CASE NO.: SA 80/2013

#### IN THE SUPREME COURT OF NAMIBIA

In the matter between:

THE MEDICAL ASSOCIATION OF NAMIBIA

First

Appellant

DR R SIEBERHAGEN

Second

**Appellant** 

and

THE MINISTER OF HEALTH AND SOCIAL SERVICES

**First Respondent** 

**MEDICINES REGULATORY AGENCY** 

**Second Respondent** 

THE REGISTRAR OF MEDICINES

**Third Respondent** 

THE ATTORNEY-GENERAL

Fourth

Respondent

Coram:

DAMASEB DCJ, MAINGA JA and O'REGAN AJA

Heard:

15 June 2015

**Delivered: 9 February 2017** 

Summary: The Medicine Related Substances Control Act 13 of 2003 (MRSCA) requires that in order to sell medicine to his or her patients, a doctor must apply for and be granted a license by a Council established under the Act. Before 2008 doctors did not require to be licensed to sell medicine to patients. The MRSCA empowers the Namibia Medicines Regulatory Council (Council) to grant a license if in 'public need and interest' and if the doctor has the 'required competence'. The MRSCA does not spell out the criteria needed for the granting of a license and what is meant by 'required competence'. The doctors challenged the licensing scheme as being unconstitutional, amongst others, for the lack of guidelines to be applied by the Council in considering a license application.

The court upholds the doctors' complaint that the MRSCA's licensing scheme is void for vagueness. The court declares the relevant provisions of the MRSCA creating the licensing scheme unconstitutional. The court, however, rejects the doctors' proposition that they have a constitutional right to sell medicine to patients without a license. The court is satisfied that there is a legitimate governmental purpose in regulating the sale of medicine by doctors to patients in order to prevent oversubscription or unnecessary subscription of medicine to maximise profit without regard to the actual needs of the patients.

Being substantially successful, the doctors are granted costs.

#### **APPEAL JUDGMENT**

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DAMASEB DCJ (MAINGA JA and O'REGAN AJA concurring):

## **Introduction**

This appeal concerns Namibian medical practitioners' claim to a constitutional right to sell medicine to their patients. The doctors are aggrieved because the current legal framework (Medicines and Related Substances Control Act 13 of 2003 (MRSCA)) which came into force on 25 July 2008, requires medical practitioners to first obtain a licence before they can sell medicine to their patients. The medical

practitioners' grievance stems from the fact that although since 1965 they were allowed by law (Medicines and Related Substances Control Act 101 of 1965, s 22A) to sell medicine and had always been considered competent and qualified to do so, since 2008 they are expected to apply for a licence to do that which they were able to do without a licence for 43 years.

## **Standing**

- [2] In these proceedings, the medical practitioners are represented by the first appellant, Medical Association of Namibia (MAN) which, it is common cause, represents the interests of medical practitioners. The second appellant is an affected medical practitioner and a member of MAN. He deposed to the main affidavit in support of the relief sought by appellants as applicants. I shall henceforth for shorthand refer to the appellants as 'the doctors'.
- [3] The doctors instituted proceedings in the High Court seeking a declaration of unconstitutionality of the following provisions of the MRSCA:
- (a) 29(7) (b)<sup>1</sup>;
- (b) 29(9) (b)<sup>2</sup>
- (c) 29(13) (b)<sup>3</sup>;
- (d) 29(19) (b)<sup>4</sup>; and

- (a) ...
- (b) a medical practitioner, a dentist, or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence.
- <sup>2</sup> (9) A person, other than the following, may not sell a Schedule 2 substance:
  - (a) . . .
  - (b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence; or
- <sup>3</sup> (13) A person, other than the following, may not sell a Schedule 3 substance:
  - (a) ..
- (b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence.
- <sup>4</sup> (19) A person, other than the following, may not sell a Schedule 4 substance:

<sup>&</sup>lt;sup>1</sup> (7) A person, other than the following, may not sell a Schedule 1 substance:

(e) 31(3).

[4] Section 31(3) states as follows:

'(3) The Council<sup>5</sup> may issue a licence on application in the prescribed form by a medical practitioner, a dentist or a veterinarian, authorising that medical practitioner, dentist or veterinarian to sell Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substances to his or her patients, subject to such conditions as the Council may determine, if the Council is satisfied that granting such a licence is in the public need and interest and that the medical practitioner, the dentist or the veterinarian has the required competence to dispense those scheduled substances. (Emphasis added)

- [5] Those provisions were challenged in the High Court on the grounds that they impermissibly:
  - (a) violate the doctors' and their patients' fundamental right to dignity, contrary to Art 8;
  - (b) violate the doctors' right to practice their chosen profession or to carry on their occupation, trade or business, contrary to Art 21(1)(j);
  - (c) violate the doctors' right to own and or dispose of their property, in breach of Art 16;

(a) ...

<sup>(</sup>b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence.

<sup>&</sup>lt;sup>5</sup> In terms of s 2 of the MRSCA:

<sup>&#</sup>x27;(1) The council known as the Medicines Control Council established by the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), continues to exist under the name Namibia Medicines Regulatory Council; and

<sup>(2)</sup> The Council may exercise the powers conferred, and must perform the functions assigned, to the Council by or under this Act.

- (d) violate Namibia's international law obligations;
- (e) confer unconstrained and absolute discretion on the second respondent in breach of Art 12 (1) (a),

of the Namibian Constitution.

- [6] The present litigation, which I will refer to as 'the doctor's constitutional challenge', is a sequel to a review application instituted by the doctors against the same respondents and resulting in an appeal to this court and reported as *Minister of Health and Social Services v Medical Association* 2012 (2) NR (SC) 566. In that review the doctors challenged the *vires* of the Regulations<sup>6</sup> made by the 1<sup>st</sup> respondent in terms of s 44 of the MRSCA. I will henceforth refer to the latter case as 'the doctors' review challenge'.
- [7] Regulation 34 (a) provided that in considering a medical practitioner's application to sell medicine the second respondent (the Council) 'must', amongst others, have regard to (a) the existence of other health facilities in the vicinity of the premises from where the prospective licensee wants to sell medicine and (b) representations, if any, by other interested persons as to whether or not a license should be granted. Section 1 of the MRSCA defines 'sell' as follows:
  - '.... sell by wholesale or retail, and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale, or

<sup>&</sup>lt;sup>6</sup> Regulation 34 (3) (a), (c), (d) and (e) published in GN 178, GG 4088 of 25 July 2008.

prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to a person, whether for a consideration or otherwise, and "sale" and "sold" have a corresponding meaning.'

