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IN THE SUPREME COURT OF SOUTH AFRICA

(APPELLATE DIVISION)

In the matter between:

THE ADMINISTRATOR OF THE CAPE ..... APPELLANT

and

RAATS RÖNTGEN AND VERMEULEN (PTY) LTD .. RESPONDENT

CORAM : BOTHA, HEFER, NESTADT JJA,
VAN DEN HEEVER et KRIEGLER AJJA

HEARD : 26 AUGUST 1991

DELIVERED : 27 SEPTEMBER 1991

J U D G M E N T

KRIEGLER AJA/...

KRIEGLER AJA:

There are two main issues in this appeal. The first is whether a scheme for repacking and distributing medicines contravenes the provisions of the Medicines and Related Substances Control Act No 101 of 1965 ("the Act") and the General Regulations promulgated thereunder ("the Regulations"). The second is whether such provisions bind the Cape Provincial Administration ("the Administration"). The issues arise for decision in circumstances which are not in dispute, save in one subsidiary respect to which will be adverted at the appropriate juncture.

For many years the Administration, in common with its counterparts in the other Provinces, has been supplying medicine to patients at provincial hospitals. Many patients present with common ailments, for which standard dosages of certain medicines are usually prescribed by the attending medical staff. In time

experience taught hospital pharmacists to anticipate the dispensing of such standard prescriptions. Medicines were taken from the bulk packs in which they had been supplied to the hospital and were repacked into standard dosages, which could then be supplied to patients as and when prescribed. The system spread to other provincial hospitals, not only in the Cape but throughout the country. The benefits in terms of time, effort and money were obvious: instead of the hospital pharmacist having to dispense large numbers of standard prescriptions ad hoc for individual patients, he could prepack them, ready to be handed out. State patients in remote rural areas could however not be catered for in this manner. They were seen by their local district surgeon who would prescribe the appropriate type and dosage of medicine; then either the district surgeon would dispense and supply the medicine or a local pharmacy would do so; the Administration would then

pay for the medicine and for the dispensing.

The cost of the rural system became prohibitive and the Administration devised a new scheme which it estimated would reduce the annual cost thereof from some R40 million to below R20 million. In a sense it entailed rural district surgeons and pharmacies playing the role of provincial hospital pharmacists. The Administration would appoint one or more so-called district pharmacists in each rural district surgeon's area, to whom it would dispatch supplies of medicines prepacked at one of three major Cape provincial hospitals. The district pharmacist would then store the medicine for issue to the district surgeon's patients as and when prescribed; the Administration would pay monthly for the service at a flat rate of R5,28 per prescription. A standard contract for appointment as a district pharmacist was drafted and applications for appointment were invited in the press.

The scheme was to commence on 1 August 1990 and applications for appointment closed on 15 June 1990. The respondent, which conducts pharmacies in a number of Boland towns, applied on 20 June 1990 for their appointment. Respondent's managing director, who signed the application on respondent's behalf, added a postscript below his signature in the following terms:

> "Onderworpe aan die bepalings van die kontrak en die wettigheid van die skema."

There was a sting in the tail. The day before the application was signed, respondent's attorneys in Malmesbury had written to the Administration contending that the scheme would contravene both sec 14 of the Act and a provision in the ethical code of the Pharmacy Board. (The section mentioned which prohibits the sale of medicine in given circumstances, will be dealt with shortly.) On 11 July

1990 Cape Town attorneys wrote another letter to the Administration on respondent's behalf, reiterating the perceived breach of sec 14 and underscoring the circumstance that the scheme involved repacking medicines. Several questions were also posed relating to whether the sale, delivery and dispensing of repacked medicine would not constitute an offence. The following day the State Attorney replied that the handling and delivery of repacked medicine by a district pharmacist to district surgeons' patients would not be an offence. Respondent then changed tack. In a letter dated 20 July 1990 its Cape Town attorneys advised the State that the scheme contravened sec 15(7) read with sec 29(e) of the Act (which relates to conditional registration of a medicine). The State Attorney's reply on 23 July 1990 that the scheme was proceeding, triggered an urgent application by respondent in the Cape Provincial Division on 31 July

1990. Citing the Administration and six other public bodies (of whom only the Administration did battle) the respondent sought an order declaring the scheme illegal by reason of its contravention of sec 29(b) of the Act read with sec 14(1) thereof; and reg 36(3) read with reg 12 of the Regulations. The founding affidavit, deposed to by respondent's managing director, impugned the scheme along corresponding lines. In essence it was contended that repacking medicines in containers differing from those approved upon registration of the medicine - and without package inserts - (1) vitiated the registration and (2) constituted a deviation from the approved standards and specifications of such medicine. By agreement the application was postponed to 22 August 1990; on 15 August 1990 the Chief: Pharmaceutical Services of the Administration deposed to the answering affidavit and joined issue with the respondent on a number of factual averments in the

founding affidavit. In the course of so doing two standard packages (complete with labels) to be used in the scheme were attached. They elicited a reply, supported by the detailed evidence of an expert, to the effect that the scheme would also contravene regs 9 and 10, which prescribe in detail how medicine containers should be labelled and what information is to be reflected on accompanying inserts. At the same time respondent amended its notice of motion accordingly and invited the Administration to deal with the new matter thus raised. A brief supplementary affidavit by the Administration's pharmaceutical head was filed dealing with the new line of attack.

