CONSTITUTIONAL COURT OF SOUTH AFRICA
2006 (3) SA 247 (CC); 2005 (6) BCLR 529 (CC)

Case CCT 27/04

THE AFFORDABLE MEDICINES TRUST First Applicant

THE NATIONAL CONVENTION ON DISPENSING Second Applicant

DR MPHATA NORMAN MABASA Third Applicant

versus

THE MINISTER OF HEALTH OF THE REPUBLIC OF SOUTH AFRICA First Respondent

THE DIRECTOR-GENERAL OF HEALTH Second Respondent

Heard on : 11 November 2004

Decided on : 11 March 2005

JUDGMENT

NGCOBO J:

Introduction

[1] This is an application for leave to appeal directly to this Court from the judgment and order of the Pretoria High Court dismissing a constitutional challenge to certain aspects of a licensing scheme introduced by the government. In terms of this

scheme, health care providers, such as medical practitioners and dentists, may not dispense medicines unless they have been issued with a licence to dispense medicines by the Director-General of the Department of Health (Director-General). The scheme also regulates the premises from which medicines are dispensed. The challenge was directed at the powers of the Director-General to prescribe conditions upon which licences may be issued, the linking of a licence to dispense medicines to particular premises and the factors to which the Director-General is required to have regard when considering an application for a licence.

Background

[2] The constitutional challenge was brought by the Affordable Medicines Trust, the National Convention on Dispensing and Dr Mabasa, who are first, second and third applicants, respectively. The first applicant has, as one of its objects, the promotion of the "rights" of medical practitioners "to dispense medicines to the general public". The second applicant is a co-ordinating body which was established "to act in the interest, and co-ordinate the activities, of its members." The third applicant is a medical practitioner who was authorised to dispense medicines under the now repealed section 52 of the Health Professions Act. The applicants allege that they act in their own interest, in the interest of, among other persons, medical practitioners "who at present have a right and legitimate expectation to be able to dispense medicines (without obtaining a licence) and to continue to do so", and in the public interest. They allege that they have the right to institute proceedings under

section 38 of the Constitution.

[3] The first and second respondents are the Minister of Health and the Director-General respectively (the respondents), who opposed the application. The other respondents are the Speaker of Parliament, the President, the Health Professions Council of South Africa, the South African Pharmacy Council, the Medicines Control Council of South Africa, the Allied Health Professions Council of South Africa and the South African Nursing Council. They are the third to the ninth respondents respectively, who each has an identifiable interest in the order sought by the applicants. No relief was sought against these respondents and they did not oppose the relief sought by the applicants.

[4] In the High Court the applicants sought an order declaring invalid:

(a) Sub-section 22C(1)(a) of the Medicines and Related Substances Act, 101 of 1965 as amended (the Medicines Act), to the extent that it permits the Director-General to issue licences "on the prescribed conditions"; and

(b) Sub-regulations 18(3)(b), (f), (g), (h) and (i); 18(4); 18(5); 18(6); and regulation 20 of the Regulations made under the Medicines Act and published in Government Gazette 24727 under Government Notice R510 of 10 April 2003 (the Regulations).

Amendment of regulation 18

[5] Regulation 18 has, however, been amended. The Regulations came into operation on 2 May 2003. On 16 October 2003, regulation 18 was amended by Government Notice R1506 published in Government Gazette No 25593 by: (a) deleting paragraph (c) of sub-regulation (3); and (b) inserting new sub-regulation (4). In its preamble, however, Government Notice R1506 provided that the existing sub-regulation (4) becomes sub-regulation (5), and said nothing about the remaining sub-regulations that were affected by the amendment. Thus on 31 October 2003, by Government Notice R1565 published in Government Gazette 25622, a correction notice was issued to correct Government Notice R1506. The effect of the correction was to amend regulation 18 by providing that sub-regulations (4), (5), (6), (7) and (8) became sub-regulations (5), (6), (7), (8) and (9) respectively. The two notices, read together, therefore provide in effect that sub-regulations (4), (5), (6), (7) and (8) now become sub-regulations (5), (6), (7), (8) and (9) respectively.

[6] Now it is plain from these Government Notices that the substance of the regulations has not been amended. All that has changed are the numbers of the sub-regulations. Regulations (4), (5), (6) and (7), which concern us in these proceedings, are now sub-regulations (5), (6), (7) and (8) respectively. Their substance remains the same. These amendments, which had already come into operation when the present proceedings were instituted in the High Court, were neither drawn to our attention nor that of the High Court. The relief sought by the applicants must be amended to reflect

the correct sub-regulation numbers.

[7] The present situation is different from that in the *Satchwell* case. In that case, this Court was concerned with confirmatory proceedings and a major difference between the replaced statutory provisions and regulations and the old ones. In the light of this, this Court held that it could not consider statutory provisions that had not been declared invalid by the High Court, and that the proper course to follow was to approach this Court by way of a direct access.

[8] Here we are not concerned with confirmatory proceedings. In addition, there are no changes to the contents of the provisions. All that has changed are sub-regulation numbers. This is a matter which could have been cured by an appropriate amendment of the Notice of Motion to reflect the correct sub-regulation numbers. It is difficult to see on what conceivable basis it could have been opposed. And I cannot conceive of any prejudice that would have been suffered by the respondents if the Notice of Motion were to have been amended. Even if it had been opposed, it is the kind of amendment which would have been granted, had it been sought. It is a formal amendment.

[9] The principles governing the granting or refusal of an amendment have been set out in a number of cases. There is a useful collection of these cases and the governing principles in *Commercial Union Assurance Co Ltd v Waymark NO*. The

practical rule that emerges from these cases is that amendments will always be allowed unless the amendment is *mala fide* (made in bad faith) or unless the amendment will cause an injustice to the other side which cannot be cured by an appropriate order for costs, or "unless the parties cannot be put back for the purposes of justice in the same position as they were when the pleading which it is sought to amend was filed." These principles apply equally to a Notice of Motion. The question in each case, therefore, is what do the interests of justice demand.

[10] It seems to me therefore that it is in the interests of justice that the relief sought by the applicants be amended so as to reflect the correct sub-regulation numbers. Accordingly, the references to sub-regulations 18(4), (5) and (6) in the relief sought by the applicants will now be references to sub-regulations 18(5), (6) and (7) respectively.

The substance of the impugned provisions

[11] The impugned provisions are part of the legislative framework that brought about the licensing scheme. Subsection 22C(1)(a) of the Medicines Act makes provision for the Director-General to issue licences to health care providers to compound and dispense medicines "on the prescribed conditions". Sub-regulation 18(3) sets out information that must be contained in an application for a licence, while sub-regulation 18(5) sets out factors that the Director-General must have regard to when considering an application for a licence. Sub-regulation 18(6) requires an

applicant for a licence to publish the notice of intention to apply for a licence in a newspaper circulating in the area where the applicant intends to conduct a practice. Regulation 20 provides that a licence is valid for a period of three years and makes provision for its renewal.

The legislative framework

[12] Prior to the introduction of the licensing scheme, the authority of the medical practitioners to dispense or compound medicines was governed by section 52 of the Health Professions Act. Under this statute, all that was required of a medical practitioner who desired to compound or dispense medicines as part of his or her practice, was to inform the Health Professions Council of South Africa, the fifth respondent, of his or her intention to compound or dispense medicines. At the discretion of the fifth respondent, the name of such medical practitioner would then be entered in the register of medical practitioners who were allowed to compound or dispense medicines. Upon registration, a medical practitioner became entitled personally to dispense medicines prescribed by him or her or by any medical practitioner or dentist with whom he or she was in partnership or with whom he or she was "associated as principal or associate or *locum tenens*."

[13] With effect from 2 May 2004, the provisions of section 52 of the Health Professions Act were repealed and replaced by a new section 52. In substance, the new section 52 now requires health care providers, including medical practitioners

and dentists, to compound or dispense medicines "only on the authority and subject to the conditions of a licence granted by the Director-General under the [Medicines Act]." At about the same time, the Medicines Act was amended by the insertion of sections 22C to 22H.

[14] As pointed out earlier, subsection 22C(1)(a) of the Medicines Act makes provision for the Director-General to issue licences to health care providers to compound and dispense medicines "on the prescribed conditions". The issue of a licence is subject, among other requirements, to successful completion of a supplementary course determined by the South African Pharmacy Council, the sixth respondent, after consultation with the Health Professions Council of South Africa, the fifth respondent and the South African Nursing Council, the ninth respondent. In the event of a refusal of a licence, an applicant is entitled to be furnished with reasons for such refusal. Section 22C prohibits any person from compounding or dispensing medicines unless such a person is authorised under "the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1)(a)." Section 22D makes provision for the renewal of a licence.

[15] On 10 April 2003, the Minister published the Regulations which were made under the Medicines Act. Among other things, the Regulations gave effect to the licensing provisions of the Medicines Act and the Health Professions Act. For purposes of these proceedings only regulations 18 and 20 are relevant.

[16] The licensing scheme that is in issue in these proceedings is therefore put in place by subsections 22C(1)(a) and section 22D of the Medicines Act read with section 52 of the Health Professions Act and read further with regulations 18 to 21 of the Regulations. However, the constitutional challenge that concerns us in these proceedings is directed only at subsection 22C(1)(a) of the Medicines Act, and the provisions of regulations 18(3)(b), (f), (g), (h) and (i); 18(5); 18(6); 18(7) and 20.

[17] The respondents allege, and it is not disputed, that the licensing scheme is there to serve a legitimate purpose.

The government purpose

[18] The respondents say that what prompted the licensing scheme are bad dispensing practices by medical practitioners. These practices include allowing lay staff to dispense medicines to patients, dispensing medicines that have expired, dispensing unlabelled or wrongly and inappropriately labelled medicines, storing medicines in inappropriate places and conditions, and repacking medicines for dispensing in inappropriate containers. The respondents allege that these dispensing practices pose a serious health risk to patients in that they increase the risk of unsafe medicines being dispensed.