[8] The outcome of the doctors' review challenge has a bearing on the constitutional challenge and it is therefore necessary that I briefly set out what was in issue there and the ratio of the Supreme Court's decision.

# The doctor's review challenge

- [9] In terms of s 31(3) of the MRSCA, the grant of a licence to a medical practitioner is conditional on the Council being satisfied that it is 'in the public need and interest' for a license to be granted if the medical practitioner has the 'required competence' to sell the scheduled substances. As previously shown, reg 34 (a) made it an important consideration for the Council, in determining whether or not to grant a license, whether or not another dispensary was in the vicinity.
- [10] As a transitional measure, doctors had three months after the coming into force of the MRSCA to apply for a license to sell. In the doctors' review challenge the High Court found the entire regulations made under the MRSCA null and void for reasons which are not necessary to state for present purposes.
- [11] In addition, the High Court effectively suspended the licensing scheme under the MRSCA until such time as the first respondent had published new regulations, notwithstanding that there was no constitutional challenge to the MRSCA licensing scheme.

- [12] On appeal the Supreme Court did not support the High Court's reasoning, and only found certain parts of the regulations invalid. It is common cause that the government took the view in the review challenge that it was justifiable to protect pharmacists from competition by doctors and that the licensing scheme could be implemented, through reg 34 (a), to achieve that objective. The Supreme Court found, however, that it was *ultra vires* the MRSCA for the regulations to seek to protect pharmacists from competition by doctors.
- [13] It is necessary to comprehensively set out the Supreme Court's reasoning in coming to that conclusion. Strydom AJA put it thus (at 595 para 92):
  - '[90] In my opinion, the words "in the public need and interest", as further amplified by its definition, do not empower the minister to protect pharmacists from competition with medical practitioners.

[91] ...

[92] It seems to me that it is immediately clear that the public need and interest to receive medicine is very much different from the public interest to have access to intoxicating liquor. Where in the first instance a restrictive interpretation was placed on the words 'public interest', the dispensing of medicine does not require such restrictive interpretation. The purpose of the dispensing of medicine is to heal or to bring relief to people who are ill or in pain and in need of treatment for their illnesses. There exists no need to limit access to medicine to pharmacists to the exclusion of medical practitioners, and there is, in my opinion, also no reason why people should not have a free choice whether to obtain their medicine from a medical practitioner or a pharmacy. The general statement by the minister. . . , is, in my opinion, too unspecific and vague to allow for an interpretation which would restrict dispensing of medicine to pharmacists in order to protect them from competition by medical practitioners. Mr Budlender submitted that pharmacists are better qualified to dispense medicine. I accept that that is so, but for that reason they can dispense and compound all medicines contained in the various schedules of the Medicines Act, whereas medical practitioners can only dispense medicine up to the 4<sup>th</sup> Schedule. Nothing was put before the court that they were not well qualified to do what they were permitted to do for the past 40 years or more.

- [93] The meaning of the words 'in the public need and interest' together with its definition, set out in s 1 of the Medicines Act, does not allow for an interpretation whereby a drastic change of policy was introduced by the minister through reg 34(3) (a), (c), (d) and (e). This drastic change is not discernible from the provisions of the Medicines Act and must be set aside.' (Footnotes omitted).
- [14] Therefore, as a matter of principle, the Supreme Court held that the regulations promulgated by the minister were *ultra vires* the empowering statute which did not authorise the minister to limit the selling of medicine to pharmacists or to limit the free choice of patients. The Supreme Court recognised that given the pharmacists' expertise in the field of medicinal products, they were able to sell a wider range of medicines than doctors and *that* gave them an advantage over doctors. It is clear from the court's remarks that regulating the sale of medicine stands on a different footing to, for example, the sale of alcohol which has very minimal benefit to human health.

#### The scheme of the MRSCA

- [15] Section 29 (2) of the MRSCA contains the prohibition that:
  - '... a person may not sell, have in his or her possession or manufacture a medicine or a scheduled substance, except in accordance with the prescribed conditions.'
- [16] The sale of Schedule 1-4 substances is regulated by subsections (7), (9), (13) and (19) of s 29 in the following way:

- (a) a pharmacist may sell Schedule 1-4 substances on a prescription or oral instruction by an authorised prescriber; but
- (b) a medical practitioner may only sell Schedule 1-4 substances if he or she holds a licence issued by the Council.
- [17] A medical practitioner who wants to be licensed by the Council to sell Schedule 1-4 substances must apply in prescribed form. Only the Council may authorise an aspirant dispensing medical practitioner to '(a) acquire; (b) possess; and (c) prescribe, use in respect of, or sell to, his or her patients'.
- [18] When abolishing the permissive legal framework in favour of a licensing regime, the legislature provided a transitional period of three months during which the medical practitioners could continue selling medicine to patients and, if they wanted to continue selling, to apply to the Council for a licence. When an application was refused, a doctor had to stop selling and is liable to criminal sanctions if he or she continues to do so without a license. For those whose applications were refused, and those who applied for the first time under the new law and were refused, the MRSCA creates an appeals procedure (s 34) against refusal of a license. An appeal committee is created by s 34(2) which should convene on an ad hoc basis to determine appeals as and when they arise.
- [19] The Council may grant a licence if it is satisfied that doing so is 'in the public need and interest' and that the medical practitioner has the 'required competence' to dispense' scheduled substances. The MRSCA does not define 'required

competence'. Section 1 however defines 'public need and interest' as 'the health care needs and interests of the greater Namibian community in respect of availability and equitable access to health care services'.

[20] A licence is to be renewed on an annual basis. It may be revoked by the Council if a condition is not met and the Council also has the power to suspend, cancel, alter or vary the license if it is of the opinion that it is in the public interest to do so.

[21] Contravention of a s 29 prohibition or breach of conditions imposed by the Council in respect of a license, is a criminal offence. A person also commits a criminal offence by making false or misleading statements in an application for a license. A conviction attracts a fine of N\$40 000 or a term of imprisonment not exceeding 10 years or both such fine and imprisonment.

## Founding affidavit

[22] The factual anchor for the doctors' constitutional challenge is a survey conducted by the MAN amongst its over 200 members who are all registered medical practitioners. The members attested to affidavits for the purposes of the survey. The doctors were requested to furnish reasons why they felt they should be allowed to continue selling medicine in the same way it was possible for them to do before the MRSCA. Based on those affidavits, Dr J A Coetzee analysed the data obtained from the doctors.