When the matter came to be argued in the court a quo respondent's main prayer was for an order in the following terms:

> "The First Respondent's proposed scheme (annexure 'E', as further outlined in the State Attorney's

letter, annexure 'J' to the founding affidavit), concerning the repackaging and distribution of medicines which must be registered in terms of the provisions of Act No. 101 of 1965 be declared illegal and/or to constitute a contravention of Section 29(b), read with Section 14(1) of the said Act in all cases in which the repackaging and distribution in terms of the proposed scheme renders as unregistered medicines which must be registered in terms of the said Act, and/or to constitute a contravention of General Regulation 36(1), 36(2) and 36(3) read with Regulation 9, Regulation 10 and Regulation 12(1) of the Regulations promulgated under the said Act in Government Notice R352 in Government Gazette No. 4594 of 21st February 1975 (as amended), where such repackaging and distribution constitute a deviation from the standards and specifications for such medicine which were furnished to the Second Respondent on the prescribed form and which were accepted by the Second Respondent with regard to such medicine and/or non-compliance with the requirements relating to labelling and package inserts in respect of registered medicines."

The learned judge reserved judgment and in due course held in favour of the respondent in a reasoned judgment, which has since been reported s.v. Raats Röntgen and Vermeulen (Pty) Ltd v Administrator, Cape and Others 1991(1) SA 827(C). He concluded (at 837 B -

D) that the scheme would be in conflict with reg 12(1) and (2) of the Regulations but would not contravene regs 9 and 10.Then, after a review of South African and comparative learning, he came to the conclusion (at 847H) that the State was bound by the Act and (at 848 B - E) that, in the alternative, the Administration was bound thereby. He accordingly granted a declaratory order (at 848 F - G) in an appropriately modified form, with costs. With the leave of the court a quo the Administration appealed to this Court against such judgment and order. Here, however, and pursuant to supplementary heads of argument handed in at the hearing, a contravention of the provisions of regs 9 and 10 was argued on respondent's behalf on a footing not considered before. The import and validity of such new ground will be considered in due course, as also whether it is open to the respondent thus to raise the argument. Suffice it at this stage to say that,

whereas previously the attack on the scheme under regs 9 and 10 had focused on the stage when medicine is issued to the patient, it was now directed at the earlier stage when the prepacked standard dosages are delivered to the district pharmacist by the Administration.

Having summarised the relevant facts, it is now necessary to sketch the statutory background to the issues. That is provided by the Act and the Regulations. As is evident from its short title, the Act is directed at the control of two main categories of substances, namely, medicines and so-called related substances. Indeed, when originally enacted in 1965 its scope was confined to the control of medicines simpliciter and it was only in 1974 that "related substances" were added by a series of amendments contained in the Drugs Control Amendment Act No 65 of 1974. The present enquiry relates to that facet of the

Act and the Regulations specifically concerned with the control of medicines; hence this review will pass over the provisions which relate only to "related substances". The general context of the Act, the legislative policy which gave birth to it, the mischiefs perceived and the means selected for their combating are manifest from an analysis thereof. The long title spells out that it was enacted "(t)o provide for the registration of medicines ..., for the establishment of a Medicines Control Council, for the control of medicines ... and for matters incidental thereto." The control of medicines was to be attained by a system of supervised registration. Consistent with such objectives the Act erected three prohibitory barriers under secs 14(1), 19(1) and 22A(1) (the first two directed at the medicine and the third at persons who sell it). At the same time it created the Medicines Control Council ("the Council"), a panel of suitably

qualified experts, (secs 2 to 9) to police the integrity of the barriers. It also created a registrar (sec 12) to maintain the requisite administrative machinery (sec 13).

Sec 14(1) is central to the mechanism of the Act. In terms thereof "no person shall sell any medicine which is subject to registration ... unless it is registered". Subsection (2) of sec 14, in turn, provides that the Council may "determine that a medicine or class or category of medicines ... shall be subject to registration in terms of this Act." It is apparent from the succeeding subsections of sec 14 that the lawgiver envisaged that the Council would review all medicines already existing at the commencement of the Act and would consider all medicines coming onto the market thereafter. In this way each and every medicine would in time come under the scrunity of the Council, which could require registration if it thought

fit. In terms of sec 15(7) "registration ... may be made subject to such conditions as may ... be determined by the council", while sec 15 generally prescribes the procedure to be followed when applying for registration of a medicine (subsec (1)), consideration of applications by the Council (subsec (2)), certificates of registration (subsec (4)) and the like. Particulars of all registered medicines are kept in the medicines register (sec 13) and in terms of sec 15(11) the registrar is to publish prescribed particulars of applications for registration in the Gazette. In this way, then, all medicines which the Council deems appropriate for registration will have been registered, certified, recorded and made known. Sec 19(1), in turn, prohibits the sale of "any medicine unless it complies with the prescribed requirements". The control and supervision of medicines are then fortified by sec 22A(1) which

prohibits the sale by laymen of medicines otherwise than under the authority of any appropriate trading licence.

The constraints on the sale of medicines is augmented by a number of ancillary provisions. First there is a very wide definition of the word "sell" in sec 1 of the Act, to wit:

> "'**sell**' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and '**sale**' and '**sold**' have corresponding meanings."

Then the definition of the word "medicine" in sec 1 is also couched in wide terms:

> "'**medicine**' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in -
>
> (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine."