[19] The respondents say that prior to the licensing scheme, the compounding and

the dispensing of medicines by medical practitioners and other health practitioners, with the exception of pharmacists, were either not adequately regulated or not regulated at all. There were no standards, norms or guidelines to ensure that dispensers of medicines adhered to good dispensing and compounding practices. The old legislative framework did not prohibit practices such as pharmaceutical companies giving incentives to medical practitioners (referred to in the papers before us as "bonussing") nor did they prohibit medical practitioners from selling on samples they received for free from pharmaceutical companies. These practices created a conflict of interest between the dispensing medical practitioners and their patients.

[20] This resulted in inappropriate prescribing and dispensing of medicines, including the supply to patients of medicines that were ineffective due to improper storage conditions, or that had expired, which could adversely affect a patient's health, and the charging of the public for medicines that had been obtained as free samples from suppliers. The respondents say all this conspires to increase the costs of health care to the public and undermines the safety, quality and efficacy of the medicines that are dispensed to patients. They say that bad dispensing practices compromise and place in jeopardy the health of patients and that of the public at large and constitute a denial of access to health care to the public.

[21] According to the respondents, the licensing scheme is directed at addressing these bad dispensing and compounding practices and their consequences. The

underlying objective behind the scheme is to increase access to medicines that are safe for consumption by the public. This is to be achieved, among other things, by ensuring that health care practitioners who dispense and compound medicines are adequately trained in good dispensing practice and maintain high standards in the safe and proper storage, labelling, handling and keeping of medicines. To this end, the respondents say that the sale of medicines, their suitability, the standard of dispensing, the suitability of premises where medicines are kept and the conditions under which they are kept, must be properly regulated.

[22] All this is common cause. The applicants do not dispute the stated government purpose. Nor its legitimacy. Instead, the applicants have sought to challenge the means used by the government to achieve its objective to increase access to medicines that are safe for consumption. They contended that the means used by the government to achieve its objective are either not rationally related to the stated objective or are not authorised by the empowering provisions of the Medicines Act. It will be convenient to deal with these contentions when considering the constitutional challenges.

[23] Suffice it to hold at this stage that on the record, the respondents have demonstrated the existence of a government purpose sought to be achieved by the licensing scheme. That purpose is to increase access to medicines that are safe for consumption. And the legitimacy of this purpose cannot be gainsaid. The finding and

the conclusion of the High Court in this regard cannot be faulted. The applicants did not contend otherwise in this Court.

The constitutional challenge

[24] In this Court, as in the High Court, the applicants challenged, in the first place, the inclusion of the phrase "on the prescribed conditions" in sub-section 22C(1)(a) contending that it is overbroad and therefore vague. They contended that it does not convey to those affected what is relevant to the exercise of that power and gives either the Minister or the Director-General wide, unlimited and un-circumscribed arbitrary legislative powers. They submitted that this is in breach of the principle of legality.

[25] In the second place, the applicants contended that the "coupling" of a licence to compound and dispense medicines to specific premises, which regulation 18 requires, is not authorised by sub-section 22C(1)(a) or section 35 of the Medicines Act. The Minister, therefore, exceeded her powers when making regulation 18 and therefore breached the principle of legality. In the alternative, the applicants contended that the requirement of "coupling" does not fall within the purview of section 22 of the Constitution, which permits only the practice of a profession to be regulated by law. In addition, they contended that coupling violates other rights in the Bill of Rights.

[26] In the third place they attacked sub-regulations 18(5), (6) and (7) on a number of grounds but principally on the ground that their provisions are vague in that they

require the Director-General to make decisions based on facts that are not objectively ascertainable. In addition, they contended that the provisions of sub-regulation 18(3) read with sub-regulation 18(5) create a framework for refusing a licence where there is a pharmacy in the vicinity of the premises from which an applicant for a licence intends dispensing medicines. This too, infringes the principle of legality, they argued.

The High Court decision

[27] The High Court found that the licensing scheme was introduced by the government in order to achieve its objective to increase access to medicines that are safe for consumption. This is a legitimate purpose to pursue. It held that the Minister did not exceed her powers when making regulation 18 which linked the licence to compound and dispense medicines to specific premises. The Minister did not therefore breach the principle of legality. The High Court also found that there is nothing arbitrary or capricious in any of the impugned provisions of regulation 18.

[28] It also held that the licensing scheme does no more than regulate the practice of dispensing medicines within permissible constitutional limits. The scheme does not infringe the right of medical practitioners to choose to practise as medical practitioners or to choose to dispense medicines as part of their practice. It does not therefore infringe section 22 of the Constitution. Nor does it infringe any of the other constitutional rights asserted by the applicants. It accordingly dismissed the

constitutional challenge and ordered the applicants to pay costs.

[29] It is against this decision that the applicants are seeking leave to appeal. I shall now deal with these constitutional challenges in turn.

Is it impermissible for the legislature to leave it to the Minister or the Director-General to prescribe the conditions upon which a licence may be issued?

[30] Sub-section 22C(1)(a) provides:

> "Subject to the provisions of this section —
> (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions."

[31] The applicants contended that the phrase "on the prescribed conditions" in sub-section 22C(1)(a) is arbitrary, capricious, overbroad and vague. They submitted that the legislature should have spelt out the precise conditions upon which the Director-General may issue a dispensing licence. Otherwise, the Director-General is left with un-circumscribed arbitrary powers, the applicants argued. In essence this challenge raises the question of whether it is permissible for Parliament to leave it to the Director-General to prescribe the conditions upon which a licence may be issued.

[32] The "prescribed conditions" referred to in sub-section 22C(1)(a) are not set out

in the Medicines Act. What the section in effect does is to leave it to the Director-General to determine what those prescribed conditions shall be. There is nothing in the Constitution which prevents Parliament from delegating subordinate regulatory authority to other bodies. In *Executive Council, Western Cape Legislature, and Others v President of the Republic of South Africa and Others*, Chaskalson P said:

> "The legislative authority vested in Parliament under s37 of the Constitution is expressed in wide terms – 'to make laws for the Republic in accordance with this Constitution'. In a modern State detailed provisions are often required for the purpose of implementing and regulating laws and Parliament cannot be expected to deal with all such matters itself. There is nothing in the Constitution which prohibits Parliament from delegating subordinate regulatory authority to other bodies. The power to do so is necessary for effective law-making. It is implicit in the power to make laws for the country and I have no doubt that under our Constitution Parliament can pass legislation delegating such legislative functions to other bodies. There is, however, a difference between delegating authority to make subordinate legislation within the framework of a statute under which the delegation is made, and assigning plenary legislative power to another body, including, as s16A does, the power to amend the Act under which the assignment is made." (footnote omitted)

[33] Nor is there anything that prevents Parliament from conferring upon the Director-General the discretion to determine those conditions. Discretion has an important role to play in decision making. And its scope may vary. In *Dawood*, this Court held:

> "Discretion plays a crucial role in any legal system. It permits abstract and general rules to be applied to specific and particular circumstances in a fair manner. The scope of discretionary powers may vary. At times they will be broad, particularly where the factors relevant to a decision are so numerous and varied that it is inappropriate or impossible for the Legislature to identify them in advance. Discretionary powers may also be broadly formulated where the factors relevant to

> the exercise of the discretionary power are indisputably clear. A further situation may arise where the decision-maker is possessed of expertise relevant to the decisions to be made." (footnote omitted)

[34] However, the delegation must not be so broad or vague that the authority to whom the power is delegated is unable to determine the nature and the scope of the powers conferred. For this may well lead to the arbitrary exercise of the delegated power. Where broad discretionary powers are conferred, there must be some constraints on the exercise of such power so that those who are affected by the exercise of the broad discretionary powers will know what is relevant to the exercise of those powers or in what circumstances they are entitled to seek relief from an adverse decision. These constraints will generally appear from the provisions of the empowering statute as well as the policies and objectives of the empowering statute.

[35] It is true, as counsel for the applicants submitted, sub-section 22C(1)(a) confers wide discretion on the Director-General. But this does not mean that the Director-General has uncontrolled and unlimited discretion to impose whatever conditions he or she likes. The exercise of discretion by the Director-General is subject to certain constraints, apart from the constitutional constraints. In the exercise of his or her discretion, the Director-General must have regard to all relevant considerations and disregard improper considerations. The conditions that he or she is permitted to impose are those that are rationally related to the purpose for which his or her discretionary powers were given.

[36] The question whether there are any constraints on the exercise of discretionary powers is essentially a matter of construction of the empowering statute. In this regard it is important to remember that sub-section 22C(1)(a), consistent with our jurisprudence, ought to be construed in a manner that is consistent with our Constitution, including the doctrine of vagueness, if possible. And credit ought to be given to the Director-General who has to administer this provision that he or she will do so in accordance with the law and the Constitution. Were the Director-General to issue a licence on conditions in conflict with the powers conferred upon him or her, the decision could be set aside.

[37] The fundamental flaw in the applicants attack on sub-section 22C(1)(a) is that it does not take sufficient account of these matters.

[38] The answer to the attack on sub-section 22C(1)(a) is that counsel for the applicants is giving too wide an interpretation on the sub-section. The power of the Director-General to prescribe conditions under sub-section is limited by the context in which these powers are to be exercised. Thus the power to prescribe conditions, must be exercised in the light of, amongst other considerations, the government purpose to increase access to medicines that are safe for consumption, the purpose for which the discretionary powers are given, and the obligations of medical practitioners who have been issued with dispensing licenses. All this provides sufficient constraint on the exercise of the discretionary powers conferred by the sub-section.

[39] Thus in determining what conditions to prescribe, the Director-General will be guided by the provisions of the Medicines Act read in the light of its objectives and policies. In particular, the Director-General will be guided by the government purpose behind the licensing scheme, namely, the need to increase the access to medicines that are safe for consumption. In addition, the Director-General will be guided by the relevant provisions of the Regulations such as those that set out the obligations of the persons who have been issued with licences.

