IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NUMBER:62661/18

DELETE WHICHEVER IS NOT APPLICABLE

(1) REPORTABLE: YES/NO
(2) OF INTEREST TO OTHERS JUDGES: YES/NO
(3) REVISED

23 AUGUST 2021
DATE

Mlhapi
.....
SIGNATURE

In the matter between:

THE ASSOCIATION OF CONCERNED PROFESSIONAL ANIMAL CONSULTANTS	**APPLICANT**
And	
THE MINISTER OF AGRICULTURE FORESTRY AND FISHERIES	**FIRST RESPONDENT**
THE REGISTRAR OF FERTILIZER, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES	**SECOND RESPONDENT**
MINISTER OF HEALTH	**THIRD RESPONDENT**

THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY	**FOURTH RESPONDENT**
ANIMATE ANIMAL HEALTH (PTY)	**FIFTH RESPONDENT**

JUDGMENT

TLHAPI J

INTRODUCTION

[1] This is an application in terms of the Promotion of Administrative Justice Act 3 of 2000 ("PAJA") to review and set aside a contended *ultra vires* decision of the second respondent, dated 10 April 2014 to register a stock remedy known as Salbutamate, 10% ("the product") and, the renewal of the registration of the said product on 1 August 2017 in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 ("Act 36"). Further, that the decision of the fourth respondent to exempt R-salbutamol sulphate ("the API"), which was the active pharmaceutical ingredient, that is, the chemical compound of the product, from control under Schedule 4 of the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act") be reviewed and set aside. The latter relief was later abandoned in the applicant's supplementary affidavit.

[2] The grounds of review are based on the following provisions of PAJA:

(a) Section 6(2)(a) in that the decisions were not authorised by the empowering legislation;

(b) Section 6(2)(b) in that the mandatory and material procedures of conditions prescribed by the empowering provision were not complied

with;

(c) Section 6(2)(d) in that the decisions were materially influenced by errors of law; and

(d) in that the decisions were taken:

(i) for a reason or reasons not empowered by the empowering provisions;

(ii) for an ulterior purpose or motive;

(iii) because irrelevant considerations were taken into account, or

(iv) relevant considerations were not considered;

(v) in bad faith; and or

(vi) arbitrarily or capriciously,

[3] The applicant approached the second respondent to withdraw the product from the market. In correspondence exchanged, it seemed that there was no appreciation by officials of the second respondent of the detrimental impact the registration of the product had on human health. It was only when the applicant realised that registration of the product had been renewed that it was prompted to launch this application, due to the failure by the second respondent to withdraw the product from the market.

[4] The application was opposed by the first second and fifth respondents on several grounds mainly that there was an unreasonable delay in instituting the application; that no good cause was provided for condonation for the applicant's non-compliance with section 7(1) of the Promotion of Administrative Justice Act 3 of 2000("PAJA") and that on various grounds, the application was without merit.

[5] An order dismissing the application with costs in favour of the first, second and fifth respondent including costs of two counsel where employed was granted on

29 January 2021. The application was dismissed on the basis of an unreasonable delay and that no condonation was justified.

BACKGROUND

[6] A very brief summary of the facts follows. The applicant contended that its concerns were raised when a letter dated the 24 January 2018 was addressed to the second respond which was annexed to the founding affidavit as FA6. The second respondent replied in a letter dated 9 February 2018 stating that Salbutamate is not regarded as a scheduled substance and could be registered as a stock remedy and had been exempted in terms of the Act. Further, that at the time of registration Regulation No. R1387 of 1999 was followed.

[7] The applicant is a voluntary association whose membership includes veterinarians, veterinary consultants, feedlot nutritionists and academics in the relevant fields. The applicant was established to promote the safety of products for use in food producing animals and, the prevention of the registration of products harmful to human consumption. It appeared that in the process of registration and renewal of the product, public health requirements had been overlooked and or ignored. The applicant contended that the API was regulated as a scheduled substance under Schedules 2,3 and 4 of the Medicines Act, it therefore excluded the product from being registered as a stock remedy unless exempted by the fourth respondent.

[8] The applicant relied on the services of two experts to provide information on the pharmacology of API and other aspects of the registration process. Ms Leneri du Toit is a consultant of 29 years experience in the registration of products in terms of the Medicines Act and, Prof Karen Du Toit is a registered pharmacist who also holds a Master's degree and doctorate in pharmaceutical chemistry and applied chemistry respectively and, further an LLB degree.