Not content with the extensive net cast by the provisions relating to medicines as such, the lawgiver directed its attention to the packaging, labelling and advertising of medicines: sec 18 of the Act provides:

"18. Labels and advertisements - (1) No person shall sell any medicine ... unless the immediate container or the package in which that medicine ... is sold bears a label stating the prescribed particulars.

(2) No person shall advertise any medicine ... for sale unless such advertisement complies with the prescribed requirements."

The terms "immediate container", "package" and "label" are also defined in sec 1; the language makes it plain that the intention was to extend the prohibition contained in secs 14(1), 19(1) and 22A(1)

to the widest limits. Conformably sec 20(1) prohibits "any false or misleading advertisement concerning any medicine" while "advertisement" is, by definition in sec 1, afforded full vigour. Furthermore sec 23 of the Act invests the Council with authority to order the disposal of medicines the availability of which it deems contrary to the public interest.

The extensive powers of registration of medicines and of control of their disposal, packaging and advertising mentioned thus far, are enhanced by further powers vested in the Minister of Health, Welfare and Pensions. It is he who appoints the Council and nominates its chairman and vice-chairman (sses 3 and 5); he has to approve the Council's determinations as to registrability under sec 14 and is afforded extensive prescriptive powers by sec 35(1) of the Act. The latter subsection lists no less than 32 topics in respect of which the Minister may legislate

by regulation while subsec (7) confers authority on him to impose substantial penalties for contraventions thereof by way of regulations. Furthermore the Minister may in terms of sec 35(1)(ii) by regulation prescribe "the forms which shall be used for any application for the registration of a medicine and the particulars that shall be furnished with any such application ..." Paragraph (vii) of sec 35(1) further empowers the Minister to prescribe "the manner in which any package containing any medicine ... shall be labelled, packed or sealed"; while paragraph (viii) authorises regulations relating to "the particulars in regard to the use thereof which shall be furnished with any medicine ... sold, and the manner in which such particulars shall be furnished".

Over and above the Minister's supervisory and regulatory functions, the Act makes provision for the Director-General: Health, Welfare and Pensions to play

a part. Under sec 22 he is to circularise inter alia medical practitioners, dentists and pharmacists with data relating to newly registered medicines; under sec 26 he may appoint inspectors, who (under sec 28) are clothed with wide-ranging powers of entry, search and seizure. Lastly, in reviewing the Act, it should be noted that sec 29(1)(b) and (c) render contraventions of secs 14(1), 18(1) and 19(1) offences for which sec 30 imposes relatively severe penalties (as much as 12 months imprisonment).

It would be advisable to pause for reflection lest the wood becomes obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and

incomprehensible to most. The man in the street - and indeed many medical practitioners - could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasizes, to register and control medicines. The enactment created a tightly-meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensibly packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.

The latter are to be found in the Regulations

which, like the Act itself, manifest the stigmata of numerous and frequent adaptation. (The Butterworths' consolidation runs to some 80 pages and includes 21 amendments.) Fortunately the current review can be confined to a handful of the Regulations. Reg 1 contains a number of definitions ("applicant", "expiry date", "lot", "lot number", "package insert", "proprietary name") expressly relating to a medicine. At the same time the verb "manufacture" is defined to include "pack" and there is a definition of "minimum legibility", both of which latter definitions (and that of "package insert") clearly relate, not to medicine, but to some container thereof. Reg 2 prescribes who may apply for registration of a medicine; reg 3, read with reg 15, prescribes the form on which such application is made. There are 19 annexures to reg 15, demonstrating that an application for registration is a painstaking and elaborate process.

Annexure "F" to the respondent's founding affidavit in the court below, an example of an application, occupies no less than 203 pages of the record on appeal. Four of the sixteen prescribed annexures relate to the medicine concerned while annexures 8A, 8B, 9A and 9B require details of the immediate and outer container thereof.

The contents of regs 9, 10 and 12(1) are sufficiently pertinent to the argument concerning the validity of the Administration's repackaging and distribution scheme to warrant fairly extensive quotation. Reg 9 (insofar as is relevant) reads as follows:

> "LABELLING OF MEDICINES INTENDED FOR ADMINISTRATION TO HUMANS
>
> 9. (1) Save as provided in subregulations (2), (3) and (4), the immediate container of every medicine in which medicine intended for administration to humans is sold shall have a label attached on which only the following particulars pertaining to the contents of such package shall appear in clearly legible indelible

letters and in at least both official languages."

Then follow 24 requirements, numbered (a) to (x), detailing precisely what information regarding the medicine in the immediate container is to be furnished, e.g. its proprietary name and the approved name of each ingredient; the registration number; the dosage form and recommended dosage; directions and indications for use; whether it should be shaken before use; etc. Reg 9(2) requires similar data to be furnished on the label of the outer container, if there is one. Subreg 9(4) then provides as follows:

"(4) The requirements of subregulation (1) shall not necessarily apply to -

(a) any medicine sold in accordance with the provisions of section 14(4);

(b) any medicine sold by a medical practioner, dentist or pharmacist in the course of his professional activities for the treatment of a particular patient; or

(c) any medicine sold by a pharmacist or by a hospital in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient:

Provided that such medicine shall be sold in a package to which is attached a label containing the following information:

(i) The name of the medicine or the name of each active ingredient or constituent medicine, unless the relevant prescription issued by the medical practitioner or dentist concerned has been clearly marked with the words '<u>non nomen propium</u>';

(ii) the name of the person for whose treatment such medicine is sold;

(iii) the directions (if any) in regard to the manner in which such medicine should be used;

(iv) the name and business address of the medical practitioner, dentist, pharmacist, pharmacy or hospital selling such medicine; and

(v) the reference number, i.e. the number allocated to such sale by the seller, as contemplated in regulation 28(1)(e)."

