dependent upon the empowering provisions which authorise them. One must therefore have regard to the intention of the Legislature as reflected in the Act, it being the enabling statute under which the Regulations Relating to Medicines and Related Substances were promulgated, in order to ascertain whether the regulations are in conformity, and not in conflict, with such

⁹ Bennion *Statutory Interpretation* 3 ed (Butterworths, London 1997) at 189.

¹⁰ *Road Accident Fund v Makwetlane* 2005 (4) SA 51 (SCA) para 12.

intention, for to the extent that they are in conflict with such intention they are ultra vires.¹¹

[40] Section 44(1)(hh) of the Act empowers the Minister to, after consultation with the Council, make regulations:

- (a) prescribing the quantities of unregistered medicine, which may be compounded and sold in the pharmaceutical trade; and
- (b) the conditions under which the compounded medicine may be sold.

[41] The scope of s 18(5) is that the medicine must be compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional, and it must be compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary in the course of carrying on his or her professional activities for a particular person or animal in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, the pharmacist, the practitioner, the registered nurse, the veterinarian or the para-veterinary professional.

[42] The second scenario in respect of which compounded medicine is not required to be registered is that it must be compounded by a pharmacist in a quantity not greater than that prescribed under the Act for sale in the retail trade, subject to the conditions prescribed, if that medicine does not contain any component the sale of which is prohibited by this Act, or any component in respect of which an application has been rejected, and if that medicine has not been advertised.

[43] It is common cause that in pursuance to s 44 (hh) of the Act, the Minister made Regulation 19 prescribing five conditions under which medicine can be compounded and sold. Those conditions are that the medicine must be compounded only by a pharmacist, the compounded medicine may be sold in the retail trade; the medicine

¹¹ *Singapi and Others v Maku and Others* 1982 (2) SA 515 (SE) at 517C – D.

must be compounded in relation to a treatment regimen of a particular patient, the quantity of the compounded medicine must be used by the patient for not more than 30 consecutive days from the date of dispensing; and the medicine in question must be compounded extemporaneously.

[44] The condition under dispute is the condition that the medicine must be compounded extemporaneously. The respondents argue that the nature of the compounding that the Legislature prescribed is an extemporaneous compounding. I do not agree. Section 18(5) of the Act confers on a pharmacist the right to compound medicine in a quantity not greater than that prescribed under the Act for sale in the retail trade. The ordinary meaning of 'retail' is not precise. The ordinary meaning of the word 'retail', according to the Oxford English Dictionary is '*the sale of commodities in small quantities*'. Webster's Third New International Dictionary defines it as 'the sale of commodities or goods in small quantities to ultimate consumers as opposed to wholesale selling'.

[45] It thus follows that when the Act confers on a pharmacist the right to compound medicine for sale in small quantities to ultimate consumers as opposed to wholesale, it implies that a pharmacist may compound medicine pro-actively to meet a foreseen needs, which the applicant's counsel describe as anticipatory compounding.

[46] The ordinary and literal meaning of extemporaneous is: '*done without preparation*' meaning that the word 'extemporaneously', excludes from its ambit anticipatory compounding. The Minister cannot by regulation take away what is granted by the Act and Regulation 19(2) is, in so far as it attempts take away the applicant's right of anticipatory compounding, *ultra vires* s 18(5)(b) of the Act. Regulation 19(2) is to that extent declared invalid.

Does section 31(5)(b) of the Act apply to the Applicant?

[47] The third declaratory order which the applicant seek is that: 'Section 31(5)(b) of the Act is not applicable to Novecy Pharmacy CC, while it does not manufacture, but only compounds the medicine which it packs and sells'.

[48] The declaratory sought by the applicant requires of the court to make a factual finding of whether or not the applicant manufactures or does not manufacture medicine. That was not the dispute placed before me and I therefore decline to make the order.

[49] The general rule is that costs follow the event and that costs are in the discretion of the Court. No reasons have been advanced why the general rule must not apply. In the present matter, the applicant was partly successful and the respondents were also partly successful. I therefore find that it will be just and fair in the circumstances to make no order as to cost.

[50] For the reasons that I have set out in this judgment, I make the following order.

1. The application to declare that: 'the applicant's right to compound and sell any specific medicine, is limited as envisaged in section 18(5)(a) and (b) of "the Act", and Regulation 19 published in terms of the Act, only in circumstances where, and for such period as, that specific medicine is and remains subject to the provisions of section 18(1) of the Act', is dismissed.

2. Regulation 19(2) of the 'Regulations relating to medicines and related substances' published under Government Notice No. 178 in Government Gazette No. 4088 dated 25 July 2008 in terms of section 44 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) is *ultra vires* s 18(5)(b) of the Act and is reviewed and set aside.

3. The application to declare that: 'Section 31(5) (b) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) is not applicable to Novecy

Pharmacy CC, while it does not manufacture, but only compounds the medicine which it packs and sells' is refused.

4. Each party must pay its own costs.
5. The matter is regarded as finalised and is removed from the roll.

S F I UEITELE
Judge

APPERANCES:

Applicant: R Heathcote SC (assisted by J Jacobs)
Instructed by Koep & Partners,
Windhoek

First to third Respondents: G Budlender SC (assisted by M Boonzaier)
Instructed by Government Attorney,
Windhoek

Fourth Respondent: No appearance