- [23] The second appellant, Dr R. Sieberhagen, filed the main affidavit in which he alleges, based on the survey and the analysis of Dr Coetzee, that the following problems were experienced since the MRSCA came into force:
  - a) The continual refusal of a license on the basis that there is a pharmacy in the vicinity implies that the Council proceeds from the premise that pharmacists are better qualified than doctors to sell medicine;
  - b) Doctors experience delays in decisions being taken on their license applications: it may take up to three years before a decision is made and that renders the annual renewal irrelevant;
  - c) There is uncertainty as to what 'required competence' entails;
  - d) The requirement for licensing has the effect that *pro Deo* treatment that can only be provided by medical practitioners is not possible if a license is refused and that results in a failure to bring services closer to remote places such as farms and mines;
  - e) The decision to grant or refuse the license is not based on experience and qualification but more on whether there is already a pharmaceutical service in the area;

- f) There is no indication whether the Appeal Committee envisaged under s 34 of the MRSCA has been established to hear all grievances arising from the refusal of licenses, which leads to even more delays.
- g) The appeal procedure is not feasible due to the logistics involved such as getting a suitable date for the hearing of an appeal and hearing all the witnesses that may be called. Accordingly, one appeal may take three days which means that the members of the Committee would have to devote a considerable number of days to deal with all the appeals.
- [24] Based on Dr Coetzee's analysis, the doctors rely, amongst others, on the following common denominators in the responses provided in the survey:
  - (a) There will be no medicine available after hours from neither a doctor nor a pharmacist in the towns where they practice, should they be refused licenses.
  - (b) Only 1 out of 108 doctors does not sell medicine as part of their medical practice, which demonstrates that selling medicine had become an integral part of a doctor's medical practice.
  - (c) Doctors doing occupational health examinations in remote areas provide medicine.

- (d) Dispensing doctors take their medicine to peripheral clinics such as to sea-going patients.
- (e) Pharmacists cannot or do not want to offer after hours services.
- (f) Dispensing improves the doctors' knowledge of medicine.
- (g) Management of chronic medication is done much better by doctors than by pharmacists.
- (h) A single medicine outlet in towns with one pharmacy is undesirable because of limited stock.
- (i) Dispensing doctors provide free marker competition in the medicine trade.
- (j) Certain specialised medicines are not available at pharmacies and are provided by dispensing doctors.
- (k) Patients prefer a one-stop service, meaning that patients prefer to have their consultation and medicine at the same outlet. It is also more practical for the patient because it eliminates extra transport and reduces the time out of work for certain categories of workers.

- (I) HIV positive patients are sensitive about confidentiality and prefer to receive their medication from their doctor. This is of fundamental importance as Namibia has approximately 100 000 people living with HIV.
- (m) By offering cheaper treatment packages doctors meet the needs of the poorer people countrywide.
- (n) The effect the refusal of a license to dispense medicine may have on medicines being available after hours, is demonstrated by the fact that at the present moment at least three towns, namely Walvis Bay, Swakopmund and Gobabis are without after hours medicine outlets.
- [25] Apart from the factors identified by the doctors as being in the public interest for the practice of allowing a doctor to sell medicine to patients alongside the diagnoses and prescribing for treatment, the doctors' responses to the survey also brought to light that since the MRSCA licensing scheme came into force, only 3 out of 108 doctors who applied were granted licenses by the Council
- [26] According to the doctors, what was before the MRSCA a perfectly legal activity had, in its wake, become criminal conduct. They maintain that the metamorphosis from a legal to an illegal activity is a diminution in their dignity.<sup>7</sup> According to the doctors, their right to dignity has been violated because they are

(2) (a) In any judicial proceeding or in other proceedings before any organ of the State, and during the enforcement of a penalty, respect for human dignity shall be guaranteed.

<sup>&</sup>lt;sup>7</sup> Art 8 of the Constitution states: Respect for Human Dignity

<sup>(1)</sup> The dignity of all persons shall be inviolable.

<sup>(</sup>b) No persons shall be subject to torture or to cruel, inhuman or degrading treatment or punishment.

now dependent for the pursuit of their chosen profession on how an administrative body, the Council, understands 'public need and interest' and 'required competence'.

[27] Another contention is that the legislature had impermissibly abdicated its legislative function by bestowing on the Council unguided discretion to the extent that the Council now enjoys plenary power in its determination of their licence applications. The reasoning underpinning this ground is that the Council had effectively been turned into a forum to determine their civil rights whilst it is not a 'tribunal' as envisaged in Art 12 (1) (a) of the Constitution which states that:

'In the determination of their civil rights and obligations . . ., all persons shall be entitled to a fair and public hearing by an independent, impartial and competent Court or Tribunal established by law . . . .'

- [28] It was demonstrated by the doctors in the founding papers that obtaining a license to sell scheduled medicine to patients is the exception rather than the rule. That means we have a situation (as will soon become apparent from the respondent's case as shown in paras 30-42 below) where a licence is denied, not because of some improper or unethical conduct of which the doctor is guilty, but because the Council proceeds from the premise that the applicant doctor is (a) likely to engage in irrational dispensing to maximise profit, (b) doctors are generating enormous profit from selling medicine, (c) medicine prices in the private sector are high.
- [29] The doctors also allege that by requiring them to apply for a licence which is subject to approval when in the past they did not require to be licenced, the licencing scheme violated two of their constitutionally guaranteed rights, to *wit*:

- (a) Art 16: the right to acquire, own and dispose of property. The argument being that upon losing the right to dispense under the MRSCA they are bereft of their goodwill and their medicine stock rendered valueless; and
- (b) Art 21(1)(j): the right to practice any profession, or carry on any occupation, trade or business.

# Government's Answering affidavit

- [30] The Acting Minister of Health and Social Services, the Hon. Rosalia Nghidinwa (the acting minister), deposed to the opposing affidavit on behalf of the respondents.
- [31] According to the acting minister, what prompted the Ministry of Health and Social Services (the Ministry) to embark on a legislative reform process were problems not unique to Namibia: the high cost of medicine; widespread and irrational prescription, and abuse of medicine. Bad dispensing practices compromise the health of patients and constitute a denial of quality health care to the public.
- [32] According to the acting minister, the Ministry realised that laws regulating dealing in drugs needed a revision to address the problems listed above. That led to the creation of a Drug Policy Committee to craft a National Drug Policy (NDP) for Namibia which was published in 1998. To guide the law reform process it was felt necessary to define long term goals and strategies in a comprehensive policy. The NDP was to serve as a guide to (a) legislative reform on drug procurement and

distribution; (b) the appropriate use of drugs by health workers and consumers; (c) human resources development, and (d) drug pricing.