The Product

[9] The registered owner of the product was the fifth respondent. In its website the product, Salbutamate was described as a " *feed additive used for increased mass gain, increased feed efficiency, improved carcass dressing percentage and improved carcass leanness in cattle and sheep.*"

[10] According to Prof du Toit the product has as its active component, the API, which is a beta-agonist; the API used alone or as a mixture gives rise to therapeutic and adverse effects when administered in clinical use. As provided in the Medicines Act, API is a scheduled 2 substance; in a respirator solution it falls under a schedule 3 substance and when used in an injection it falls under a schedule 4 substance. At the time of registration the product was therefore controlled under the Medicines Act. Prof du Toit contended that the maximum residue level (MRL) values of the product had not been provided on registration. Several countries had therefore banned the use of API as a substance in 'food producing animals due to the possibility of food poisoning of humans consuming meat, especially liver and kidneys of animals exposed to the substance. Prof du Toit and Ms du Toit have confirmed that API has not been registered in other countries due to these adverse effects on humans

The Legislative Framework Relating to Stock Remedies and Registration Process

[11] The applicant contended that before registering a product as a stock remedy in terms of section 36 of the Act, it had to be determined first whether its active ingredient was regulated by the Medicines Act. Relevant to such determination were the provisions of the Foodstuffs and Disinfectants Act 54 of 1972 and the regulations on the "MRL" (maximum residue limit) in Schedule to GN R 1809 regulations in GG1410 dated 3 July 1992 as amended, which protected consumers from foodstuffs which may be harmful to human health in terms of the Medicines Act.

[12] Salbutamate as a feed additive fell within the definition of 'foodstuffs' and was not a substance as defined in section 36 of the Act. MRL values should have been provided before registering Salbutamate as a stock remedy, none were provided and the second respondent could not have accepted the default value because of the health concerns and the product should not have been registered. The fact that no MRL values were provided resulted in a conditional approval of the stock remedy pending MRL evaluation. To date no MRL values are available in respect of the product.

[13] Registration according to Ms du Toit is conducted by expert consultants. An applicant shall provide samples or such particulars and data for investigation as demanded by the Registrar before registration. The second respondent shall only register the stock remedy if satisfied with the quality and effectiveness of the purpose intended. The Registrar is therefore obliged to consider issues relating to public health concerns of consumer health risk. The period of registration is limited to one year and an application for renewal must be made at least three months before expiry. The registration where the MRL evaluation was outstanding and the registration for a period of three years was irregular. Further, a renewal in essence constituted a fresh application where all the requirements had to be satisfied

No exemption in terms of the Medicines Act

[14] The applicant contended that the Rule 53 record confirmed the concerns that the registration of the product failed to meet registration requirements. The record it said did not contain any evidence or reasons showing a rational motivation for registering the product. The third respondent on recommendation of the fourth respondent SAHPRA was authorised to exclude a scheduled substance such as R-salbutamol from operation under the Medicines Act. An exemption was therefore a prerequisite to registration. The applicant gave a history by Scinetic (a division of Agri Operation Ltd) in its effort to apply for the exemption of R-salbutamol from the

Medicines Act since 2006 and, addressed the responses between the second, third and fourth respondent.

[15] The applicant concluded that the exemption would only be valid if published by the third respondent in a government gazette and in this regard no documentation was produced. The applicant also contended that there was evidence that there were concerns relating to effects on the health of those who had consumed the substance in meat products over a lengthy period. Further, there was no record to show that the required threshold for MRL and default MRL values had been determined, therefore the registration process was entirely flawed. In essence the applicant was suspicious of the process of evaluation of the registration of the product given the health concerns raised even before 2014. Another concern raised was that the product had been banned and not registered in other countries. Criticism was also levelled on the reliance by the second respondent on the expert opinion of Dr Jacques R Snyman whose report failed to deal with the required MRLs data evaluation before registration.

Fifth Respondent

[16] Ms Marlien Prinsloo (Ms Prinsloo) is the technical manager of the fifth respondent who has been involved with registration and further development of the product and holds a BSc (Agric); BSc (Agric) Hons; MSc (Agric) in Animal Science. Her master's degree was completed on a study relevant to the issues considered being in the 'residue kinetics and safety of API in ruminants. Apart from the product herein beta-agonist as a growth promoter had been used in the meat production for 24 years in the swine and cattle industry. Zilmax (zilpaterol and Ractopamine were such beta-agonist grown promoters also promoted and used in the meat industry, which included veterinarians who were members of the applicant. Some of the veterinarians, including members of the applicant promoted a large scale use of unregulated "extra-label" or "off-label administration of growth promoters to feedlot animals.

