



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

Case Number: 48004/2021

- (1) REPORTABLE: YES / ~~NO~~
(2) OF INTEREST TO OTHER JUDGES: YES / ~~NO~~
(3) REVISED.

DATE 13/02/2024

SIGNATURE



In the matter between:

SAFELINE PHARMACEUTICALS (PTY) LTD

Applicant

and

DIRECTOR-GENERAL, NATIONAL DEPARTMENT

OF HEALTH

First Respondent

**DIRECTOR: AFFORDABLE MEDICINES,
NATIONAL DEPARTMENT OF HEALTH**

Second Respondent

ABBVIE (PTY) LTD

Third Respondent

SOUTH AFRICAN HEALTH PRODUCTS

REGULATORY AUTHORITY

Fourth Respondent

**Tender for medicines- adoption of therapeutic effects to compare medicines-
power of the Department of Health to determine a therapeutic class- the
Medicines and Related Substances Act 101 of 1965 – powers of the Regulator or
the Department of Health to determine a therapeutic class – exclusive or
concurrent powers.**

JUDGMENT

UNTERHALTER J

Introduction

[1] The applicant, Safeline Pharmaceuticals (Pty) Ltd ('Safeline'), has registered and sells a product, Poractant Alfa (Alfa), that is used to treat Respiratory Distress Syndrome (RDS). RDS occurs in premature babies, most frequently in babies born in the 28th to 30th week of gestation. RDS is a syndrome in which the baby struggles to receive oxygen and remove carbon dioxide. RDS is treated with pulmonary

surfactants, administered directly into the airways. Alfa is a pulmonary surfactant. The third respondent, Abbvie (Pty) Ltd ('Abbvie') has registered and sells a product, Beractant. It is also a pulmonary surfactant used to treat RDS.

[2] The Department of Health ('the Department'), cited and represented in these proceedings by the first and second respondents, has for many years procured Alfa and Beractant for use in public hospitals. The department initiated a tender and invited bids to procure pulmonary surfactants for the period May 2021 - 30 April 2024 ('the 2021 tender'). The invitation to bid was formulated on the basis of two therapeutic classes, described as: Surfactant – group 1 ((class 1) and Surfactant group 2 (class 2). The description of each class and its members is best depicted in the table that follows:

Therapeutic Class and Series Number	Therapeutic class description	Members of the therapeutic class
Class 1	Surfactant - group 1	Phospholipids, Total (Beractant}, 100mg/4ml, 1 Vial Vs Natural Phospholipids (Poractant Alfa), intra-tracheal solution, 120mg in 1.5ml, 1.5ml
Class 2	Surfactant - group 2	Phospholipids, Total (Beractant), 200mg/8ml, 1 Vial Vs Natural Phospholipids (Poractant Alfa), intra-tracheal solution, 240mg in 3ml, 3ml

Both class 1 and class 2 count Alfa and Beractant as members of the therapeutic class. The difference between and within the two therapeutic classes is the size of the vial in which each product is supplied.

[3] The bid invitation referenced Clause 20.2 of the Special Conditions of Contract. This provision explained the basis upon which Alfa and Beractant were classified as medicines of the same therapeutic class. Clause 20.2 reads as follows:

"The Policy for Classifying Medicines into Therapeutic Classes for Purposes of Therapeutic Interchange defines a therapeutic class as a group of medicines which have active ingredients with comparable therapeutic effects. Medicines in a therapeutic class may or may not belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may possess different mechanisms of action, result in different adverse reactions, have different toxicity and drug interaction profiles. In most cases, these medicines have close similarity in efficacy and safety profiles, when administered in equipotent doses for a specific indication.

The ministerially appointed National Essential Medicines List Committee (NEMLC) formulates and revises the Standard Treatment (STGs) Guidelines and Essential Medicines List (EML). Therapeutic classes are mentioned in the "Medicine treatment" section of the national STGs which provides a class of medicines followed by an example such as, HMGCoA reductase inhibitors (Statins) e.g. simvastatin. These therapeutic

classes have been designated where none of the members of the class offer any significant benefit over members of the class for a specific indication. The NEMLC will designate therapeutic classes for a condition, where appropriate."

Central to the definition of a therapeutic class is the grouping together of medicines which have active ingredients with comparable therapeutic effects. These medicines may or may not belong to the same pharmacological class.

[4] On 29 March 2021, the Department awarded the tender to Abbvie for the supply of Surfactant class 1 and class 2. A contract was entered into between the Department and Abbvie for the period 1 May 2021 – 30 April 2024.

It is common ground between the parties that the contract has been almost fully performed and will end less than three months after this matter was heard in court.