- [33] The areas identified as deserving special attention were:
  - (a) Inequitable access to pharmaceutical services;
  - (b) A lack of qualified human resources in the public sector; and
  - (c) Pricing policies.
- [34] The NDP records that private medical practitioners who dispense and sell medicines may be tempted to prescribe inappropriately to increase their income while information on pricing is not readily available to the public.
- The stated aim of the policy is to avail pharmaceutical services that meet the needs of the public 'in the prevention, diagnosis and treatment of diseases, using efficacious, high quality, safe and cost effective products'. The guiding principles, amongst others, are availability, equitable access, affordable prices and 'to promote the rational use of drugs through sound prescribing, good dispensing practices and appropriate usage'.
- [36] It is also proposed that medical practitioners and nurses 'in private practice with proven competency in dispensing medicines' may be issued with a license by a

licensing authority to dispense medicine '*in the absence of adequate pharmaceutical* services' and that 'the licenses be reviewed annually'.

[37] The NDP also states that the Government will endeavour to maximise coordination between different sectors in the transportation and distribution of essential drugs, particularly to less accessible areas of the country. The NDP also speaks to 'Rational Drug Use' and proposes the enactment of 'strict guidelines' on the authorisation of prescribers and dispensers.

[38] The NDP also proposes that wholesale and retail percentage mark-up systems be replaced with pricing systems based on fixed professional fees at retail and wholesale to achieve reasonable prices and transparency.

[39] In her answering affidavit, the acting minister makes common cause with the NDP objectives and emphasised that, for 'ethical considerations', the MRSCA separates the functions of prescription and selling. That division of duties, it is said removes the possibility of medicine being prescribed and dispensed by a medical practitioner for monetary gain at the expense of the health of the patient. She maintains that the licensing scheme will enable medical practitioners to perform functions that fall within their competency 'in the public need and interest'.

[40] Extrapolating from the revenue figures provided by the doctors in their affidavits, the acting minister states that there is a worrying imbalance between some doctors' trade in medicine and their clinical practices. Such that the turnover generated by about 112 doctors only from the medicine trade is 'a staggering' N\$140

769 190: two medical practitioners deriving as much as 80% of their income from dispensing alone and 28 out of 112 doctors making between 50% to 80% of revenue from dispensing alone.

- [41] The acting minister identifies high medicine prices in the private sectors as one of the problems addressed in the NDP. Relying on the statistics from the survey done by MAN amongst its members, the minister asserts that dispensing of medicine has become the core activity of some doctors' practices generating 'staggering' profits. The minister therefore concludes that 'where the revenue received from the sale of medicine is high, the incentive to overprescribe is real'.
- [42] According to the acting minister, the licensing scheme is rational and does not create any material barrier to the practice of medicine. She emphasised that regulation is not a limitation or restriction as contemplated by Art 21(2) of the Constitution.

### Judgment of the High Court

[43] The High Court's judgment is reported as *Medical Association of Namibia Ltd* and another v Minister of Health and Social Services and others 2015 (1) NR (HC) 1. The court a quo found in favour of the government in respect of all the constitutional complaints raised by the doctors. It found, in particular, that, objectively viewed, the impugned licensing scheme did not offend the Constitution as the purpose is to regulate the selling of scheduled substances by requiring that it be done by a licensed medical practitioner. According to the High Court, in the interest of the

greater society, regulation is essential in order to curb the excessive and irrational use of drugs in Namibia.

[44] On the question whether the licensing scheme violates the doctors' right to practice their chosen profession, the court *a quo* held that Art 21(1)(j) does not confer a right to practice a profession free from regulation as was recognised by this court in *Trustco Ltd t/a Legal Shield Namibia and another v Deeds Registries Regulation Board and others* 2011 (2) NR 726 (SC) at 735 paras 25-28 (*Deeds Registries*). The court *a quo* held that the government's reasons for enacting the licensing scheme are rational and that the licensing scheme does not constitute a material barrier to the practice of medicine. The court *a quo* took the view that the legislative reform brought about by the MRSCA is an indication that the state was acting in the interest of the greater majority by reconciling and balancing conflicting interests in a reasonable, just and fair manner. The court extended the same reasoning to the allegation that s 31 violated the applicant's right to own property.

## The grounds of appeal

- [45] The main ground of appeal is that the High Court erred on the law and the facts in failing to distinguish between 'limitation' and 'regulation', in respect of each and every constitutional attack launched by the doctors on the impugned provisions of the MRSCA. The complaint is that the licensing scheme impermissibly 'limits' the doctors' constitutionally guaranteed rights.
- [46] I am satisfied that the doctors' complaint of a violation of their right to practice their profession, or to carry on any occupation, trade or business; and the complaint

that the impugned provisions confer too broad a discretionary power to the Council without clearly discernible constraints, are dispositive of the appeal. For that reason, I will confine the discussion hereafter to those issues.

Principal submissions of the parties on appeal

The doctors

[47] Mr Heathcote, assisted by Ms Schneider, appeared on behalf of the doctors in the appeal. Counsel pointed out that the court *a quo* erred in finding that the licensing scheme is a regulation when, in reality, it is a limitation which had to pass muster under Art 21(2).

[48] Counsel submitted that the MRSCA confers on the Council unguided and arbitrary discretion in conflict with rights entrenched in the Chapter 3 Bill of Rights. According to him, the unconstrained power exercised by the Council in relation to license applications, and the lack of clarity as to what is entailed in the concepts of 'public need and interest' and 'required competence', results in arbitrariness in the administration of the MRSCA's licensing scheme.

#### The respondents

[49] Mr Maleka, SC, assisted by Mr Marcus, represented the respondents on appeal. According to the government, the practice of medicine consists of a clinical and non-clinical part: the former involves examination of patients, diagnosing illnesses and prescribing medicine for treatment. The latter involves selling and dispensing medicines to patients under the doctor's care. Historically, the second part has never been a core function of a doctor's medical practice. But since the right

was extended in 1965, selling medicine by doctors became, as Maleka put it, 'part and parcel of their practice.' Since then doctors had raked in 'enormous' proceeds from selling medicine as demonstrated in the doctors' constitutional challenge.