(Reg 28 requires that a dispenser should keep a prescription register and paragraph (1)(e) thereof requires a reference number to be allocated to each prescription and its recording in the register.)

Reg 10, in turn, deals with the requisite package inserts. Subreg (1) thereof contains the following:

> "PACKAGE INSERTS
>
> 10. (1) Save as provided in subregulations (2) and (3), each package of a medicine shall be accompanied by a package insert, either as a separate entity or as an integral part of the package, on which are printed in both official languages and in type having a minimum legibility as defined in regulation 1(vi) of the regulations, under the headings and in the format specified in this regulation, the following particulars only relating to such medicine:"

(Then follow 18 categories of information to be furnished, most of which contain a variety of data. Clearly the intention of the draftsman was that a

package insert was to be very informative indeed.) Regs 10(2) and (3)(a) are not relevant and can be skipped while subregs (3)(b) and (c) are identical to paragraphs (b) and (c) of reg 9(4) and need not be repeated.

Lastly, reference should be made to reg 12(1), which reads as follows:

> "COMPLIANCE WITH REQUIREMENTS
>
> 12. (1) Every medicine shall comply with the standards and specifications which were furnished to the council on the form prescribed by regulation 15 and which have been accepted by the Council with regard to such medicine."

It will be recalled that reg 12 founded the invalidating order in the court a quo. Regs 9 and 10, however, were considered by the learned judge to be inapplicable. The reasoning (at 837D) with regard to regs 9 and 10 was that, on the evidence presented, the Administration would "sell" (i.e. issue) medicines to

patients via the agency of the district pharmacist or a hospital "in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient ..." Although the learned judge did not expressly say so, he obviously had the savings contained in reg 9(4)(c) and 10(3)(c) in mind. And in so doing, counsel for the respondent contended, he erred. A new line of attack was adopted which amounts to this: even if one assumes (which counsel says one should not) that reg 12(1) will not be transgressed by the scheme; and that the issue of a prepacked prescription to the patient by the pharmacist will not transgress regs 9 and 10, the transmission of bulk supplies by the provincial hospital to the district pharmacist will not come under the saving umbrella of regs 9(4)(c) and 10(3)(c). Such transmission will be a "sale" as contemplated by the all-embracing definition of "sell"

in sec 1 of the Act; admittedly such "sale" will be by a hospital for the treatment of a patient but, so respondent's counsel contends, the individual packages of prepacked medicines will not have been so "sold" "in accordance with a prescription" nor "for the treatment of a particular patient".

In developing the argument counsel submitted that on the facts adduced on behalf of the Administration, both in its answering affidavit and in the supplementary affidavit filed in response to the new matter raised in reply, there was no answer to the point: on any reading of the scheme as described by the head of the Administration's pharmaceutical department, there would be a "sale" which falls foul of the regulations - the procedure will inevitably entail prepacked medicine being transmitted, conveyed or delivered for sale without the requisite label or insert. Moreover, so it was contended, the point was

not all that belated: in the founding affidavit the repacking into different containers, sealed and packed differently and without container inserts, was pertinently raised and was dealt with in the Administration's answer.

I do not agree. The whole thrust of the respondent's case in the correspondence, although admittedly adverting to repacking, was directed towards the conclusion that the scheme's illegality was to be found in the perceived loss of registration of the medicine, or in a departure from the standards and specifications approved by the council when it granted registration. That was unequivocally the case made out in the main prayer in the original Notice of Motion, which claimed an order declaring that:

> "The First Respondent's proposed scheme ... concerning the repackaging and distribution of medicines which must be registered in terms of the provisions of Act No. 101 of 1965 (was) illegal

> and/or ... constitute(d) a contravention of Section 29(b), read with Section 14(1) of the said Act in all cases in which the repackaging and distribution in terms of the proposed scheme renders as unregistered medicines which must be registered in terms of the said Act, and/or (constituted) a contravention of General Regulation 36(3) read with Regulation 12(1) of the Regulations ..., where such repackaging and distribution constitute a deviation from the standards and specifications for such medicine which were furnished to the Second Respondent on the prescribed form and which were accepted by the Second Respondent with regard to such medicine."

Neither the amended notice of motion nor even the heads of argument filed on respondent's behalf, mentioned that it was the "sale" by the provincial hospital to the district pharmacist which was regarded as an objectionable feature of the scheme. Consequently, although there were oblique references to packaging and inserts in the founding affidavit, and although there were specific and detailed criticisms of

the repackaging containers and the absence of inserts, the Administration's scheme was not challenged - nor, of course defended - on the footing advanced at the hearing of the appeal. Had this been an ordinary commercial dispute the respondent would for those reasons probably have been denied audience on the point under discussion and would have been left with the option to start afresh if so minded. But the issues are of such a nature and the public interest in their definitive resolution so clamant, that, if possible, any suggested ground of illegality of the scheme should be considered. In any event, there is some weight in the contention that the scheme in its entirety has been depicted with sufficient particularity to warrant examination of the point. Lastly, and in itself conclusively, it is a point of so little worth that it should be dispatched with expedition.