[5] Safeline brought proceedings to challenge the award of the tender and the decision of the Department to classify Alfa and Beractant as belonging to the same therapeutic class ('the contested classification'). The amended notice of motion, prior to the hearing of the matter, in sum, sought to review and set aside the adoption in the invitation to bid of the contested classification, as well as the award of the tender to Abbvie. It also sought declaratory relief to the effect that the Department's adoption of the contested classification is unlawful. In the course of the oral hearing, this relief was debated with counsel for Safeline. He sensibly recognised that as the contract that followed upon the award of the tender was nearing its end, there was no point in seeking to have the award of the tender set aside, much less to order an award of the tender in favour of Safeline. The substantive relief that Safeline now seeks is

confined to a declaratory order as to the legality of the contested classification and a declaratory order as to the legality of the award.

[6] Although there were complaints made by the Department and Abbvie as to questions of delay in bringing the review and mootness, I am satisfied that there remains a live issue that warrants the attention of this court. It is this. In its replying affidavit, Safeline references the ongoing use by the Department of the contested classification for the purposes of its 2024 – 2027 tender (‘the 2024 tender’) for the supply of Surfactant. The Department has filed a further affidavit in these proceedings, without complaint by Safeline. The Department does not deal with this tender and its use of the contested classification. In these circumstances, the issue of the contested classification will continue to feature in the procurement practices of the Department for the supply of Surfactant. Rather than foster further litigation in the future, it is in the interests of the parties that the contested classification, and its consequences for the legality of the tender brought under review in these proceedings, be resolved. I will therefore entertain the declaratory relief sought and condone any non-compliance with the time for seeking such relief in the interests of securing resolution of these matters, more especially in the parties’ future dealings over matters of significance for public health.

The Contested Classification

[7] Safeline’s primary challenge is that the Department has no power to adopt the contested classification. The power to classify medicines lies elsewhere. The Medicines and Related Substances Act 101 of 1965 (‘the Medicines Act’) established the South African Health Products Regulatory Authority (‘the Regulator’). Safeline contends that the Regulator enjoys the exclusive competence to classify medicines. The Department, in adopting the contested classification, did not rely upon the Regulator. Rather, pursuant to its own Policy for Classifying Medicines, the Department relied upon the National Essential Medicines List Committee (‘the List

committee'), and its sub-committee, the Expert Review Committee ('ERC'), to decide which medicines belong in the same therapeutic class. Safeline submits that the List Committee has no such power. Hence, the adoption of the contested classification by the Department, and, in particular, by its bid committee, to draw up and publish the invitation to bid for the 2021 tender was unlawful. And since the contested classification was thus integral to the 2021 tender, the award made in favour of Abbvie was also unlawful. The further adoption by the Department of the contested classification for the purposes of the 2024 tender is equally unlawful, hence Safeline seeks declaratory relief in respect of the contested classification.

[8] There can be no doubt that the Department has the power to procure medicines for use in public hospitals. Section 217(1) of the Constitution is predicated upon the recognition that an organ of state may contract for goods or services. Section 239 of the Constitution defines an organ of state to include a department of state in the national sphere of government. The Department is such a department of state. In terms of s 217(3) of the Constitution, the Preferential Procurement Policy Framework Act 5 of 2000 ('PPPFA') prescribes the framework for preferential procurement. The PPPFA is of application to an organ of state which is defined in s1 to include a national department. This legislation also proceeds from the recognition that a department of state enjoys the power to contract for goods and services. The Supreme Court of Appeal has characterised a decision as to the procurement of goods and services by an organ of state to be one, 'that lies within the heartland of the exercise of executive authority by that organ of state.'¹

[9] The question that arises is whether the power of the Department to procure medicines, and Surfactant in particular, encompasses the power to specify in an invitation to bid that procurement will take place on the basis of the contested classification. When Safeline contends that the Department lacks this power, its challenge makes two claims. The first is that the Department cannot invite bids on

¹ *Tshwane City & Others v Nambiti Technologies (Pty) Ltd* 2016 (2) SA 494 (SCA) at paragraph 43

the basis of the contested classification because this classification rests upon the definition of a therapeutic class that the Department has no power to make.

[10] This proposition cannot be accepted. Plainly, the adoption of a classification for the purpose of inviting bids for a public tender may be scrutinised on well-known grounds of review, such as rationality or reviewable unreasonableness. But it is at the very heart of the constitutional requirement of s217 that, for public procurement to be fair, transparent, competitive and cost-effective, the procurer, here the Department, must be able to determine the class of goods that are to be compared. To do this, the Department must decide which goods or services are adequate substitutes, so as to serve the function for which they are being procured. Once the Department has determined this, price plays a critical role in ranking bids.