[50] Mr Maleka contended that for most doctors selling of medicine does not form a core function of their practices as, on the doctors' own version, 83 out of 122 doctors generate less than 50% of professional income from medicine trade. Mr Maleka argued that doctors generate considerable income from non-clinical functions and that would allow them to 'comfortably' pursue their professions. According to counsel, profit considerations and free market competition in medicine trade should play a limited and insignificant role in the pursuit of the calling of medical practice, which is to conserve life, to practice with conscience and dignity (with the health of the patient being the first consideration), and not to use medical knowledge contrary to the laws of humanity.

[51] Mr Maleka confirmed that the separation of functions with regard to prescription and selling of medicines is intended to curb the irrational use of drugs and to regulate bad dispensing practices. In that regard, he again confirmed that the licensing of medical practitioners in private practice 'with proven competency in dispensing' is only possible under the MRSCA 'in the absence of adequate medical services'.

[52] Crucially, Mr Maleka pointed out that the rationale behind the legal framework is to curb the irrational use of drugs by prescribers, dispensers and patients; and that both the MRSCA and the NDP achieve that aim through a licensing scheme for

scheduled medicines by delineating the different functions of health professionals and subjecting it to considerations of 'public need and interest' and 'required competence'. The argument goes that the objective of providing safe medication to the public is compromised by the potential for doctors to place profit before the interest of patients through irrational dispensing practices. This, counsel submitted, is an important objective underlying the licensing scheme.

[53] Mr Maleka counters the violation of the right to practice argument by saying that the doctor has the choice to apply and that there is no restriction that permanently precludes a doctor from procuring a license if she elects to do so. Since parliament must be allowed to choose a regulatory model, Mr Maleka argued, even if one were to accept that the patient's interests are better served if doctors are allowed to sell medicines, the court must accord deference to the legislative choice.

[54] Mr Maleka counters the vagueness point by arguing that s 31 (3) of the MRSCA confers a discretionary power which requires an assessment of specific set of circumstances of each medical practitioner, subject to Art 18 of the Constitution.

[55] It is the government's case that the licensing scheme does not violate Art 21(1) (j) as it merely regulates the dispensing and selling of medicine by doctors and that the regulation under the MRSCA is rational; does not constitute a material barrier to the practice of medicine, and is justifiable under Art 21(2) of the constitution. (*Mweb Namibia (Pty) Ltd v Telecom Namibia Ltd and others* 2011 (2) NR 670 (SC) at 685; *Trustco Insurance Limited and others v The Deeds Registries Regulation Board* 2011 (2) NR 726 (SC), para 31).

- [56] On the question whether the MRSCA creates a material barrier to the practice of medicine, counsel submitted that no evidence was presented by the doctors that the licensing scheme prevents medical practitioners from carrying on their medical practices or that it discouraged aspirant doctors from choosing medical practice. According to counsel, not being able to sell medication as of right is not a barrier since medical practitioners can still do that with a license.
- [57] The government counters the doctors' constitutional challenge broadly on the following bases:
  - (a) That the doctors have failed to show that selling medicine is essential to the practice of a medical practitioner.
  - (b) That the doctors have failed to show that without selling medicine a medical practice is unviable.
  - (c) That selling medicine by doctors is an incentive to over-prescribe or to prescribe unnecessarily for profit a practice that is harmful to public health.
  - (d) That drug prices in the private sector are high because of the high percentage mark-up at retail.

#### The issues

[58] The issues that fall for decision in this appeal are therefore as follows:

- (a) Is selling medicine essential to the carrying on of the profession, occupation, trade or business of a medical practitioner? If so;
- (b) Is there a legitimate governmental purpose in limiting the right of (i) a medical practitioner to sell medicine to patients and (ii) for patients to source medicine from either the doctor or a pharmacist? If yes:
- (c) Does the licensing scheme under the MRSCA constitute a limitation on a medical practitioner's right to sell medicine to patients and the patient's right to source medicine from either the medical practitioner or the pharmacist?
- (d) If the licensing scheme is a limitation, does it pass muster under Arts 21(2) and 22?
- [59] Considering that the doctors' review challenge was not concerned with the question whether the licensing regime is unconstitutional, it follows that the constitutionality of the licensing scheme falls for decision in the present case. Needles to add that the Supreme Court was alive in the doctors' review challenge that that case did not concern the constitutionality of the licensing scheme created under the MRSCA. (Doctors' review challenge at 596 para 98).
- [60] I will first set out the applicable law and thereafter proceed to discuss the issues falling for decision.

### The Law

[61] The approach taken when legislation is challenged on the ground that it impermissibly infringes the right to practice a profession, occupation, trade or business, contrary to Art 21(1) (j), was set out by this court in *Deeds Registries*. O'Regan AJA set out the test as follows (at 735, para 27):

'The approach thus has three steps: the first is to determine whether the challenged law constitutes a rational regulation of the right to practise; if it does, then the next question arises which is whether even though it is rational, it is nevertheless so invasive of the right to practise that it constitutes a material barrier to the practice of a profession, trade or business. If it does constitute a material barrier to the practice of a trade or profession, occupation or business, then the government will have to establish that it is nevertheless a form of regulation that falls within the ambit of art 21(2)'.

[62] In *Africa Personnel Services v Government of Namibia* 2009 (2) NR 596 (SC) at paras 65-68 (*APS*), this court explained the approach to be taken in determining whether an impugned law passes muster under Art 21(2) and Art 22. The government bears the *onus* to justify the limitation of a constitutionally protected right or freedom. It must also show that the limitation falls 'clearly and unambiguously within the terms of the permissible constitutional limitations, interpreted objectively and as narrowly as the Constitution's exact words will allow'. The limitation must be an exception, and the restriction on the exercise of the freedom or right must be strictly construed so that it is not abused to confine the freedom's exercise to a scope narrower than what the Constitution permits. The limitation can only be justified on the 'criteria' listed in the sub-article (being 'reasonable' also expressed as rationality; 'necessary' and 'required'.)

[63] Conferment of discretionary power to be exercised by administrative bodies or functionaries is unavoidable in a modern state. However, where the legislature confers a discretionary power, the delegation must not be so broad or vague that the body or functionary is unable to determine the nature and scope of the power conferred. That is so because it may lead to arbitrary exercise of the delegated power. Broad discretionary powers must be accompanied by some restraints on the exercise of the power so that people affected by the exercise of the power will know what is relevant to the exercise of the power and the circumstances in which they may seek relief from adverse decisions. Generally, the constraints must appear from the provisions of the empowering statute as well as its policies and objectives: Affordable Medicines Trust and others v Minister of Health and others 2006 (3) SA 247 (CC) at 267 paras 33-34.