At the root of the respondent's argument lies the extended definition of "sell" contained in sec 1 of the Act, which embraces a variety of activities not falling within the ordinary meaning of the word. The most striking extension is to be found in the concluding words "for a consideration or otherwise", which qualify the words "supply or dispose of". (That the ambit of their qualification is so limited, is clear: the word "and" after the word "sale" and before the word "barter", in conjunction with the use of a comma before the "and", introduce a division denoting the commencement of a further list of contemplated activities. In addition neither barter nor exchange can notionally be imagined without a consideration; hence the qualifying words can only refer to the two activities immediately preceding them, namely, "supply" and "dispose of".) Be that as it may, there are clearly discernible - and logical - limits to the

compendium of activities enumerated by the definition; and there is a sensible nexus between them. The first part of the definition, from the specific verb "sell" to its substantive counterpart "sale", denotes selling (in its ordinary connotation) and ancillary or facilitatory acts by the seller. Then the definition embraces vicarious performance of such acts ("authorize", "direct" or "allow"). The definition then proceeds to include preparation or posession for sale (whether directly or vicariously), pauses at the comma and concludes with a final list of acts ("barter" etc).

Notwithstanding the wide ambit of the words and the ostensibly diverse range of acts enumerated, there is an identifiable common denominator characterising the whole. That is some transaction or action of a commercial or quasi-commercial nature related, albeit remotely, to selling - or delivery

pursuant thereto - with a view to consumption. Thus the word "supply" was not intended to apply - and could not conceivably have been intended to apply - to the administration of an injection by a nurse at the bed-side of the hospital patient or to a mother cajoling her off-spring to gulp a proferred spoonful of cough-syrup. Nor can transmission, conveyance or delivery of medicine by one pharmacist to another in one and the same dispensary have been contemplated. A definition, however widely worded, is not an invitation to obtuseness or flights of fancy; the legislature is not to be presumed to have attended the Mad Hatter's teaparty but to have had specific, discernible and sensible objectives in mind. The interpretation contended for by counsel for the respondent necessitates reading into the definition of "sell" in sec 1 of the Act conduct ludicrously beyond the limits of sensible or purposive interpretation. If the

despatch of crates of prepacked (and ready to dispense) medicines to district pharmacists were to constitute "selling", there could hardly be a limit to the acts vis-a-vis medicine which would not fall within the definition. Any physical delivery, regardless of the circumstances and irrespective of the purpose, would be included. That is not the intendment of the definition.

Turning then to the facts: the draft contract for the appointment of district pharmacists (annexed to the founding affidavit) makes it plain that prepacked stocks of medicines supplied in terms therof remain the property of the Administration. Clause 1 requires the pharmacist to store ("op te berg"), to control ("te beheer") and to issue ("uit te reik") medicines supplied ("voorsien") thereunder. In terms of clause 3 the pharmacist's comprehensive remuneration ("omvattende vergoeding") is calculated at a flat rate

per prescription dispensed by him; paragraphs 9 to 12 of the annexure to the contract, read in conjunction with clauses 1 and 3 of the contract itself, make it clear that the pharmacist's position is tantamount to that of a skilled storeman in control of the Administration's stock; he must look after it and periodically account to the Administration for his stewardship; and he is to part with it only as and when instructed in writing by the local district surgeon by means of a particular form of prescription. There is nothing in the draft contract to suggest that the supplying, transmission or delivery by the Administration to its duly appointed district representative partakes of the nature of a "sale" within the meaning of the term as defined in sec 1 of the Act.

Turning next to the key provisions of the Act relating to the sale of medicines, the inapplicability of the prohibitions to such supplying is afforded

additional weight. Sec 14(1), which proscribes the selling of unregistered medicines which ought to be registered, clearly does not apply to conduct of the kind under discussion. Indeed, if the type of disposal inherent in the scheme as between the Administration and district pharmacists were to be "selling", the mere transmission of a medicine to the Council with a view to registration thereof would constitute an offence. Likewise the very possession of as yet unpacked commercial stocks of a particular medicine in the hands of a manufacturer or the transmission thereof to the wholesaler for packaging and labelling would offend against the provisions of sec 18(1) of the Act. By like token a manufacturer who delivered stocks of medicine from his warehouse to a factory for quality control and appropriate upgrading to prescribed standards would, by such very delivery, render himself liable to prosecution under sec 19(1).

In the result the supply by the Administration to district pharmacists of prepacked medicines must be held not to fall within the ambit of the word "sell" as defined in sec 1 of the Act. Nor does it constitute a contravention of either reg 9(1) or reg 10(1), which strike at a "sale" as defined. Counsel for the respondent did not suggest that the court a quo had erred in concluding that the supply by the district pharmacist to the patient did not offend against the provisions of regs 9 and 10. Nor could such argument have prevailed: the dispensing would fall four-square within the excepted "sales" covered by regs 9(4)(b) and (c) as long as the labels contained the data reflected on the specimen packages annexed to the answering affidavit. That information complies with the requirements of the proviso to reg 9(4). Reg 10(1) is an a fortiori case: the package of medicine dispensed to the patient by the district pharmacist on

the prescription of the district surgeon would, by virtue of the saving contained in reg 10(3)(c), not have to be accompanied by an insert.