[40] Sub-regulation 18(8) is particularly relevant in this context. It sets out the obligations of persons who have been issued with licences. It indicates the kind of conditions that the Director-General may impose. These relate to the keeping of the records relating to medicines compounded and dispensed; ensuring that the dispensary and any premises where medicines are kept, are suitable for dispensing or compounding and that dispensing is in accordance with good dispensing practice; keeping medicines under the required conditions and the keeping of the premises where medicines are compounded and dispensed. This statutory framework provides sufficient guidance to the Director-General as to the kind of conditions that may be prescribed under the powers conferred by sub-section 22C(1)(a) of the Medicines Act. It follows therefore that the challenge directed at the phrase "on the prescribed conditions" must fail.

Did the Minister exceed her powers in requiring a licence to be linked to premises?

[41] At the outset it must be pointed out that the licencing scheme in itself is not under challenge. The primary challenge is directed at what was described as "the coupling of the licence to dispense medicines to specific premises." As counsel for the applicants put it in the course of oral argument, "we are here because of coupling". By coupling, the applicants refer to the requirement that a dispensing licence be issued in respect of specific or particular premises which requirement, they contended, is introduced by the provisions of regulation 18. They contended, in the first place, that neither sub-section 22C(1)(a) nor section 35 of the Medicines Act requires that a licence be linked to particular premises and that therefore the Minister exceeded her powers in developing a policy of linking licences to dispense medicines to particular premises in the regulations and thus breached the principle of legality.

[42] The fundamental flaw in the applicants' attack on the linking of a licence to particular premises is the assumption that a medical practitioner who practises as a *locum tenens* will not be able to get a licence to dispense because such medical practitioners do not have premises of their own from which they practise. A *locum tenens* will be denied a licence, the applicants argued, because regulation 18 precludes the Director-General from issuing a licence to a health-care provider who has no particular premises from which to dispense medicines. In particular, they relied upon sub-regulation 18(3)(b) which requires an applicant for a licence to provide information relating to "the exact location of the premises where compounding and/or

dispensing will be carried out"; sub-regulation 18(8) which deals with the keeping of premises from which medicines are dispensed; and the fact that licences issued thus far specify the premises from which medicines may be dispensed. Confronted by a licence that was issued to Dr Ahmed who practises as a *locum tenens*, the applicants were constrained to submit that such a licence had been unlawfully issued by the Director-General.

[43] The applicants made much of the fact that unlike the previous legislative scheme, neither the Medicines Act nor the regulations make reference to a *locum tenens.* That is true. The absence of a reference to *locum tenens* in the new scheme does not mean that a *locum tenens* is excluded from obtaining a licence to dispense medicines as the applicants contended. This is a matter of construction.

[44] Regulation 18 does not expressly require the licence to dispense medicines to be linked to specific premises. However, the regulation contemplates that health-care providers who wish to dispense medicines will do so from some premises. Such premises will either be the premises that a medical practitioner occupies and practises from or premises of another medical practitioner with whom the medical practitioner is associated as an assistant or *locum tenens*. It is these premises that must be "suitable for dispensing or compounding and dispensing in accordance with good pharmacy practice". *And it is in this context that the requirement to furnish "the exact location of the premises where compounding and/or dispensing will be carried out",*

must be understood.

[45] Thus a medical practitioner, who wishes to dispense medicines as part of his or her practice, may be issued with a licence reflecting the premises from which he or she conducts his or her practice as the premises from which medicines will be dispensed. In the case of a medical practitioner who practises as an assistant, the licence will reflect the premises of the principal, these being the premises from which such medical practitioner will dispense medicines. Similarly, a *locum tenens* will dispense medicines from the premises of the principal who has been issued with a licence to dispense medicines. But as a *locum tenens* may work for different principals who may not be known in advance, the licence may be issued subject to the condition that he or she may only dispense medicines from premises of principals who have been issued with licences to dispense medicines.

[46] I conclude therefore that there is nothing in regulation 18 which prevents the Director-General from issuing a licence to a *locum tenens* subject to the condition that he or she may only dispense medicines from premises in respect of which a dispensing licence has been issued. Sub-section 22C(1)(a) contemplates that a licence will be issued subject to "prescribed conditions". So does sub-section 52(1)(a) of the Health Professions Act. A *locum tenens* may only dispense medicines from the premises of those medical practitioners who have been issued with licences to dispense medicines from their premises. It is in this context that the *locum tenens*

licence that was issued to Dr Ahmed must be understood.

[47] Regulation 18 can only be said to be linking a licence to particular premises in the sense that: (a) it requires medicines to be dispensed from some premises, and (b) these premises must be suitable for dispensing or compounding medicines in accordance with good pharmacy practice as required by sub-regulation 18(8). Regulation 18 does not preclude the Director-General from issuing a licence to a *locum tenens*. It now remains to consider whether in making regulations that require that a licence to dispense medicine be linked to the premises from which dispensing takes place the Minister exceeded the powers conferred by the Medicines Act.

Is the linking of a licence to specific premises authorised by the Medicines Act?

[48] Our constitutional democracy is founded on, among other values, the "[s]upremacy of the constitution and the rule of law." The very next provision of the Constitution declares that the "Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid". And to give effect to the supremacy of the Constitution, courts "must declare that any law or conduct that is inconsistent with the Constitution is invalid to the extent of its inconsistency". This commitment to the supremacy of the Constitution and the rule of law means that the exercise of all public power is now subject to constitutional control.

[49] The exercise of public power must therefore comply with the Constitution, which is the supreme law, and the doctrine of legality, which is part of that law. The

doctrine of legality, which is an incident of the rule of law, is one of the constitutional controls through which the exercise of public power is regulated by the Constitution. It entails that both the legislature and the executive "are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law." In this sense the Constitution entrenches the principle of legality and provides the foundation for the control of public power.

[50] In exercising the power to make regulations, the Minister had to comply with the Constitution, which is the supreme law, and the empowering provisions of the Medicines Act. If, in making regulations the Minister exceeds the powers conferred by the empowering provisions of the Medicines Act, the Minister acts *ultra vires* (beyond the powers) and in breach of the doctrine of legality. The finding that the Minister acted *ultra vires* is in effect a finding that the Minister acted in a manner that is inconsistent with the Constitution and his or her conduct is invalid. What would have been *ultra vires* under common law by reason of a functionary exceeding his or her powers, is now invalid under the Constitution as an infringement of the principle of legality. The question, therefore, is whether the Minister acted *ultra vires* in making regulations that link a licence to compound and dispense medicines to specific premises. The answer to this question must be sought in the empowering provisions.

[51] The contention by the applicants that regulation 18 was made under sub-section 22C(1)(a) because it refers to that sub-section was rightly rejected by the High Court.

Regulation 18 does no more than remind its reader that a licence to dispense medicines is issued by the Director-General as provided for in sub-section 22C(1)(a). It does not purport to invoke sub-section 22C(1)(a) as the source of the authority to make it. The source of authority to make regulations is section 35 of the Medicines Act.

[52] Section 35 empowers the Minister to make regulations. It confers wide powers on the Minister to make regulations relating to the safety, quality and efficacy of medicines. These powers include the power to: regulate, control, restrict or prohibit the sale or use of any medicine; make regulations with regard to any matter to ensure the safety, quality and efficacy of medicines; regulate conditions under which medicines may be sold; make regulations with regard to any matter which shall or may be prescribed under the Medicines Act; and generally for the efficient carrying out of the objects and purposes of the Medicines Act. These powers are wide enough to include the power to make regulations relating to the storage and keeping of medicines. The applicants conceded that the Minister may make regulations pertaining to the storage and keeping of medicines, and that she may regulate the premises from which medicines are dispensed.

[53] In addition, sub-section 22C(1)(a) contemplates that a licence will be issued subject to "prescribed conditions". So does sub-section 52(1)(a) of the Health Professions Act. These provisions confer on the Director-General the power to

prescribe conditions to which the licence to dispense medicines will be subject. Such conditions, however, must be in the furtherance of the policies and objectives of the Medicines Act, namely, to increase access to medicines that are safe for consumption. If the public is to have access to medicines that are safe, the activity of dispensing medicines cannot reasonably be delinked from the premises from which such dispensing takes place.

[54] The control and regulation of persons who may dispense medicines and the premises from which medicines may be dispensed are essential to the promotion of access to medicines that are safe for consumption by the public. Such control and regulation ensures that persons who dispense medicines are properly trained in good dispensing practice and that the premises from which dispensing takes place are suitable for storage and thus the dispensing of safe medicines. Dispensing from specific premises that are regulated facilitates the inspection of the premises in order to ensure that good dispensing practice is observed. The storage of medicines and the appropriateness of the premises from which medicines are dispensed are aspects of dispensing medicines.

[55] For all these reasons, the contention that the Minister exceeded her powers in making regulations that link a licence to dispense medicines to particular premises, cannot be sustained. The finding of the High Court in this regard must, therefore, be upheld. But the applicants had another string to their bow. They contended that if the

scheme of the Medicines Act authorises the linking of the issuing of a licence to dispense medicines to specific premises, it falls outside the purview of regulation permitted by section 22 of the Constitution.

Does the linking of a licence to dispense medicine to particular premises infringe section 22 of the Constitution?

[56] The applicants contended in effect that the linking of a licence to dispense medicines to particular premises falls outside the purview of section 22 of the Constitution. This is so, they argued, because it limits the choice of a profession and does not limit the practice of a profession as permitted by section 22. It will be convenient to determine first the scope of the right comprehended in section 22, and thereafter to consider whether the regulation in issue regulates the choice or the practice of a profession.

(a) The scope of section 22

[57] Section 22 of the Constitution provides :

> "Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law."

[58] In broad terms this section has to be understood as both repudiating past exclusionary practices and affirming the entitlements appropriate for our new open and democratic society. Thus in the light of our history of job reservation, restrictions

on employment imposed by the pass laws and the exclusion of women from many occupations, to mention just a few of the arbitrary laws and practices used to maintain privilege, it is understandable why this aspect of economic activity was singled out for constitutional protection. Yet the significance of the section goes further.