## Is dispensing medicine an essential part of medical practice?

[64] Given the government's stance that dispensing and selling medicine is not essential to the practice of a medical practitioner, the first issue falling for determination is if the doctors have brought selling of medicine within the ambit of Art 21(1) (i). The Concise Oxford English Dictionary defines the word 'profession' as:

'a paid occupation, especially one involving training and a formal qualification.'

[65] In my view, dispensing medicine requires the application of skill, the exercise of diligence, compliance with ethical rules and, above all, acceptance of responsibility for the wellbeing of the recipient of one's service and the consequences flowing from a poor or irresponsible conduct associated with the rendering of the service. Those, in my view, are the essential characteristics of a

profession. Towards that end, it is clear on the record that only persons professionally qualified to undertake the activity may sell medicine.

- [66] The doctors' affidavits amply demonstrate that persons qualified as medical practitioners undergo training that equips them to prescribe medicine and, a fortiori, to provide it to the patient for use. For that reason, in my view, the selling of medicine is no less the proper province of medical practice. After all, the doctors are claiming to do that which they are qualified for and are able to do and have done so for 43 years.
- [67] In an age where, for example, because of stigma attaching to a prevalent disease such as AIDS, patients prefer, for reasons of secrecy, to receive their medication directly from the treating doctor rather than in an exposed setting of a pharmacy, and doctors consider that to be the most effective way of treating their patients, it appears to me unreasonable to suggest that selling medicine is not part of the profession of medical practitioner.
- [68] Contrary to what appears to be government's position, an activity does not only qualify as part of a profession if without it its practice becomes meaningless, but also where it had over a period of time been so widely practised without legal restriction as to be perceived, not only by the profession, but the general public, as a legitimate province of the implicated profession.
- [69] I am not persuaded by the government's premise that because prior to 1965 doctors could not sell medicine that activity could not have become part of a medical

practitioners' profession. The point rather is that the fact that the right was granted in 1965 and continued uninterrupted for 43 years makes it academic to suggest that the profession could not have structured and organised their practices on the basis that the right would continue, barring a rational basis for its removal or limitation.

[70] Within the contours of the law governing it and the supervision of a controlling body, each profession engages in activities which define the parameters of what is its legitimate sphere of operation. The doctors have done so in regard to the selling of medicine and have legitimately come to consider it as constituting part of medical practice which, if it wishes to regulate, the government must do so in compliance with Art 21(1) (*j*) read with Arts 21 (2) and 22 of the Constitution.

# Regulating the right to carry on a profession, trade or business

[71] It is now settled that there is no absolute right to carry on a profession, trade or business. It is recognised that the government may, by law, regulate the exercise of that right. It is also settled in our jurisprudence that our courts will not dictate economic policy and that the legislature is at large as to the form and degree of economic regulation. (*Namibia Insurance Association v Government of the Republic of Namibia* 2001 NR (HC) 1 at 11G-15D; *Mweb* supra at 68). Subject to the rider, of course, that the regulation does not do harm (limit) constitutionally protected rights and, if it does, it can be justified under Arts 21(2) and 22. (*Kauesa* at 185H-I - 186A-I; *APS* at 655.)

[72] I am satisfied that there is a legitimate governmental purpose in regulating the dispensing and sale of medicine because, as recognised in the NDP and conceded

by the doctors, there is a need to control irrational and harmful dispensing practices, in particular to address the danger of service providers dispensing medicine repeatedly in order to maximise profit margins to the potential detriment of the public.

Does the licensing scheme constitute a limitation under Art 21(2)?

[73] It is trite that the courts must allow the legislature to choose a regulatory framework as long as it is one of a range of reasonable alternatives (*Deeds Registries* supra at 736 para 31).

[74] Mr Heathcote attacks the foundational departure point of the court *a quo* that the licensing scheme is a mere regulation of the profession which did not infringe Art 21(1) (j). He maintains that the learned judge *a quo* erred in law and fact in failing to distinguish between 'limitation' and 'regulation' in approaching the constitutional challenge on the various grounds advanced. He quoted the following passages from the learned Indian author Dr Durga Das Basu et al '*Human Rights in Constitutional Law*', 3<sup>rd</sup> Ed (2008) at 373-7:

'A fundamental right may be subjected to both "regulation" and "restriction". There are some constitutions which use both words "regulated" and "restricted". Where only "restricted" is used, the power to regulate is implied to be included on the power to restrict.

The broad distinction between regulation is that while "regulation" simply regulates the manner of exercise of a fundamental right as to its time and place without affecting its content, "restriction" puts a curb or limitation on the ambit of the right. Not only punishment for the exercise of a fundamental right, but also any form of prior restraint, such a licensing, would prima facie, be unconstitutional'.

- '1. When a law is impugned as having imposed a restriction on a fundamental right, what the Court has to examine is the *substance* of the legislation, without being beguiled by the mere appearance of the legislation.
- 2. The legislature cannot disobey the constitutional prohibitions by employing an *indirect* method. The legislative power being subject to the Fundamental Rights, the Legislature cannot indirectly take away or bridge the Fundamental Rights which it cannot do directly.'

#### And that:

'The better view, therefore, is: Where the complaint of infringement of a fundamental right cannot be brushed aside as frivolous or vexatious, and the infringement is established *prima facie*, the Court should call upon the State to discharge its onus of proving that the infringement is justified under the relevant limitation clause.'

- [75] I am in respectful agreement with this approach.
- [76] No doubt, prior to the MRSCA coming into force, the doctors organised their practices on the assumption that they enjoy the right to dispense medicine to their patients. Dispensing doctors acquired stock, employed staff and made investments, in the expectation of continuing their practices in a particular way.
- [77] When the law came into force in 2008 the doctors stood to lose financially unless they obtained the licence in circumstances of uncertainty as demonstrated in the founding papers. They could go to jail if they did not obtain a license to sell medicine. In addition, unless they obtained a license, they were saddled with medicines stock they must throw away and not even dispose of by way of donation given the very wide definition of 'sell' as demonstrated in paragraph 7 above.