That then leaves a possible contravention of reg 12(1), which the court a quo found to be entailed in the scheme. At p 835 G - I of the reported judgment the submission on respondent's behalf which, in the event, carried the day was summarised in terms aptly encapsulating the corresponding argument in this court. It reads as follows:

> "In support particularly of his contention that the scheme fell within the purview of s 14, he submitted that it was evident from all the relevant provisions of the Act, considered in context, that the registration of a medicine (as prescribed in s 14) was not confined to its substance (or formulation), but also encompassed the identity of the 'seller' (the applicant in this case) and all the standards and specifications furnished to and accepted by the Council in terms of reg 15, inter alia in respect of containers and packaging. As the Administration would be an unregistered 'seller' of medicines in unregistered containers and

packaging materials, it would act in contravention of the prohibition contained in s 14."

Having considered the opposing arguments advanced on behalf of the Administration, the learned judge (at 837A) adopted what he styled "a purposive approach to the interpretation of the Act" and concluded

"that the words 'standards and specifications' as used in reg 12(1) and (2) are intended to cover all standards and specifications furnished to and accepted by the Council in terms of reg 15 upon the registration of a medicine, including the container specifications and control procedures furnished in annexures 8A and 8B abovementioned.

I hold accordingly that the ... scheme .. will be in conflict with reg 12(1) and (2) ... and therefore illegal."

Fundamental to such conclusion were two findings by the learned judge (at p 836 F - J), both of which were supported by respondent's counsel in this Court. First he rejected a contention on the Administration's behalf that regs 12(1) and (2) related

only to the medicine and not to its container and packaging. That, he held, was too narrow an interpretation of the plain wording of the regulation. Secondly he held that, inasmuch as there was no prohibition in the Act or Regulations against deviation from standards and specifications other than in reg 12, one had to read that regulation as pertaining to all standards and specifications furnished under reg 15 when application was made for registration of a medicine. Otherwise, so the learned judge reasoned, the elaborate application and testing procedure would be rendered nugatory as "any 'seller' (other than the holder of the registration certificate) would be at liberty to deviate from any of the standards and specifications furnished to and accepted by the Council in accordance with reg 15."

Neither the learned judge's reasoning nor the conclusion can be supported. The wording of reg 12(1)

is indeed plain: it is every medicine that is to comply with the acccepted standards and specifications; and such acceptance is expressed as having been "with regard to such medicine." That is what the language used by the draftsman unequivocally signifies, especially if it is kept in mind that the word "medicine" has a determined meaning by virtue of its definition in sec 1 of the Act. And reading the provision purposively leads to the same conclusion. What the regulation had in mind was to ensure that a medicine, once approved and registered, would be kept up to standard. The scheme of things is quite simple. The standards and specifications with regard to a medicine must be disclosed in annexures submitted with the application for registration of such medicine; the alleged standards and specifications are then evaluated by the Council and the accuracy of such allegations is checked by analysing the medicine; the standards and

specifications thus alleged, once approved and verified, then constitute the standards and specifications with which all future commercial supplies of such medicine must comply. Subregulation 12(1) is directed at characteristics of the medicine - and of the medicine alone. Likewise reg 12(2) is not concerned with any deviation not related to the medicine as such. A reading of reg 12 as introducing a reference to containers, package inserts or the like would, indeed, not only do violence to the language of the regulation as it stands, but would confuse pharmaceutical considerations relating to the medicine itself with wholly different considerations relating the suitability and strength of containers, the adequacy and legibility of labels and inserts, etc.

Moreover, a contextual approach to the interpretation of reg 12 indicates that it is concerned with the medicine alone. Sections 14, 15, 19 and

22A(1) of the Act deal specifically with medicine, which is the main subject matter of the Act as a whole; when the draftsman animadverted to packaging he did so in a separate section, sec 18. The distinction is maintained in sec 35(1), where the Minister's power to regulate applications for registration of medicines is afforded by paragraph (ii), while his power to prescribe standards for labels, packing and inserts is governed separately by paragraphs (vii) and (viii). Another feature of the Act which highlights the distinction between standards and specifications relating to medicines and those relating to packaging, labelling and the like should be noted. In the case of medicines the expertise of the Council is necessary to establish the requisite qualities; but when it comes to labelling and the like the Minister, acting through his departmental officials (and no doubt consulting the Council), is to fix standards. The pharmaceutical and

associated technicalities are too complex for the officialdom to handle but not printing, packing and labelling.

The Regulations maintain the distinction: regs 2, 4, 5 and 6 govern applications for registration of medicines, regs 7 and 8 prescribe what information regarding medicines is to be recorded in the register and on registration certificates. Neither the register nor the certificate contains any data relating to packaging etc. Then reg 9 deals only with labelling and reg 10 with package inserts. When reg 12 then, in terms, deals with standards and specifications with regard to <u>medicines</u> it cannot be read as dealing with subject matter which, both in the Act and in the Regulations, and indeed conceptually, falls into a different category. It was intended to deal - and on its unequivocal wording purports to deal - only with medicines. Regs 9 and 10, on the other hand, deal only

with labels and package inserts. Consequently it is obvious that the exceptions they allow (in regs 9(4) and 10(3) respectively) do not relate to the medicine as such. That is governed by reg 12 which, of course, contains no corresponding exceptions to the rule that medicines are to adhere to their approved standards and specifications. Conformably, where a pharmacist issues medicine to a patient in accordance with a specific prescription the medicine itself must still be up to standard (reg 12) while the full information contained on the label and the insert may be absent (regs 9(4) and 10(3).