[59] What is at stake is more than one's right to earn a living, important though that is. Freedom to choose a vocation is intrinsic to the nature of a society based on human dignity as contemplated by the Constitution. One's work is part of one's identity and is constitutive of one's dignity. Every individual has a right to take up any activity which he or she believes himself or herself prepared to undertake as a profession and to make that activity the very basis of his or her life. And there is a relationship between work and the human personality as a whole. "It is a relationship that shapes and completes the individual over a lifetime of devoted activity; it is the foundation of a person's existence".

[60] Though economic necessity or cultural barriers may unfortunately limit the capacity of individuals to exercise such choice, legal impediments are not to be countenanced unless clearly justified in terms of the broad public interest. Limitations on the right to freely choose a profession are not to be lightly tolerated. But we live in a modern and industrial world of human interdependence and mutual responsibility. Indeed we are caught in an inescapable network of mutuality. Provided it is in the public interest and not arbitrary or capricious, regulation of vocational activity for the

protection both of the persons involved in it and of the community at large affected by it, is to be both expected and welcomed. These considerations are reflected in the text of section 22.

[61] It is against this background that section 22 must be understood and construed.

[62] The first sentence of section 22 guarantees the right to choose a profession, while the second provides for the regulation of the practice of a profession. It is true that this provision does not expressly guarantee the right to practise the chosen profession. However, the second sentence gives a clue as to the content of the right comprehended in the provision. It indicates that the right guaranteed in the provision also embraces the right to practise the chosen profession. This must be so because the choice of a profession is implicit in the practice of a profession, and the practice of the profession is a manifestation of the choice of a profession. It is inconceivable that the framers of the Constitution would guarantee the right to choose a profession but not the right to practise the chosen profession.

[63] The two sentences in section 22 must therefore be read together as defining the content of the right guaranteed by the provision. There are two components to this right: it is the right to choose a profession and the right to practise the chosen profession. This is implicit, if not explicit from the text of section 22. It refers to the right to choose a trade, occupation or profession in the first sentence and the

regulation of the practice of a trade, occupation or profession in the second sentence. It contemplates that the chosen profession would be practised and protects both the right to choose a profession and the right to practise the chosen profession.

[64] This construction of section 22 accords with the approach of the German Federal Constitutional Court (the German Court) to article 12(1) of the Basic Law, which is almost identical to section 22. Article 12(1) provides:

> "All Germans shall have the right freely to choose their trade, occupation, or profession, their place of work, and their place of training. The practice of trades, occupations, and professions may be regulated by or pursuant to a law."

[65] The leading decision on article 12(1) is the *Pharmacy* case of 1958. In that case the court held that both concepts of *choice* and *practice* "represent a complex unity and, although viewed from different angles, are incorporated into the notion of 'vocation activity'." Noting, among other things, the difficulty of drawing a clear line between choice and practice, and the fact that article 74(19) of the Basic Law authorise the legislature to regulate admission to certain professions, the court found that choice and practice of a profession constituted poles of a continuum. It held that article 12(1) guarantees the unitary right of freedom of occupational activity that embraces both the choice and the practice of a profession.

[66] Construed purposively, therefore, section 22 embraces both the right to choose a profession and the right to practise the chosen profession.

[67] The applicants contended that the regulation in issue here goes to the right to choose a profession. They contended that dispensing medicines is a core function of medical practitioners. In this regard, we were referred to the history of the medical profession dating as far back as 1823. This history, it was submitted, shows that dispensing medicine was an inherent part of the practice of medical practitioners. The regulation at issue here, it was submitted, therefore goes to the choice of the medical profession. It goes beyond what is permissible under section 22. It will be convenient therefore to deal first with the applicants' contention that the regulation in issue here goes to the choice of a profession.

Does the linking limit the choice of a profession?

[68] The question is whether the requirement to dispense medicines from licensed premises limits the right to choose a profession. Where the law that regulates the practise of a profession, viewed objectively, would affect negatively the choice of a profession, that regulation limits the right to choose a profession. To that extent such regulation does not fall within the permissible regulation of the practice of a profession permitted by section 22. It must therefore be evaluated under section 36(1) of the Constitution. However, if the law that regulates the practice of a profession, when viewed objectively, would not affect negatively the choice of a profession, such regulation must be evaluated under section 22. In each case, therefore, the question is whether the law which purports to regulate the practice of a profession, viewed

objectively, would impact negatively on the choice of a profession. In the view I take of the regulation involved in this case, it is not necessary to determine the precise degree of impact on choice that will constitute a limitation of section 22.

[69] The requirement to dispense medicines from licensed premises affects the conduct of the medical profession. It regulates the conduct of medical practitioners who are qualified to practise as such, in particular, those who wish to compound and dispense medicines as part of their practices. It requires such medical practitioners to undergo supplementary training in, among other things, good dispensing practice, and once they have undergone such training, to dispense medicines in accordance with such good dispensing practices, including keeping suitable premises from which dispensing will take place. Clearly it does not purport to regulate entry into the medical profession, nor affect continuing choice of practitioners as to whether to remain medical practitioners or not. It merely regulates the specific circumstances in which medical practitioners may, if they choose, continue to compound and dispense medicines.

[70] The regulation at issue here deals with how those health care providers who wish to compound and dispense medicines as part of their practices may do so. It assumes that a person is qualified to practise as a medical practitioner. It requires those medical practitioners who would like to compound or dispense medicines as part of their practices, to do so from premises that are suitable for that purpose in

accordance with good dispensing practices, a requirement that is admittedly essential to ensuring the safety of medication that is consumed by the public. Those medical practitioners who do not wish to dispense medicines, as some of them choose not to, need not comply with this requirement.

[71] There is no suggestion that this requirement, viewed objectively, would have the effect of influencing negatively a person's decision whether to become a medical practitioner. Indeed it is difficult to fathom how a person who has chosen to pursue a medical profession and is prepared to undergo some six years of academic training to that end, can ever be deterred from that ambition by the requirement that, if, upon qualification, he or she wishes to dispense medicine as part of his or her practice, he or she would be required, among other things, to dispense medicines from premises that comply with good dispensing practice.

[72] In my view, the regulation at issue here unquestionably regulates the practice of the medical profession. Moreover, it regulates practice in a manner that, viewed objectively, will not affect the choice of a profession in any negative manner. The submission that it goes to choice of the medical profession must therefore be rejected. The question that falls to be determined therefore is whether the regulation at issue meets the standard for permissible regulation of the practice of a profession under section 22. But first, what is that standard?

The standard for determining permissible regulation under section 22

[73] Unlike its predecessor, section 22 contains no express limitation on the power to regulate the practice of a profession. It accords Parliament the general power to enact legislation that regulates the practice of a profession. Under our Constitution, the legislature is vested with legislative authority. Within its province, the legislature has wide powers indeed. However, these powers are subject to constitutional control. The same is true of the exercise of all public power.

[74] The exercise of all legislative power is subject to at least two constitutional constraints. The first is that there must be a rational connection between the legislation and the achievement of a legitimate government purpose. As this Court has observed, the idea of the constitutional state presupposes a system whose operation can be rationally tested. Thus when Parliament enacts legislation that differentiates between groups and individuals, it is required to act in a rational manner. In *New National Party of South Africa v Government of the Republic of South Africa and Others*, the Court held that the rational connection test is the standard for reviewing legislation holding that:

> "The first of the constitutional constraints placed upon Parliament is that there must be a rational relationship between the scheme which it adopts and the achievement of a legitimate governmental purpose. Parliament cannot act capriciously or arbitrarily. The absence of such a rational connection will result in the measure being unconstitutional."

[75] The same is true of the exercise of public power by members of the executive

and other functionaries. The Constitution places "significant constraints upon the exercise of public power through the bill of rights and the founding principle enshrining the rule of law." The exercise of such power must be rationally related to the purpose for which the power was given. As this Court held in the *Pharmaceutical* case:

> "[85] It is a requirement of the rule of law that the exercise of public power by the Executive and other functionaries should not be arbitrary. Decisions must be rationally related to the purpose for which the power was given, otherwise they are in effect arbitrary and inconsistent with this requirement. It follows that in order to pass constitutional scrutiny the exercise of public power by the Executive and other functionaries must, at least, comply with this requirement. If it does not, it falls short of the standards demanded by our Constitution for such action.
>
> [86] The question whether a decision is rationally related to the purpose for which the power was given calls for an objective enquiry. Otherwise a decision that, viewed objectively, is in fact irrational, might pass muster simply because the person who took it mistakenly and in good faith believed it to be rational. Such a conclusion would place form above substance and undermine an important constitutional principle." (footnote omitted)

[76] The other constitutional constraint is the Bill of Rights. Legislation must not infringe any of the fundamental rights enshrined in the Bill of Rights. The rights in the Bill of Rights may, however, be limited by a law of general application. But such a limitation is limited by the limitations contained in section 36(1) of the Constitution or "elsewhere in the Bill [of Rights]." A limitation that does not comply with such limitations, infringes the right in question.

[77] These two constitutional constraints define the scope of the regulation of the practice of a profession which is permitted under section 22. Legislation that regulates practice will pass constitutional muster if (a) it is rationally related to the achievement of a legitimate government purpose; and (b) it does not infringe any of the rights in the Bill of Rights. What the Constitution therefore requires is that the power to regulate the practice of a profession be exercised in an objectively rational manner. As long as the regulation of the practice, viewed objectively, is rationally related to the legitimate government purpose, a court cannot interfere simply because it disagrees with it or considers the legislation to be inappropriate.

[78] In the *Pharmaceutical* case, this Court, in the context of the exercise of all public power by members of the executive and other functionaries, explained the scope of the rationality standard as follows:

> "Rationality in this sense is a minimum threshold requirement applicable to the exercise of all public power by members of the Executive and other functionaries. Action that fails to pass this threshold is inconsistent with the requirements of our Constitution and therefore unlawful. The setting of this standard does not mean that the Courts can or should substitute their opinions as to what is appropriate for the opinions of those in whom the power has been vested. As long as the purpose sought to be achieved by the exercise of public power is within the authority of the functionary, and as long as the functionary's decision, viewed objectively, is rational, a Court cannot interfere with the decision simply because it disagrees with it or considers that the power was exercised inappropriately. A decision that is objectively irrational is likely to be made only rarely but, if this does occur, a Court has the power to intervene and set aside the irrational decision." (footnote omitted)

[79] These comments apply equally to legislation.