[78] In my view, the measure does not involve merely prescribing hours of selling medicine or the frequency with which it can be done. Without a license a doctor can't sell. The present is therefore not the sort of case where the legislature merely sets minimum requirements for the pursuit of a profession. It involves placing restrictions on an activity that had been carried on for a considerable length of time by, in the first place, criminalising its pursuit without a license and, secondly, requiring that a person who had previously not needed it to apply for a license which has a limited duration of one year.

[79] I come to the conclusion that the effect of s 31(3), viewed objectively, limits the doctor's right to sell medicines to patients. To survive, the licensing scheme must pass muster under Arts 21(2) and 22. In view of my conclusion below that the licencing scheme is void for vagueness, I do not find it necessary to decide whether the scheme passes the test of proportionality under Art 21(2).

[80] A very important plank of the doctors' challenge against the licencing scheme is that it has made the Council an 'omnipotent legislature'. It is said that the expressions in 'public need and interest' and 'required competence' permit the Council to disregard the doctors' rights as the vagueness, uncertainty and unintelligibility of that phraseology has the consequence of conferring wide and unfettered exercise of discretion on the Council. It is suggested in that context that those concepts do not provide any objective standard or norm and in that way imposes an unreasonable restriction on the fundamental right to carry on a doctor's profession, occupation, trade or business. For that proposition, Mr Heathcote relied on some comparative jurisprudence which held the concept 'public interest'

unconstitutional for vagueness: From India, *Harackhand Ratachand v Union of India* and others 1970 AIR 1453 and Canada, *S v Morales* 1992 77 CCC (3d) 91 (SCC).

- [81] Focusing on the 'unfettered' discretion conferred on the Council arising from the uncertainty of the concepts of 'public need and interest' and 'required competence', Mr Heathcote drew the court's attention to some South African cases which interpreted the concept 'law of general application' under the South African Constitution.
- [82] Mr Heathcote submitted that the licensing scheme does not, to the extent that it limits the doctor's right to sell medicine to their patients, comply with Art 22(a) of the Constitution which provides that a law providing for a limitation of a fundamental freedom shall be of general application and shall specify the ascertainable extent of such limitation and identify the article or articles of the Constitution on which the authority to enact such limitation is claimed to rest.
- [83] In Janse van Rensberg NO and another v Minister of Trade and Industry NO and another 2000 (11) BCLR 1235 (CC) at 1247C-D, the South African Constitutional Court (Constitutional Court) emphasised that:

'The constitutional obligation of the Legislature to promote, protect and fulfil the rights entrenched in the Bill of rights, entails that, where a wide discretion is conferred upon a functionary, guidance should be provided as to the manner in which those powers are to be exercised'

[84] In Dawood, Shalabi and Thomas v Minister of Home Affairs 2000 (3) SA 936 (CC) at para 47, the Constitutional Court held that:

'If broad discretionary powers contain no express constraints, those who are affected by the exercise of the broad discretionary powers will not know what is relevant to the exercise of those powers or in what circumstances they are entitled to seek relief from an adverse decision.'

[85] It is settled jurisprudence by the Constitutional Court that to pass the test of 'law of general application', a statutory measure conferring discretionary power on administrative officials or bodies must be sufficiently clear, accessible and precise to enable those affected by it to ascertain the extent of their rights and obligations (*Dawood* para 47); it must apply equally to all those similarly situated and must not be arbitrary in its application (*S v Makwanyane* para 156), and it must not simply grant a wide and unconstrained discretion without accompanying guidelines on the proper exercise of the power (*Dawood* para 47).

- [86] That approach commends itself in the interpretation and application of Art 22 (a) of the Namibian Constitution.
- [87] I agree with Mr Heathcote that the licensing scheme of the MRSCA suffers from the defect that it does not provide guidelines, principles and norms for the exercise by the Council of its power to grant or refuse licenses under s 31 (3). (It is noteworthy that the NDP itself recognised the need for 'strict guidelines' to govern the authorisation of prescribers and dispensers). The absence of clear guidelines and standards results in arbitrariness as exemplified in the present case where medical practitioners who are perfectly equally situated are treated differently with no legal basis for such discrimination a proposition not denied by the government. That, counsel for the doctors submitted, is a sufficient basis for declaring the

licensing scheme unconstitutional because the concepts of 'public need and interest' and 'required competence' do not qualify as a 'law of general application' since they are understood, not according to objective criteria, but the Council's subjective opinion. That allows the Council, as Mr Heathcote added not without justification, to continue to apply the policy of protecting pharmacists from competition by doctors but now under the guise of 'public need' and 'interest' and 'required competence'.

[88] I agree that the absence of clear criteria opens the licensing scheme to potential abuse which, in the language of an American Supreme Court case relied on by the doctors (*Yick Wo v Peter Hopkins, Sheriff of the City and County of San Francisco* 118 US 356 (1886) at 373) makes it possible for functionaries in taking decisions affecting others to proceed:

'.... from enmity or prejudice, from partisan zeal or animosity, from favouritism and other improper influences and motives which are easy of concealment and difficult to be detected and exposed, and consequently the injustice capable of being wrought under cover of such unrestricted power ....'

And in the words of Justice Jackson in *Railway Express Agency v New York* 336 US 106 (1949) at 111-13:

'[T]here is no more effective practical guaranty against arbitrary and unreasonable government than to require that the principles of law which officials would impose upon a minority must be imposed generally. Conversely, nothing opens the door to arbitrary action so effectively as to allow those officials to pick and choose only a few to whom they will apply legislation and thus escape the political retribution that might be visited upon them if larger numbers are affected.'

[89] To meet the government's argument that the licensing scheme is capable of being saved from unconstitutionality because the Council must still comply with Art 18 of the Constitution, Mr Heathcote relied on *Dawood* supra at 467B-C where the Constitutional Court rejected a similar argument in the following terms:

'The fact, however, that the exercise of a discretionary power may subsequently be successfully challenged on administrative grounds, for example that it was not reasonable, does not relieve the legislature of its obligation to promote, protect and fulfil the rights entrenched in the Bill of Rights'.

[90] As previously noted this court said in the doctors review challenge (at para 92):

'The purpose of the dispensing of medicine is to heal or to bring relief to people who are ill or in pain and in need of treatment for their illnesses. There exists no need to limit access to medicine to pharmacists to the exclusion of medical practitioners, and there is, in my opinion also no reason why people should not have a free choice whether to obtain their medicine from a medical practitioner or a pharmacy.'