Nor is there any substance in the proposition that unless reg 12 be read as encompassing packaging, labels and inserts, the whole application procedure would be rendered futile. On the contrary, regs 9 and 10 are couched in general terms which make it clear that, save in the exempted circumstances contemplated

under subregs 9(4) and 10(3), whenever medicine is sold, every immediate container and outer container thereof is to bear the prescribed label and is to be accompanied by the prescribed insert. Any "sale", taking place (in non-exempted circumstances) without a label or an insert complying with the prescribed standards constitutes an offence punishable under reg 36(1) and (2) respectively. A departure from standards and specifications in contravention of reg 12, on the other hand, is dealt with under a different paragraph of reg 36. Reg 36(3) provides that a contravention of reg 12 constitutes an offence. Consequently there is no lacuna in the Regulations which could ex necessitate warrant reading words into reg 12 which are not there.

No other ground for invalidating the Administration's scheme has been suggested, nor can any be perceived. As the scheme is lawful, it follows that the second main issue need not necessarily be

considered. Nevertheless it is desirable to deal with it as there may be minor adjustments to the scheme which could give rise to doubts regarding its legality.

The question whether the Act is binding on the Administration, falls into two parts, namely, (a) whether it binds the executive branch of the State; and (b) whether it does not in any event bind a provincial administration.

With regard to the first question it is for present purposes unnecessary to engage in an extensive review of the authorities. That was done by the learned judge a quo, who articulated the distillation of his endeavours as follows (at p 844H to 845B):

> "1. The State is not bound by its own enactments, except by express words or by necessary implication, ie if an intention to be bound appears clearly from the nature of the enactment.
> 2. For the purpose of deciding whether a statute falls within the narrow scope of the

exception, the Court may look not only upon the language of the enactment, but also at the surrounding circumstances and may consider its objects, its mischiefs and its consequences.

In other words, the purpose of the statute, the circumstances pertaining at the time when it was passed and the consequences if the State were exempted or bound, are all factors that must be taken into account. Considerations of public policy are therefore also relevant.

3. However, the mere fact that a statute was passed for the public benefit is not in itself a sufficient consideration from which an inference that the State was intended to be bound may be justified. It must be shown that if the State were not bound, the purpose sought to be achieved by the enactment would be frustrated. ...

4. In the inferential process to determine the intention of the Legislature, other common law presumptions employable as indicators of such intention are not excluded and may also be thrown into the scale."

The summary accords with established principles consistently applied by this court over many years. (See Union Government v Tonkin, 1918 A.D 533 at 540 and

541, per Innes CJ; South African Railways and Harbours v Smith's Coasters (Pty) Ltd, 1931 AD 113 at 127 and 129, per De Villiers CJ; Evans v Schoeman N.O. 1949(1) SA 571(A) at 576 to 578, per Centlivres JA.) No reason has been suggested and no authority cited to warrant a departure from that which is known, tested and workable. On the contrary, two recent judgments in kindred jurisdictions by Courts of high authority support the view that there is no reason to reconsider this Court's approach (Lord Advocate v Dumbarton District Council; Lord Advocate v Strathclyde Regional Council, [1990] 1 All E.R. 1 (H.L.), and Bropho v The State of Western Australia and Another 64 ALJR 374 (H.L.).

Here, as is so often the case, the rub lies in applying clear principles to unclear facts. The learned judge a quo (at p 846I to 847H) found that the object of the Act was "to protect the population of the

country against the evils of the uncontrolled dissemination of potentially harmful medicinal substances." He then took into account that it would result in no prejudice to the State if it were to be bound by the Act; and that it would be absurd if "the State should be at liberty to do the very mischief that the Act was intended to suppress in the national interest ..." The identification by the learned judge of the object of the Act cannot be faulted; not so however the perceived absence of prejudice and the perceived absurdity if the Act were not to bind the Executive. There may well be prejudice to the State if it were , in one or other of its multifarious governmental activities, to be subjected to the constraints of the Act. Examples spring readily to mind, eg the urgent manufacture in bulk of a particular medicine by or for a department of State to combat an epidemic or the procurement of medical supplies by the

military authorities at a time of crisis. The present circumstances, of course, present a vivid example - a saving of R20 million p.a. of sorely needed public funds could be blocked by a regulation which was aimed at protecting the very class of person for whom the Administration's scheme caters.

But that is really beside the point. The question to be asked is not whether the State would be prejudiced if a particular Act were to apply to it, but whether the attainment of the objectives of this particular enactment would be frustrated if it did not. Posed thus, the answer is self-evident. Tight control of the quality, manufacture and dissemination of medicines is what the Act envisages. Such objective would not be jeopardised if the State, the very watchdog which exercises such control, were itself not subjected to control.

Nor is it helpful, in seeking an answer to the

question under discussion, to postulate wanton licence on the part of civil servants if the Act were not binding on the State. The question is not whether the objects of the Act would be frustrated if the State, ie its servants, were free to sell unregistered medicines or to do so without the requisite labels or package inserts. It is whether the protection of the public in the manner envisaged by the Act would be frustrated unless its provisions were binding upon the State and its servants. That is a very much narrower test - and not conclusive in itself. Ultimately the enquiry is directed at ascertaining whether the Legislature, contrary to its usual practice, intended the Executive to be subject to its set of prescripts embodied in a particular enactment instead of laying down rules to be obeyed by its subjects.