[80] The standard for determining whether the regulation of the practice of a profession falls within the purview of section 22 can therefore be formulated as follows: if the regulation of the practice of a profession is rationally related to a legitimate government purpose and does not infringe any of the rights in the Bill of Rights, it will fall within the purview of section 22. Where the regulation of a practice, viewed objectively, is likely to impact negatively on the choice of a profession, such regulation will limit the right freely to choose a profession guaranteed by section 22, and must therefore meet the test under section 36(1). Similarly, where the regulation of practice though falling within the purview of section 22, but limits any of the rights in the Bill of Rights, it must meet the section 36(1) standard.

[81] In *Van Rensburg v South African Post Office Ltd*, a case which concerned section 22, the full bench of the Eastern Cape High Court described the restriction on the right to practise a trade imposed by the provisions of the Post Office Act 44 of 1958 as a "restriction [that] falls within the reasonable regulation of the conduct of the postal service" and therefore which falls within the purview of section 22. It said:

> "By giving the Post Office an exclusive right to practise the trade, occupation or profession of conducting the postal service in South Africa, the Post Office Act restricts the appellant's right *to practise* this trade, occupation or profession. But it does not take away his right to choose it . . . this restriction falls within the reasonable regulation of the conduct of the postal service."

It is not clear from this *dictum* whether the court intended to formulate any test by referring to "reasonable regulation". Elsewhere, the court seems to suggest that restrictions on the practice of a profession must be "necessary or desirable". If the court intended to adopt reasonableness as a standard for reviewing legislation that regulates the practice of a profession, I am, with respect, unable to agree.

[82] In *New National Party*, the Court explained why the rational connection was more appropriate in reviewing legislation than reasonableness, and said:

> "Decisions as to the reasonableness of statutory provisions are ordinarily matters within the exclusive competence of Parliament. This is fundamental to the doctrine of separation of powers and to the role of Courts in a democratic society. Courts do not review provisions of Acts of Parliament on the grounds that they are unreasonable. They will do so only if they are satisfied that the legislation is not rationally connected to a legitimate government purpose. In such circumstances, review is competent because the legislation is arbitrary . . . If the legislation defining the scheme is rational, the Act of Parliament cannot be challenged on the grounds of 'unreasonableness'. Reasonableness will only become relevant if it is established that the scheme, though rational, has the effect of infringing the right of citizens to vote. The question would then arise whether the limitation is justifiable under the provisions of s 36 of the Constitution and it is only as part of this s 36 enquiry that reasonableness becomes relevant. It follows that it is only at that stage of enquiry that the question of reasonableness has to be considered." (footnote omitted)

[83] In *S v Lawrence; S v Negal; S v Solberg*, this Court had to consider, among other issues, the test for determining what constraints upon economic activity and the earning of a livelihood fall outside the purview of section 26(2) of the Interim Constitution, the predecessor of section 22. The Court adopted the rational basis test,

holding that "s 26(2) should be construed as requiring only that there be a rational connection between the legislation and the legislative purpose sanctioned by the section." In adopting this test the Court found that the language of section 26(2) neither required measures to be reasonable nor proportional, both of which were the requirements of section 33 of the Interim Constitution, the predecessor of section 36(1) of the Constitution. It added, "[t]he proportionality analysis which is required to give effect to the criterion of 'reasonableness' in s 33 forms no part of a s 26 analysis."

[84] It is true, the wording of section 26(2) is different to that of section 22. The effect of section 26(2) was that a measure "'designed' to promote the protection or improvement of any of the matters referred to in the subsection, and is a measure justifiable in an open and democratic society based on freedom and equality" did not infringe sub-section 26(1). It is also true that the Court assumed that the correct approach to sub-sections 26(1) and (2) was to read them together as indicating that all constraints upon economic activity and the earning of livelihood which fall outside the purview of sub-section 26(2) were in breach of section 26. These are important differences. However, what is significant is the rationale for the adoption of the rational basis test.

[85] The rationale for the adoption of the rationality test in the *Lawrence* case, appears from the following passage:

> "To maintain the proper balance between the roles of the Legislature and the courts s

> 26(2) should be construed as requiring only that there be a rational connection between the legislation and the legislative purpose sanctioned by the section . . . The rational basis test fits the language of the section which, unlike s 33, sets as the criterion that the measures must be justifiable in an open and democratic society based on freedom and equality, but does not require in addition to this that the measure be reasonable. The proportionality analysis which is required to give effect to the criterion of "reasonableness" in s 33 forms no part of a s 26 analysis." (footnote omitted)

[86] As the *Lawrence* case makes it plain, the Court sought to achieve a proper balance between the role of the legislature on the one hand, and the role of the courts on the other. The rational basis test involves restraint on the part of the Court. It respects the respective roles of the courts and the legislature. In the exercise of its legislative powers, the legislature has the widest possible latitude within the limits of the Constitution. In the exercise of their power to review legislation, courts should strive to preserve to the legislature its rightful role in a democratic society. It is this guiding principle that should inform the test for determining whether legislation that regulates practice but does not, objectively viewed, impact negatively on choice, passes constitutional scrutiny.

[87] It is necessary in this regard to consider the approach of the German Court. As pointed out earlier, article 12(1) of the Basic Law is almost identical to our section 22. Like our section 22 it provides that (a): all Germans have the right freely to choose their profession; and (b) its second sentence provides that the practice of a profession may be regulated by law. And as pointed out earlier, the German Court has construed article 12(1) as comprehending a unitary right of freedom of occupational activity that

embraces both the choice and practice of a profession.

[88] The starting point of the German Court is the recognition of the difficulty of drawing a clear distinction between regulation that affects choice of a profession on the one hand and regulation that affects practice on the other. It held that article 12(1) "grants the legislature the power to make regulations affecting either the choice or the exercise of an occupation." However, the court held that the legislature may not regulate the right to choose a profession to the same degree that it regulates the right to practise a profession. The scope of the regulation is narrower where the regulatory power is directed at the right to choose. Where the regulatory power is directed at the right to practise a profession, the scope of regulation is wide. In this regard the court reasoned thus:

> "For it is clear from the text of Article 12(1) that occupational choice is to remain 'free' while the practice of an occupation may be regulated. This language does not permit an interpretation that assumes an equal degree of legislative control over each of these 'aspects.' The more legislation affects the choice of a profession, the more limited is the regulatory power.
>
> . . . .
>
> The legislature is thus empowered to make regulations affecting either the choice or the practice of a profession. The more a regulatory power is directed to the choice of a profession, the narrower are its limits; the more it is directed to the practice of a profession, the broader are its limits".

[89] The German Court has developed what is called "the gradation theory (Stufentheorie)" as a standard for determining whether regulation of choice or practice is permissible under article 12(1). This theory establishes varying degrees of judicial

review according to the degree of intrusion. It laid down the general principles governing this theory and said:

> "The practice of an occupation may be restricted by reasonable regulations predicated on considerations of the common good. The freedom to choose an occupation, however, may be restricted only for the sake of a compelling public interest; that is, if, after careful deliberation, the legislature determines that a common interest must be protected, then it may impose restrictions in order to protect that interest – but only to the extent that the protection cannot be accomplished by a lesser restriction on freedom of choice. In the event that an encroachment on freedom of occupational choice is unavoidable, lawmakers must always employ the regulative means least restrictive of the basic right."

[90] The German Court made a distinction between a law that regulates practice and one that regulates choice. It held that the practice of an occupation may be limited "by reasonable regulations predicated on considerations of the common good." It added "[l]awmakers are freest when they regulate the practice of an occupation." They may impose limitations on the right to practise a profession in order to prevent danger to the general public. The individual is protected "only against excessively onerous and unreasonable encroachments." By contrast where the regulation infringes on choice of an occupation, "the restrictive measures selected must entail the least possible interference." Implicit in the adoption of reasonableness as the standard for determining whether legislation under challenge falls within the purview of article 12(1), is the requirement of proportionality.

[91] The similarities between section 22 of our Constitution and article 12(1) of the

Basic Law make the German approach somewhat attractive. However, it is our Constitution that is being construed. It must be construed in the light of our constitutional scheme and our jurisprudence. As pointed out earlier, under our jurisprudence, the exercise of legislative and executive power is subject to two constraints, namely, the minimum threshold requirement of rationality and that it must not infringe any of the rights contained in the Bill of Rights. If exercise of power limits any such rights, it must pass the section 36(1) test. And proportionality analysis is central to the section 36(1) enquiry.

[92] Under our constitutional scheme, the proportionality analysis is required to give effect to the criterion of reasonableness in section 36(1). To require reasonableness, and thus the proportionality analysis, in the context of section 22 would be to ignore the language of section 22. It is clear from the text of the provision that choice and practice are not to be regulated to the same extent. Where the regulation, viewed objectively, would have a negative impact on choice, the regulation must be tested under section 36(1). In other cases, the test is one of rationality.

[93] That said, however, the scope of permissible regulation that we adopt here is not entirely inconsistent with the German approach. It recognises that it is not always possible to draw a clear line of distinction between regulation that affects the practice of a profession on the one hand and one that affects choice on the other. It requires

that where, objectively viewed, the regulation of the practice of a profession impacts negatively on choice such regulation must be tested under section 36(1). Such regulation does not fall within the purview of section 22, and must therefore meet, amongst other requirements, the standard of reasonableness, of which proportionality analysis is an important component. The same standard must be met where the regulation of the practice of a profession limits any of the rights in the Bill of Rights. However where, as here, the regulation, objectively viewed, does not impact negatively on choice, it need only satisfy the rationality test. In the result, restrictions on the right to practise a profession are subject to a less stringent test than restrictions on the choice of a profession.