- [91] If that standard were applied, we see no reason why most doctors should not be licensed. Yet, after that judgment, granting of a license is the exception rather than the rule. It is not disputed that of the 108 applications submitted by members of the MAN, only 3 were approved.
- [92] I have trawled the record to find what standards the Council applies in granting or refusing licences, and frankly am unable to find any objectively ascertainable standard. The system appears at best to be opaque and, at worst, arbitrary. What we are confronted with are instances such as:

- a) 4-year delay in a license being granted;
- b) queries on the outcome of license applications going unanswered;
- c) an applicant being asked to justify why he should be licensed.
- [93] The licensing scheme appears to be more about placing hurdles for medical practitioners than it is about affording greater access and availability of medicine to the needy public.
- [94] It bears repeating that the institutional failures associated with the licensing scheme are not denied. It is also not denied that in part the failures of the licensing scheme arise from a lack of clarity about what considerations are applied in the granting or refusal of the doctors' applications for dispensing licenses.
- [95] The doctors have established on balance of probabilities that the Council's interpretation of 'public need and interest' and 'required competence', coupled with the institutional failures inherent in the licensing scheme, have effectively denied those doctors who are able and desiring to do so the right to dispense medicine and that of the patient to source medicine either from their doctor or a pharmacist rights recognised in the doctors' review challenge.

[96] The uncertainty and unpredictability inherent in the licensing scheme demonstrates that it is not carefully designed to achieve the NDP objective of providing 'efficacious, high quality, safe and cost effective pharmaceutical products.'

[97] The legislature appears to have designed a licensing scheme that is inherently so unworkable and impracticable as to result in institutional failure to the prejudice of the very public it professes to serve. For example, what is the legitimate governmental purpose in the one year limit on the validity of the licence issued by Council, if regard is had to delays of up to 3 years for an application to be considered? Laws are, as the Constitution enjoins, for good order and government and in the interest of the people (Art 63(1)).

[98] I also agree with Mr Heathcote that the government made no attempt at all to justify the impugned provisions in terms of Art 22(b). He therefore asked that we strike out the words 'public need and interest' and 'required competence' from s 31 (3) of the MRSCA, including the words 'who holds a license contemplated in section 31(3) subject to the conditions in that license' from s 29(7)(b), 29(9)(b), 29(13)(b) and 29(19) (b). The case has been made out for such relief.

## <u>Disposal</u>

[99] We do not accept the doctors' argument that they should be free to sell scheduled medicines without any regulation. There is a legitimate governmental purpose to regulate dispensing of medicine to prevent irrational dispensing practices and to avail safe and efficacious medicine to as many people as possible at affordable prices. It is not our place to say what those standards should be as long

as they do not seek to perpetuate an illegal policy rejected by this court: of shielding pharmacists from competition and removing the patient's choice to source medicine either from a treating doctor or a pharmacist.

[100] Government's concern about some doctors' dispensing practices constituting up to 80% of their medical practices is not an unreasonable one. Regulation aimed at striking a balance between dispensing and a doctor's clinical practice is, in my view, a legitimate governmental purpose.

[101] On the other hand, there is merit in the doctors' complaint that the MRSCA does not make clear by what standard the discretion given in s 31(3) is to be exercised. That opens the door to potential abuse and arbitrariness which does not pass constitutional muster.

[102] In the light of the conclusion to which I have come, I do not find it necessary to decide if the impugned provisions violate the doctors' right to dignity under Art 10, or amounts to expropriation of property without just compensation, as contemplated by Art 16.

[103] The next question that arises is whether the licensing scheme contained in ss 29 and 31 of the MRSCA may be severed from the Act. The principle of severance is an important one in a constitutional democracy. It is based on a principle of the separation of powers that requires courts to tailor orders of constitutional invalidity as closely as possible. Accordingly, courts should seek where possible to carve out unconstitutional provisions in a statutory or regulatory scheme

so as to enable the remainder of the statute or regulations to continue in operation. Of course, a court may only sever provisions from a statute if, after severance, what remains is workable and consistent both with the Constitution and with the constitutionally legitimate objectives of the legislation. In this case, government did not suggest that severance was inappropriate, and in my view the statutory provisions that regulate the licensing scheme may be severed from the MRSCA without rendering it unworkable or inconsistent with the Constitution or the constitutionally legitimate intentions of Parliament. Accordingly, this is a case where the court should order severance: *Johannesburg City Council v Chesterfield House (Pty) Ltd* 1952 (3) SA 809 (AD) at 822 D-E and *Coetzee v Government of the RSA* 1995 (4) SA 631 (CC) at para 16 -17.

[104] The clear misunderstanding of its role by the Council since the doctors' review challenge judgment, as evidenced by the lack of progress in processing license applications, compels me to refrain from exercising the discretion to suspend the declaration of unconstitutionality in terms of Art 25 (1) (a). All evidence points to the need to strike down the scheme as presently conceived and leave it to Parliament, if it still intends to create a compliant licensing scheme that meets the legitimate governmental purposes demonstrated in this case, to go back to the drawing board guided by this judgment.

#### Costs

[105] Although the doctors have failed to establish that they are entitled to sell medicine without being licenced, they have achieved substantial success in having

the current licensing scheme struck down. They are therefore entitled to their costs, both *a quo* and on appeal.

## <u>Order</u>

[106] In the result, the following order is made:

- 1. The appeal succeeds and the judgment of the High Court set aside and substituted for the following order:
- '1. The words ". . . . who holds a licence contemplated in section 31(3), subject to the conditions of that license" where they appear in s 29(7)(b), 29(9)(b), 29(13)(b), 29(19)(b) and s 31(3) of the Medicines and Related Substances Control Act 13 of 2003 (the Act) are declared to be inconsistent with the Constitution and therefore invalid, and are accordingly severed from those provisions.
  - 2. Section 31(3) of the Act is declared to be of no force and effect.
- 3. The applicants are awarded costs against 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> respondents, jointly and severally, the one paying the other to be absolved; and such costs to include the costs of one instructing and one instructed counsel.'
- 2. Costs of appeal are awarded to the appellants against the  $1^{st}$ ,  $2^{nd}$ ,  $3^{rd}$  and  $4^{th}$  respondents, jointly and severally, the one paying the other to be

absolved; and such costs to include the costs of one instructing and two instructed counsel.

DAMASEB DCJ

MAINGA JA

O'REGAN AJA

APPEARANCES:	
Appellants:	R Heathcote (with him H Schneider)
	Instructed by Francois Erasmus &
	Partners
Respondents:	I V Maleka SC (with him N Marcus)
	Instructed by The Government
	Attorney