[11] The Department, as Clause 20.2 of its Policy for Classifying Medicines, referenced above, makes plain, seeks to define therapeutic classes of medicines for the purposes of procurement. A therapeutic class is a group of medicines which have active ingredients with comparable therapeutic effects, but need not belong to the same pharmacological class, and may differ in other respects, such as their chemistry, toxicity, and adverse reactions. There is no reason why the Department should not adopt a policy of this kind for the purpose of procurement. It is a policy that gives preference to therapeutic effects. And that is a perfectly defensible basis upon which the Department invites bids to procure medicines to provide treatment in public hospitals. It values what a medicine can be used to treat, rather than its molecular or chemical identity with another medicine. It is certainly an entirely rational and reasonable policy to adopt for the purpose of procuring medicines for the public health service. Indeed, as the Department and Abbvie stressed, it encourages competitive bidding because more medicines have comparable therapeutic effects than molecular identity. And more competition, in principle, lowers prices and provides alternative sources of supply. All of which is a faithful implementation of s 217 of the Constitution.

[12] In sum, the Department has the power to procure medicines. Intrinsic to this power is the classification of goods or services into classes which permit of comparison. Therapeutic efficacy is an entirely rational criterion of classification. It follows that the contention that the Department lacks the power to define a therapeutic class must be rejected.

[13] Safeline, however, makes a second claim. Even if the Department may adopt therapeutic efficacy as its criterion of classification, the Department, and its internal functionaries, the List committee and the ERC, do not have the power to determine which medicines are to be so classified as falling into a class based on therapeutic efficacy. This statutory function rests with the Regulator under the Medicines Act. The contested classification was adopted by the bid committee on the recommendation of the List committee. But, Safeline argues, the Department lacks the power to make the contested classification. Rather, that power rests with the Regulator.

[14] In order to make out this contention, Safeline must show that the power of classification is enjoyed by the Regulator, and that it is an exclusive competence. That is to say, the Regulator alone can exercise this power, and hence, the Department having done so, this amounts to an *ultra vires* exercise of power.

[15] I turn to consider this argument. The Regulator was established in terms of s2 of the Medicines Act. In s 2A, the objects of the Regulator are set out. They are widely framed: to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, and related matters. Section 2B lists the functions of the Regulator. These include: the assessment and registration of medicines that meet defined standards of quality, safety, efficacy and performance by means of a process that is transparent, fair, objective and timely. Safeline placed particular emphasis upon s35(1)(iii). This provision permits the Minister of Health, in

consultation with the Regulator, to make regulations providing for the classifications of medicines. General Regulations have been promulgated in terms of s35. Section 2 of the General Regulations sets out the requirements for therapeutic equivalence. A medicine is considered therapeutically equivalent if both medicines are pharmaceutically equivalent or pharmaceutical alternatives. Medicines are pharmaceutically alternatives 'in that they contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength'. An active moiety, the founding affidavit explains, is the core molecule responsible for a medicine's beneficial or adverse effect.

[16] The Medicines Act, as its preamble makes plain, provides for the registration of medicines and related substances intended for human use. The Regulator's principal function is to assess and evaluate applications to decide whether a medicine, subject to registration, should be registered. Registration is the regulatory gateway that determines whether a medicine, subject to registration, may be sold. The substantive provisions of the Medicines Act provide for a variety of other matters. These include: measures to ensure the supply of more affordable medicines; the labelling and advertisement of medicines; the control of medicines and scheduled substances; licensing and generic substitution. What is not to be found in the substantive provisions of the Medicines Act is any general power to classify medicines. And no power is conferred upon the Regulator to classify medicines for the purposes of the public procurement of medicines; let alone to do so in conformity with the constitutional norms of s 217 of the Constitution.

[17] The objects and functions of the Regulator, as set out in the Medicines Act, are broadly framed. But they do not attach to any specific substantive duty or competence to classify medicines for the purpose of public procurement. Section 35(1)(iii), referenced above, and upon which Safeline placed much emphasis, does not confer a general power of classification upon the Regulator. It permits the Minister to make regulations, 'providing for the classification of medicines, medical devices, or IVDs into classes or categories *for the purposes of this Act*' (my

emphasis). Those purposes do not include the Regulator undertaking the classification of medicines for the public procurement of medicines. That is borne out by the relevant regulation that the Minister has promulgated. Section 2 of the General Regulations determines therapeutic equivalence by reference to pharmacological equivalence or active moiety, that is molecular equivalence. This concept of therapeutic equivalence is simply not the same as an assessment of therapeutic effects which the Department has chosen to use for the purposes of its procurement of medicines, and which I have found to be within its powers to adopt.

[18] As I understood the position of Safeway, it accepts that classification by recourse to therapeutic equivalence, as defined in s2 of the General Regulations, is not classification undertaken by reference to therapeutic effects. But, it contends, that simply demonstrates that the Minister has yet to promulgate regulations that would regulate the basis upon which the Regulator undertakes classification by recourse to therapeutic effects. It does not mean that, in terms of the Medicines Act, the Regulator cannot do so.