[94] Where, as here, the Constitution gives the power to regulate a right, not every regulation of that right amounts to a limitation of the right in question. But at the same time Parliament may not unconstitutionally limit the right to practise a profession under the guise of regulating it. Where the regulation of the right amounts to a limitation of that right, such a limitation will have to be tested under section 36(1). In this case we are concerned with regulation that merely regulates in the sense of facilitating the proper exercise of the right to practise a profession. It does not limit the right to practise. The applicants did not contend otherwise.

[95] The question that falls to be determined, therefore, is whether the linking of a licence to dispense medicines to particular premises is rationally related to the

government purpose of increasing access to medicines that are safe for consumption. It is to that question that I now turn.

Is the linking of a licence to dispense medicines rationally related to the governmental objective to increase access to medicines that are safe for consumption?

[96] As pointed out earlier, the conditions under which medicines are kept and stored are essential to the safety of medicines. Medicines must be stored under the recommended conditions to ensure their efficacy and safety. The premises where they are kept must therefore be suitable for compounding and dispensing medicines in accordance with good dispensing practice. The requirement that dispensing medical practitioners must dispense medicines from particular premises facilitates regular inspection of those premises for compliance with good dispensing practice. The applicants did not contend otherwise.

[97] The applicants accept that the storage of medicines and the appropriateness of the premises from which medicines are dispensed require regulation and control in the public interest. In its comment on the draft Regulations, the second applicant stated that it "recognises the need for adequate dispensing controls and conditions, and supports the government's goals to ensure that high quality and appropriate medicines are safely distributed from clean and suitably equipped dispensing premises by properly trained dispensers." In addition, in a letter of 2 October 1996, the second applicant stated that it "supports the regular inspection of premises to ensure that

Good Dispensing Practice is maintained." These comments on behalf of the applicants underscore the importance of the need to ensure that medicines are dispensed from premises that are subject to control and regular inspection. Such regular inspection can effectively be conducted if the premises from which medicines are dispensed are known.

[98] In addition, in written argument on behalf of the applicants, it is made clear that:

> "[The applicants] also have no objection to a condition being stipulated that dispensing doctors should be required to comply with a Code of Good Dispensing Practice which would deal with the requirements relating to the premises from which such dispensing takes place. Such Code of Good Dispensing Practice would deal with the requirement, *inter alia*, of keeping and storing medicines, keeping of various statutory registers, the disposal of expired medicines, etc and also with the requirements relating to the premises from which such dispensing takes place. It should be noted that the applicants have always supported the fact that the premises from which dispensing takes place should conform to certain standards and indeed that such premises should be inspected and licensed on a regular basis. This licence, should however be separate from the licence to dispense. The licence to dispense recognises competency while the licence for a dispensary deals with physical and statutory requirements. Such a split would solve the problem of a doctor, or doctors with satellite practices, from having to apply for a licence to dispense for each practice, instead of a licence to dispense which would be issued to the person, and a 'dispensary' licence for each place of dispensing."

[99] But the applicants seem to prefer that two separate licences be issued, one for the dispensing medical practitioner and the other for the premises. "Such a split", they submit, "would solve the problem of a doctor or doctors with satellite practices, from having to apply to have a licence to dispense for each practice". But they are

wrong in assuming that such doctors will have to apply separately for each practice. A medical practitioner with satellite practices will be issued with a single licence reflecting all the premises from which he or she will be dispensing medicines. And whenever a medical practitioner wishes to expand his or her practice to other premises, such medical practitioners will have to apply for the addition of those premises to his or her licence as premises from which medicines will be dispensed as well.

[100] In all the circumstances, I conclude that linking the licence to dispense medicines to particular premises is rationally connected to the government objective to increase access to medicines that are safe for consumption by the public. This kind of regulation falls within the purview of section 22.

[101] The applicants contended further that the linking of a licence to particular premises also infringes the rights to dignity, freedom of movement and property.

The challenge based on the infringement of other constitutional rights

[102] The applicants contended that the requirement to apply for a new licence whenever a medical practitioner is moving to new premises interferes with the freedom of movement. I think that it can be accepted that the right to practise a profession includes the right to decide where one will practise one's profession. This being a right relating to the practice of a profession, it is subject to regulation under

section 22. The requirement of a licence does not take away the right to choose where to practise medicine. But what it does is merely to require that if the practice is to involve compounding and dispensing of medicines, this should be done from premises in respect of which a licence to dispense medicines has been issued. This does not infringe the right to freedom of movement as contemplated in section 21 of the Constitution. Nor does this infringe any property rights of the applicants as contemplated in section 25.

[103] There is nothing in the regulations to suggest that medical practitioners will be prevented from practising their profession from wherever they choose. It is true sub-regulation 18(5)(a) requires the Director-General to have regard, among other factors, to the existence of other health care providers in the vicinity of the premises from where an applicant for a licence intends to dispense medicines. The applicants contended that this provision will be used to refuse licences where there are pharmacies in the area concerned. The respondents disavowed this. According to the respondents the existence of pharmacies in the vicinity and the geographical limits will not be impediments to the granting of a licence. Sub-regulation 18(5)(a) is dealt with more fully below.

[104] Nor does the licensing scheme infringe the right to the dignity of medical practitioners. I cannot conceive of anything that would harm the medical profession if those medical practitioners who wish to dispense medicines as part of their practices

are required to comply with good dispensing practice in order to promote access to medicines that are safe for consumption by the public. If anything, this should enhance their dignity in the eyes of the public that they serve.

[105] The constitutional challenges based on the infringement of the rights to freedom of movement, dignity and property must therefore fail.

Are the impugned provisions of the regulations void for vagueness?

[106] The applicants also directed the challenge based on vagueness at certain provisions of regulation 18(3) and (5), which provide:

> "LICENCE TO DISPENSE OR COMPOUND AND DISPENSE MEDICINES
> (3) The application shall contain at least the following information:
> (a) the name and both residential and business addresses (both physical and postal) of the applicant;
> (b) the exact location of the premises where compounding and/or dispensing will be carried out;
> . . .
> (d) telephone and fax numbers of the applicant, where available;
> (e) proof of registration with the relevant statutory council;
> (f) proof of publication of the notice contemplated in subregulation (6);
> (g) motivation, as to the need for a licence in a particular area;
> (h) any other information that the Director-General may require; and
> (i) proof of ability to supply a patient information leaflet.
> . . .
> (5) In considering an application referred to in subregulation (1), the Director-General shall have regard to the following:
> (a) the existence of other licensed health facilities in the vicinity of the premises from where the compounding and dispensing of medicines is intended to be carried out;
> (b) representations, if any, by other interested persons as to whether a licence should be granted or not;

(c) the geographic area to be served by the applicant;
(d) the estimated number of health care users in the geographic area referred to in paragraph (c);
(e) demographic considerations including disease patterns and health status of the users to be served; and
(f) any other information that he or she deems necessary.
(6) At the same time when an application referred to in subregulation (1) is made, the applicant must also give notice by publication in a newspaper circulating in the area where the applicant intends to conduct his or her practice of his or her intention to apply for a licence.
(7) Any person may support or oppose an application referred to in subregulation (1) by making written representations to the Director-General within 30 days of publication of the notice contemplated in subregulation (6)."

[107] The argument went as follows: The impugned provisions require the Director-General to make a decision based on factors that are not objectively ascertainable. The consequence of this is that the Director-General is authorised to make decisions that are arbitrary because the Director-General is not given guidance as to how to exercise the powers conferred on him or her. The impugned provisions of the regulation are therefore in breach of the principle of legality by reason of vagueness. It was also contended that the provisions of the regulations provide a framework for the refusal of a licence where there are pharmacies in the vicinity. The challenge to regulation 18(3) is related to the challenge to regulation 18(5). It will be convenient to deal first with regulation 18(5).

The challenge to sub- regulation 18(5)

[108] Sub-regulation 18(5) was challenged on the basis that it is vague and does not

conform to the principle of legality. The doctrine of vagueness is one of the principles of common law that was developed by courts to regulate the exercise of public power. As pointed out previously, the exercise of public power is now regulated by the Constitution which is the supreme law. The doctrine of vagueness is founded on the rule of law, which, as pointed out earlier, is a foundational value of our constitutional democracy. It requires that laws must be written in a clear and accessible manner. What is required is reasonable certainty and not perfect lucidity. The doctrine of vagueness does not require absolute certainty of laws. The law must indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate their conduct accordingly. The doctrine of vagueness must recognise the role of government to further legitimate social and economic objectives. And should not be used unduly to impede or prevent the furtherance of such objectives. As the Canadian Supreme Court observed after reviewing the case law of the European Court of Human Rights on the issue:

> "Indeed . . . laws that are framed in general terms may be better suited to the achievement of their objectives, inasmuch as in fields governed by public policy circumstances may vary widely in time and from one case to the other. A very detailed enactment would not provide the required flexibility, and it might furthermore obscure its purposes behind a veil of detailed provisions. The modern state intervenes today in fields where some generality in the enactments is inevitable. The substance of these enactments remains nonetheless intelligible. One must be wary of using the doctrine of vagueness to prevent or impede state action in furtherance of valid social objectives, by requiring the law to achieve a degree of precision to which the subject-matter does not lend itself. A delicate balance must be maintained between societal interests and individual rights. A measure of generality also sometimes allows for greater respect for fundamental rights, since circumstances that would not justify the invalidation of a more precise enactment may be

accommodated through the application of a more general one." (citations omitted)

[109] Where, as here, it is contended that the regulation under consideration is vague for uncertainty, the court must first construe the regulation applying the normal rules of construction including those required by constitutional adjudication. The ultimate question is whether so construed, the regulation indicates with reasonable certainty to those who are bound by it what is required of them.

[110] Does sub-regulation 18(5) convey a reasonably certain meaning to those who are affected by it?

[111] Sub-regulation 18(5) sets out factors to which the Director-General must have regard in considering an application for a licence. The provisions of this sub-regulation require the Director-General in considering an application for a licence, to have regard to, among other factors, the existence of other licensed health facilities in the vicinity of the premises from where the compounding and dispensing of medicines is intended to be carried out, the geographic area to be served by the applying medical practitioner, the estimated number of health care users in the geographic area to be served by the applying medical practitioner and the demographic considerations including the disease patterns and health status of the users to be served. These factors have to be taken into consideration when deciding whether to refuse or issue a licence to dispense medicines. They are formulated in unambiguous terms. There is

no room for any doubt about what those factors are. They tell the Director-General what factors he or she is required to have regard to in deciding an application for a licence to dispense medicines. In these circumstances the provisions of sub-regulation 18(5) cannot be said to be vague.