The statute in question in the present case clearly contains no express provision to the effect

that it is binding on the State. The subject matter is, broadly speaking, public health, a matter first entrusted to the Central Government by the Public Health Act No 36 of 1919 (which remained on the statute book until its replacement by the Health Act No 63 of 1977). The specific mischief in such field of responsibility sought to be combated by the Act was the dissemination of medicines either inherently harmful or potentially so when misused. The Act therefore created a specialist body (the Council) to scrutinise all medicinal substances, and clothed the titular head of the appropriate department of the Central Government with a number of powers and duties: he was to select the panel of experts; his department was to provide the requisite administrative, policing and enforcement agencies; he was to determine and prescribe by regulation how medicines were to be registered, labelled, advertised and packed as also what

explanatory information was to be furnished when it was sold. What is more, the Minister was (by sec 36) empowered (subject to certain conditions) to exclude any medicine from the operation of any or all of the provisions of the Act. On the face of it, therefore, the Legislature was content, as it virtually invariably is, to appoint the Executive as the general overseeing authority with regard to the working and enforcement of the Act. Such a role cannot readily be reconciled with an intention on the part of the law-maker to subject the law-enforcer to its own enforcement. It is indeed unlikely that such a dual role could have been intended and certain specific provisions serve to emphasize this general improbability. Thus it is inconceivable that departmental inspectors, empowered by sec 26 to enter, search and seize, could exercise such powers vis-a-vis their own colleagues - or superiors. To whom would they report their findings, who would act thereon and,

more pertinently, who would be prosecuted for any governmental transgression of the Act so uncovered? Sec 33 provides that employers and their managers, agents or employees are vicariously liable to prosecution for one another's contraventions of the Act. Therefore, if the Act applies to the State, unless the penal provisions are severed from the balance of the Act's provisions, the ludicrous situation could arise that a Minister (or a Director-General) is prosecuted on the instructions of one underling for a transgression by another. And there is no logical or interpretational justification for severing the penal provisions from the rest of the Act. The conclusion is clear.

The only question remaining, in the light of the aforegoing conclusion, is whether or not the Administration, in contradistinction to the executive branch of the central government, is excluded from the

provisions of the Act. The court a quo held that it was not (at p 847I to 848C). I can agree with neither the conclusion nor with the underlying reasoning. We are not concerned here with possibly competing spheres of legislative competence as between a provincial council and the central legislature. Nor are we concerned with any competing spheres of executive competence as between a provincial executive committee and the central executive. What is in issue here is simply whether the administrative structure of a province, under the control and direction of its administrator, was intended by the Legislature to be subject to the provisions of the Act. More particularly the question is whether it intended so to distinguish between the central executive (which is excluded from the operation of the Act) and a provincial administration. That it could have done so, is clear. The Legislature, the paramount law-maker in

the South African state, could have drawn any distinction it saw fit to draw. Why it should have decided to do so, is difficult to imagine. The relationship between the central executive and provincial administrations was fixed at the time of Union and has since remained essentially unchanged:

> "Die Provinsiale Administrasie is 'n afdeling van die staatsbewind. Dit het geen Staatsminister as politieke hoof nie. Die uitvoerende gesag en bygevolge die naaste eweknie van 'n politieke hoof is die Administrateur-in-Uitvoerende Komitee (wat ek die Administrateur sal noem). Hy neem die plek in wat een of meer Staatsministers sou beklee het as daar geen Provinsiale Administrasies was nie."
>
> (per Steyn CJ in Van der Linde v Calitz 1967(2) SA 239(A) at 260H.)

The cases cited by the learned Chief Justice (R v Naylor, 1919 T.P.D. 30 at 36; Natal Provincial Administration v South African Railways and Harbours, 1936 N.P.D. 643 at 661 and 666; Kent N.O. v South African Railways and Another, 1946 AD 398 at 410 and

436), afford instructive historical information regarding the constitutional status of the administrator of a province vis-a-vis the Crown (as it then was), but add little to the terse clarity of his statement of principle: A provincial administration is a part of the executive branch of State. At the time of the enactment of Act No 101 of 1965 an Administrator held office under secs 66 and 67 of the Constitution, Act 32 of 1961; he was appointed by the State President, held office at his pleasure and represented him in relation to provincial government. Since Union, the establishment, maintenance and management of hospitals had been an important function of provincial government (see sec 84(1)(e) of Act 32 of 1961 and sec 85 of the South Africa Act 1909).

In each of the provinces extensive hospital services had been established (many ante-dating Union). Consequently cogent evidence would be required before

one could conclude that the Legislature intended such an elaborate and important component of the State's public health establishment to be dealt with on a basis differing from that applicable to the central executive. There is no such evidence to be found in the language of the Act, nor in its objects, structure or pattern. The Act must therefore be held not to apply to the Administration.

In the result the following order is granted:

1. The appeal is upheld with costs, including the costs of two counsel.

2. The order of the court a quo is set aside and for it is substituted an order dismissing the application with costs, including the costs of two counsel.

J C KRIEGLER
ACTING JUDGE OF APPEAL

BOTHA JA)
HEFER JA)
NESTADT JA) - Agree
VAN DEN HEEVER AJA)