[19] That is not the correct interpretation of the Medicines Act. The Regulator has a power to classify medicines, but only for the purposes of the Medicines Act. And those purposes, as I have explained, do not include classification for the public procurement of medicines. Once that is so, Safeway's challenge must fail. The Regulator does not enjoy the power to make the contested classification, and the Department may decide upon such a classification for the purpose of the public procurement of medicines, provided such classification satisfies the usual standards of lawful administrative action.

[20] If my interpretation of the Medicines Act is incorrect, and the Regulator does enjoy a power of classification of the kind that is appropriate to the public procurement of medicines, Safeline's challenge faces a further obstacle. It is at best an incidental power, removed from the principal matters that the Medicines Act requires the

Regulator to regulate. If, then, the Department could have approached the Regulator to undertake the contested comparison by reason of its expertise, there is no reason to interpret the Medicines Act on the basis that the Regulator has the exclusive competence to undertake such a classification. Classification for the purposes of public procurement, as I have explained, forms no part of the substantive regulatory remit of the Regulator. If the Regulator enjoys an incidental power of classification to undertake the contested comparison, there is no reason to interpret the Medicines Act to imply that the Regulator alone has this power. It is rather a question as to where the Department can procure the required expertise to make the contested comparison. The Department has found that expertise in the List committee. I find that there is no reason why the Department should not rely on that expertise. It is not required to make use of the Regulator to make the contested comparison because, even if the Regulator has the competence to do so, it does not enjoy an exclusive competence. For this reason also, the contested classification challenge must fail.

The Pricing Challenge

[21] Safeline complains that the Department awarded the tender for Surfactants group 1 & 2 to Abbvie on the basis of a flawed, and unlawful, comparison of the prices bid by Safeline and Abbvie in the 2021 tender. Although this challenge figured more emphatically on the papers, during oral argument counsel for Safeline, helpfully, stated its submission as follows. It is common ground that Safeline tendered its product, Alfa, at a lower price than did Abbvie for its product, Beractant, in the weight band defined as babies weighing between 1001g and 1200g. Safeline contended that the Department should have split its award so as to award the tender to Safeline in the weight band in which it offered the lower price.

[22] This challenge cannot prevail. On an aggregative price comparison, across all the relevant weight bands, Abbvie was more price competitive. It may have been open to the Department to split the award according to weight bands, but it was not

unlawful to adopt an approach to the assessment of pricing that made an aggregative comparison. That is so because the Department explained that there is a paucity of 'patient-level data' to make weight-based dosing estimations. This explanation triggered no small controversy on the papers as to what the relevant studies showed on this issue. In motion proceedings, that is a dispute I cannot resolve. The Department gave a reasoned basis for its aggregative price comparison, and that suffices for the purposes of meeting the challenge of reviewable illegality.

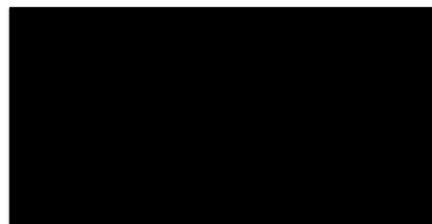
Conclusion

[23] It follows that Safeline's application must be dismissed. The declaration sought on the basis that it was unlawful for the Department to classify Alfa and Beractant in the same therapeutic class cannot succeed because I have found that the Department enjoyed the power to make the classification that it did, for the purpose of its procurement of Surfactants. So too, the relief sought to review the award of the tender by the Department fails because the Department enjoyed the power to adopt the contested classification and did not make a reviewable error in its comparison of prices.

[24] The parties were agreed that costs should follow the result, save in one respect. Safeline had to bring an application to compel the production of a complete record. It is entitled to those costs. Safeline sought condonation for the late filing of its supplementary founding affidavit. That was not opposed, and it is granted.

[25] In the result:

- (i) The application is dismissed with costs, those costs include the costs of two counsel, where so employed.
- (ii) The costs of the applicant's rule 30 application shall be paid by the first and second respondents, the one paying the other to be resolved.



DN UNTERHALTER
JUDGE OF THE HIGH COURT
OF SOUTH AFRICA, GAUTENG DIVISION
PRETORIA

Heard on: 06/02/2024

Judgment: 13/02/2024

Appearances:

For the Applicants:

**ADVOCATE GOVENDER and
ADVOCATE M DAFEL**

Instructed by:

MORTIMER GOVENDOR ATTORNEYS

For the First and Second Respondents:

**ADVOCATE RATHIDILI SC and
ADVOCATE NTHAMBELENI**

Instructed by:

THE STATE ATTORNEY

For the Third Respondent:

**ADVOCATE MAENETJE SC and
ADVOCATE A MOLVER**

Instructed by:

ADAMS & ADAMS ATTORNEYS