[112] As I see it, the problem with sub-regulation 18(5) lies elsewhere. The applicants contended that the provisions of sub-regulation were intended to provide a framework for refusing a licence where there are pharmacies in the vicinity of the premises from where an applicant intends to dispense medicines in line with the government's National Drug Policy (NDP). The policy on the licensing of health practitioners and premises is described as follows in the NDP:

> "Only practitioners who are registered with the relevant Council and premises that are registered and/or licensed in terms of the Medicines and Related Substances Control Act (No 101 of 1965) may be used for the manufacture, supply and dispensing of drugs. Medical practitioners and nurses will not be permitted to dispense drugs, except where separate pharmaceutical services are not available. In such instances/ situations where dispensing by doctors and nurses has to take place, such persons will be in possession of a dispensing licence issued by the Medicine Control Council. Criteria for the granting of such licences will include *inter alia*, the application of geographical limits. Special concessions will be granted with regard to certain categories of providers such as occupational health services. Proven competency of such persons to dispense drugs will be by virtue of the successful completion of a suitable training programme. All licences will be reviewed and renewed annually. These inspection functions will be delegated to the provinces." (underlining added)

[113] In response to these allegations, the Director-General who deposes to the affidavits on behalf of the respondents denied the existence of a policy to refuse

licences where there are pharmacies in the neighbourhood. It is allege that the purpose of the provisions of sub-regulation 18(5) is, among other things, to provide the Director-General with some idea as to what particular areas are being serviced by medical practitioners who dispense medicines. This was said to be necessary to "enhance the scope for efficient utilisation of resources . . . [and] allow the government to plan and implement its health programme more effectively". The Director-General has disavowed any intention of using geographical area or proximity to a pharmacy as a basis for refusing a licence, adding that "the geographical area where the medical practitioner intends to dispense medicines from is no impediment to obtaining a licence". However, nothing is said about the NDP or the apparent contradiction between the denial of the existence of policy to deny licences where there is a pharmacy in the neighbourhood and the policy contained in the NDP which suggests that medical practitioners will not be issued with licences where there are pharmacies in the neighbourhood.

[114] The response by the on behalf of the respondents leaves a good deal to be desired. In the first place, the provisions of sub-regulation 18(5) were intended to provide guidance to the Director-General in deciding whether to grant a licence, by providing him or her with factors to which regard must be had. These factors could not have been intended to provide the Director-General with mere information as suggested on behalf of the respondents. Were this to have been the case, these factors would have been elsewhere in the regulations than in a provision that contains factors

that are intended to influence a decision whether or not to grant a licence. Both the language of sub-regulation 18(5) and the context in which it occurs, simply do not admit of such a construction. The purpose of this provision must be determined in the light of its language and the context in which it occurs.

[115] In addition, the applicants have squarely raised the NDP and, in particular, the aspect that provides that medical practitioners will not be issued with a licence to dispense medicines where there are pharmacies in the neighbourhood. The applicants have relied upon this policy to challenge sub-regulation 18(5). Although not said in so many words, there can be no question that the present litigation has a lot to do with the fear that medical practitioners will be denied licences where there are pharmacies in the neighbourhood. What is more, there is a clear contradiction between the policy as stated in the NDP and the allegations made on behalf of the respondents that there is no policy to deny a licence to medical practitioners where there are pharmacies in the neighbourhood.

[116] These matters called for a direct response from the respondents. The Court is now left to speculate on why the respondents neither deny the existence of the NDP nor explain the obvious contradiction between the denial of the existence of the challenged policy and the policy as articulated in the NDP. In my view, this contradiction is inexplicable except on the basis that the deponent to the opposing affidavit on behalf of the respondents was either not entirely candid with the Court or

that the respondents have backed down on their initial policy as stated in the NDP. If the latter is true, it is difficult to understand why this explanation was not given by the respondents. Be that as it may, the matter must be approached on the footing that at all material times, and, in particular, until the opposing affidavits were filed, the respondents had a policy of denying licences to medical practitioners where there are pharmacies in the neighbourhood.

[117] The NDP makes clear that "[m]edical practitioners and nurses will not be permitted to dispense drugs, except where separate pharmaceutical services are not available." For medical practitioners and nurses to dispense medicines "[i]n such instances/situations", they will have to be in possession of dispensing licences. And more importantly, "[c]riteria for the granting of such licences will include *inter alia*, the application of geographical limits." The need to have regard to the existence of other health facilities in the vicinity was intended to give effect to this policy. The geographic and demographic considerations provide criteria for implementing the policy of denying licences to medical practitioners and nurses where there are pharmacies in the vicinity of the premises from which a medical practitioner intends to dispense medicines. It is in the light of this policy that the provisions of sub-regulation 18(5) must be understood and construed.

[118] Properly construed, the manifest purpose of sub-regulation 18(5) is to limit the rights of medical practitioners to dispense medicines where there are pharmacies in

the neighbourhood. This purpose is consistent with the NDP which makes it clear that: (a) medical practitioners will not be issued with licences where there are pharmacies in the neighbourhood; (b) to dispense medicines in such situations, medical practitioners will have to be issued with licences; and (c) criteria for the granting of such licences will include the geographical limits. And such criteria are apparent from the factors which sub-regulation 18(5)(a), (c), (d) and (e) direct the Director-General to have regard to in considering licences, namely, the existence of pharmacies in the neighbourhood, the geographical area to be served by the applying medical practitioner, the estimated number of health care users in the geographical area to be served by the applying medical practitioner and the demographic considerations including the disease patterns and health status of users to be served.

[119] The purpose of sub-regulation 18(5)(a), (c), (d) and (e) is manifestly to protect pharmacies against competition from medical practitioners and nurses. This purpose is not discernable from the Medicines Act. Nothing in the Medicines Act empowers the Minister to develop such a policy through the Regulations. It follows therefore that the provisions of sub-regulation 18(5)(a), (c), (d) and (e) that develop the policy of denying a licence where there are pharmacies in the neighbourhood are *ultra vires* the empowering statute.

[120] There is a further reason why the provisions of sub-regulation 18(5)(a), (c), (d) and (e) are bad. What the respondents are in fact saying is that notwithstanding the

requirement that the Director-General must have regard to these factors in deciding whether to grant a licence, the Director-General may not refuse a licence on the basis of these factors. These factors are not there to assist the Director-General to decide whether to issue or refuse a licence. They have got nothing to do with whether a licence should be issued or not. They are there for a different purpose: to "allow the government to plan and implement its health programmes more effectively."

[121] But there is nothing in sub-regulation 18(5) that tells the public or Director-General that a licence may not be refused on the basis of these factors. On the contrary, the impression created is that they are relevant considerations, hence the pharmacies have been relying on these provisions to raise objections to licences, but without success. As pointed out earlier, laws, including regulations, must be formulated in an accessible manner. They must indicate with reasonable certainty to those who may be affected by the exercise of the power to grant or refuse a licence, what is relevant to the exercise of that power or in what circumstances they may seek relief. From what the respondents now say, the provisions of sub-regulation 18(5)(a), (c), (d) and (e) cannot be said to meet this standard.

[122] In addition, once it is accepted, as it must be, in the light of the denial by the respondents, that the existence of pharmacies in the vicinity and the geographical limits are impediments to obtaining a licence, then the need to have regard to the existence of other health care providers in the vicinity, geographical limits and

demographic considerations, before a licence can be issued falls away. They no longer serve any purpose which explains why objections based on them were simply ignored by the Director-General. Indeed counsel for the respondents was unable to suggest any other reason for the existence of sub-regulation 18(5)(a). None suggests itself. It is a relic of a discarded policy. It should have been discarded likewise. The same goes for sub-regulation 18(5)(c), (d) and (e) which were designed to provide criteria for implementing the discarded policy.

[123] For all these reasons, sub-regulation 18(5)(a), (c), (d) and (e) are *ultra vires* the empowering statute and are accordingly unconstitutional. This conclusion renders it unnecessary to decide whether these provisions, to the extent that they protect pharmacies against competition from medical practitioners, constitute a limitation of section 22 of the Constitution. The appropriate remedy is to strike down these provisions. The provisions of sub-regulation 18(5)(a), (c), (d) and (e) form a discrete cluster that may easily be severed from the rest of the regulations without destroying the licensing scheme. What is left behind passes constitutional muster.

[124] Different considerations apply to the provisions of sub-paragraph (b) and (f) of sub-regulation 18(5). They have broad application. They must be read together as permitting the Director-General to have regard to representations by interested persons as to whether a licence should or should not be granted. These provisions perform an important public interest function by allowing interested persons to place before the

Director-General information that might assist him or her to decide whether or not to grant a licence.

[125] Sub-paragraph (b) of regulation 18(5) allows the Director-General the opportunity to receive representations from interested persons as to why a licence should or should not be granted. And there is nothing vague about the phrase "interested persons". All members of the public are potential patients and are therefore interested persons. An interested person is easily ascertainable. It follows that the attack on sub-regulation 18(5)(b) must fail.

[126] Sub-paragraph (f) of sub-regulation 18(5) allows the Director-General to take into consideration "any other information that he or she deems necessary". The applicants submitted that this provision is arbitrary and gives no guidelines or norms to guide the Director-General. This provision no doubt gives the Director-General broad discretion in deciding what information to consider. As pointed out earlier, discretion plays an important role in any legal system. It permits abstract and general rules to be applied to specific and particular circumstances in a fair manner. Where, as here, factors that are relevant to the exercise of the discretion are clear, discretionary powers may be broadly formulated. In addition, the discretionary powers of the Director-General are constrained by the objectives of the Medicines Act, namely, to increase access to medicines that are safe for consumption. It follows therefore that the challenge to sub-paragraph (f) of sub-regulation 18(5) must fail.

The challenge to sub-regulation 18(3)

[127] The applicants did not suggest that sub-regulation 18(3) is vague. Instead the applicants contended that the information required by sub-regulation 18(3)(b), (f) and (g) must be evaluated in the light of the provisions of sub-regulation 18(5)(a)-(e) which sets out the factors to which the Director-General must have regard in deciding whether to grant a licence. They contended that these provisions were included in the regulations to create a framework for refusing applications for licences where there are pharmacies in the vicinity of the area where an applicant intends to dispense medicines. This is in line with the respondents' originally stated intention, the applicants submitted.

[128] Whatever the original intention of the respondents was, the provisions of sub-regulation 18(5)(a), (c), (d) and (e) have been found to be unconstitutional and they cannot be relied upon to deny a licence. This being the case, the challenge to sub-regulation 18(3) falls away.

The challenge to sub-regulations 18(6) and (7)

[129] The provisions of sub-regulations 18(6) and (7) must be read together with the provisions of sub-regulation 18(5)(b) and (f). Once it is accepted, as it must be, that there is a need to permit interested people to make available to the Director-General information which is relevant to whether a licence should or should not be granted, there must be a mechanism for informing the public of the pending applications for

licences to enable them to comment on them. Sub-regulation 18(6) provides that mechanism by requiring an applicant for a licence to publish a notice of intention to apply for a licence, while sub-regulation 18(7) permits anyone to make representations to the Director-General supporting or opposing the applications. These provisions have been formulated with sufficient clarity to enable those affected by them to know what is expected of them.

[130] These provisions serve an important public interest in that they enable any person who has information that might be relevant to the granting or refusal of the licence, to make such information available to the Director-General for a proper decision. The regulations are silent on whether such information should be made available to the applicant. There can be no question that, if the Director-General intends to rely on information adverse to an applicant, fairness will require the Director-General to afford the applicant the opportunity to comment on such information.

[131] In all the circumstances, the challenge to sub-regulations 18(6) and (7) must fail.

The challenge to regulation 20

[132] The applicants mounted a challenge to regulation 20 based on freedom of movement and residence. They also contended that the period of three years for

which a licence must be renewed is arbitrary. This regulation provides that a licence is valid for three years but may be renewed after its expiry. It is authorised by section 22D of the Medicines Act which makes provision for the renewal of licences. The section does not stipulate the period of the validity of the licence.

[133] Regulation 20 provides:

> "PERIOD OF VALIDITY OF A LICENCE ISSUED IN TERMS OF REGULATIONS 18 AND 19 AND RENEWAL OF LICENCES
> 20. (1) A licence issued in terms of regulation 18 shall be valid for a period of 3 years whereas a licence issued in terms of regulation 19 shall be valid for a period of 5 years from the date of issue.
> (2) A licence referred to in subregulation (1) which has expired may be renewed upon application to the Director-General or the Council, as the case may be.
> (3) An application referred to in subregulation (2) shall –
> (a) contain at least the information or documentation referred to in regulations 18(3) and 19(1)(c), as the case may be;
> (b) be accompanied by a prescribed fee; and
> (c) be made at least 90 days before the expiry of the existing licence."

[134] There is nothing arbitrary about requiring medical practitioners to renew their licences to dispense medicines. The applicants themselves support the requirement that a dispensing medical practitioner obtain a certain number of Continuous Professional Development (CPD) points in respect of dispensing. They say that this would ensure that dispensing medical practitioners remain up to date with current practices as is required in other areas of medical practitioners' scope of practice. But the same result can be achieved by requiring the renewal of licences. Nor does this requirement infringe the freedom of movement. The challenge to regulation 20 must

likewise fail. Before dealing with the question of costs, it is necessary to deal with the application to lead further evidence.

Application for leave to lead further evidence

[135] Shortly before the hearing of this matter the applicants sought leave to lead further evidence. There is a current tendency to tender further evidence on appeal only days before an appeal hearing. To this tendency, this Court has remarked:

> "It is appropriate to note that it has become a regrettable practice in this Court that affidavits are tendered on appeal often only days before an appeal hearing, if not on the day of the appeal itself. This is an unacceptable practice which must be discouraged. The late filing of affidavits in circumstances which do not meet the stringent test for admission set out in this judgment will not be permitted by this Court. Attorneys should take care to consider the test for the admission of late affidavits and satisfy themselves before filing the affidavits that they do qualify for admission in terms of the rules of this Court and the principles elucidated in this judgment."

[136] Further evidence on appeal will only be admitted in exceptional circumstances. Recently, this Court has said:

> "The Court should exercise the powers conferred by section 22 'sparingly' and further evidence on appeal (which does not fall within the terms of rule 31) should only be admitted in exceptional circumstances. Such evidence must be weighty, material and to be believed. In addition, whether there is a reasonable explanation for its late filing is an important factor. The existence of a substantial dispute of fact in relation to it will militate against its being admitted."

[137] The evidence sought to be introduced included a dispensing licence issued to

Dr Ahmed. The respondents did not object to this evidence in so far as it introduced the licence issued to Dr Ahmed. Nor did they dispute the accuracy of the contents of the licence. The evidence relating to the dispensing licence issued to Dr Ahmed was not only credible and material, it was not disputed by the respondents. Its admission, therefore, would not result in any prejudice to the respondents. As would have been apparent from this judgment, that evidence was relevant to the issues that had to be decided. In these very exceptional circumstances, the evidence relating to the dispensing licence issued to Dr Ahmed ought to be received into evidence. The rest of the evidence tendered does not meet the test for the admission of further evidence and cannot therefore be admitted.

Costs

[138] The award of costs is a matter which is within the discretion of the court considering the issue of costs. It is a discretion that must be exercised judicially having regard to all the relevant considerations. One such consideration is the general rule in constitutional litigation that an unsuccessful litigant ought not to be ordered to pay costs. The rationale for this rule is that an award of costs might have a chilling effect on the litigants who might wish to vindicate their constitutional rights. But this is not an inflexible rule. There may be circumstances that justify departure from this rule such as where the litigation is frivolous or vexatious. There may be conduct on the part of the litigant that deserves censure by the court which may influence the court to order an unsuccessful litigant to pay costs. The ultimate goal is to do that

which is just having regard to the facts and circumstances of the case. In *Motsepe v Commissioner for Inland Revenue*, this Court articulated the rule as follows:

> "[O]ne should be cautious in awarding costs against litigants who seek to enforce their constitutional right against the State, particularly where the constitutionality of the statutory provision is attacked, lest such orders have an unduly inhibiting or 'chilling' effect on other potential litigants in this category. This cautious approach cannot, however, be allowed to develop into an inflexible rule so that litigants are induced into believing that they are free to challenge the constitutionality of statutory provisions in this Court, no matter how spurious the grounds for doing so may be or how remote the possibility that this Court will grant them access. This can neither be in the interests of the administration of justice nor fair to those who are forced to oppose such attacks."

[139] In awarding costs against the applicants, the High Court noted that the applicants were not indigent persons. In addition, it noted that they were "in a position to finance the litigation which they pursued 'with vigour'". While accepting that as a general matter an unsuccessful litigant in constitutional litigation should not be ordered to pay costs, the court concluded that in the circumstances of this case it would not be unfair to order the applicants to pay costs. The court was no doubt influenced by both the vigour with which they pursued the litigation and their perceived ability to pay. The court erred in this regard. The court did not pay sufficient account to the general rule in constitutional litigation referred to above. The fact that the litigant has pursued litigation with vigour is not a material consideration. Nor is the ability to finance the litigation a relevant consideration. This litigation cannot be described as vexatious or frivolous. On this basis alone the order for costs made by the High Court ought to be set aside. But there is the further reason why it

should be set aside, namely that the applicants have been partially successful.

[140] It is true that the applicants have partially succeeded. But there are other considerations that are relevant to this enquiry. The applicants' main argument, and to which they devoted a great deal of time, was based on coupling. As pointed out earlier in this judgment, counsel for the applicant made it quite clear that the applicants were in court because of coupling. On this issue we have found against them. In addition, they also attacked the provisions of sub-section 22C(1)(a) of the Medicines Act. They also failed in this regard. Nor should one lose sight of the fact that initially the attack was directed against the licensing provisions of the Medicines Act, but this attack was later abandoned. These matters cannot be ignored in determining what the appropriate order for costs is. In my view, in all the circumstances of this case, fairness dictates that there should be no order for costs both in this Court and in the High Court.

Disposition of the matter

[141] It is apparent from this judgment that the application for leave to appeal not only raised important constitutional questions relating to the scope of permissible regulation under section 22 of the Constitution and the principles governing the doctrine of legality, but it had some prospects of success. In all the circumstances, the application for leave to appeal should be granted. The appeal succeeds to the extent that sub-regulation 18(5)(a), (c), (d) and (e) are declared unconstitutional.

Order

[142] In the event, the following order is made:

(a) Leave to appeal is granted.

(b) The appeal is upheld in part.

(c) There is no order for costs.

(d) The order of the High Court is set aside and is replaced with the following:

The constitutional challenge to sub-section 22C(1)(a) of the Medicines and Related Substances Act, 101 of 1965 as amended; and sub-regulations 18(3)(b), (f), (g), (h) and (i); 18(5)(b) and (f); 18(6); 18(7) and regulation 20 of the Regulations published in Government Gazette 24727 under Government Notice R510 of 10 April 2003, is dismissed.

Sub-paragraphs (a), (c), (d) and (e) of sub-regulation 18(5)of the said Regulations are declared inconsistent with the Constitution and therefore invalid.

There will be no order for costs.

Langa DCJ, Madala, Mokgoro , Moseneke, O'Regan, Sachs, Skweyiya, Van der Westhuizen, Yacoob JJ concurred in the judgment of Ngcobo J.

For the applicants: HJ Fabricius SC and SP Mothle instructed by MacRobert Inc.

For the respondents: MTK Moerane SC, P Coppin and B Vally instructed by State

Attorney (Pretoria).