[17] It is contended that the application is motivated by financial interests of some individuals, who include some members of the applicant who opposed the use of R-salbutamol as a stock remedy after realizing that it was a competitor to be reckoned with in the local market. The aim by concentrating on the alleged adverse effects of R-salbutamol was to have it removed from the local market in order for Zilmax to regain market appeal. No mention is made of the real adverse effects of zilpaterol and ractopamine used in feedlots as a stock remedy. The appeal in R-salbutamol as compared to zilpaterol was in the fact that only half of the usual dosage of racemic salbutamol is required.

[18] The fifth respondent gave a history of how it took over the registration process of R-salbutamol from Sterling, which held the patent in a joint venture after it was liquidated and, completed the registration process which complied with the relevant requirements at the time. Registration endured over a period of three years and not one year as contended by the applicant. An overview was given of the components of R-salbutamol and its effects in animals. An overview was also given of the involvement of various experts including those having ties with the applicant in as far as they presented different findings or views of the product to those presented by the applicant. The fifth respondent contended that Salbutumate 10% has been used and distributed since its first registration on 10 April 2014 by numerous entities, in feedlots, animal nutritional consultants in the feedlot industry and some were mentioned in the papers and confirmatory affidavit annexed. No adverse events have been associated with the product, neither have any complaints been reported to the second respondent and the applicant that public health considerations have been overlooked. The applicant has not mentioned a single incident of adverse effects. The applicant has failed to disclose that there was disapproval of the use of zilpaterol in the US and Canada.

[19] Regarding the MRL safety levels, the fifth respondent contended that in relation

to humans what was relevent was the acceptable daily (ADI) intake and 'the safe withdrawal period determined for the stock remedy's active pharmaceutical ingredient (API). It depended on the residue depletion studies together with the ADI present in animal tissue to determine what was safe for human consumption. The higher the MRL the safer the beta-agonist for humans and vice versa. It was contended that these concerns were addressed before registration.

[20] The fifth respondent also relied on the expert opinion of Prof J Snyman a clinical pharmacologist and consultant having, 30 years' experience in his filed and Prof J Schlebusch a pharmaceutical consultant and pharmacist having 29 years' experience in the control of medicines. Prof Snyman opined on the pharmacological properties of R-salbutamol and Prof Schlebusch opined on the registration requirements of stock remedies. Both experts refuted the assertions of the applicant's description of R-salbutamol with the racemic molecule salbutamol. They denied that there were adverse effects or health concerns demonstrated in its use. They also denied that there were flaws in the registration process. They pointed to what they contended was the overall inaccurate version of the applicant. No record of adverse effects had been advanced in the founding papers.

First and Second Respondent

[21] The first and second respondents contended that before registration there was a meticulous evaluation undertaken and concerns where present, were raised with the fifth respondent for further attention. Where further evaluation technical advice was sought they relied on Prof Naidoo during 2013 and, he raised concerns regarding the clinical trials and he recommended further information on toxicity following oral exposure and, that the deficiencies be corrected. He further noted the shortcomings in cattle, sheep and pigs. The shortcomings were addressed and registration followed At the time of registration of the product R-salbutamol was not a controlled substance under the Medicines Act, that it was not required to be exempted and that it could

lawfully be registered as a stock remedy. They contended that there was no merit in applicant's contention that the MRL requirements were not complied with. In considering registration the evaluation involved a determination whether the product was suitable for what it was intended, was sufficiently effective and whether the requirements had been complied with.

Reliance by the applicant on Prof Du Toit's opinion was questioned in that no reasons were disclosed why Salbutamol was banned in other countries and no reasons were given and whether such ban had anything to do with the consumption of the chemical at a default value. The applicant conceded in reply that registration cycle period was three years and not one as opined by Ms Du Toit.

Unreasonable Delay / Condonation

[22] It is important to restate the time line. The decision was taken on 10 April 2014, registration was renewed on 1 July 2017, on 17 November 2017 R-Salbutamol was exempted from control under the Medicines Act, the review of the exemption has been abandoned; on 24 January 2018 the applicants addressed a letter to the second respondent who responded on 9 February 2018 and the application for review was launched on 28 August 2018. The respondents contend that the review application was brought four years after the impugned decision was taken, or if the applicants only became aware of the unlawfulness of the registration on 1 August 2017 the applicant failed to institute the proceedings within 180 days and /or within a reasonable period. Further, that since it was trite that condonation was not for the taking, that in the absence of an application with sufficient explanation for the lateness, this application should be dismissed.

[23] Section 7(1) of PAJA provides:

" Any proceedings for judicial review in terms of Section 6 (1) must be instituted without unreasonable delay and not later than 180 days after the date:

(a).....

(b)..... On which the person concerned was informed of the administrative action, became aware of the action, the reason for it, or might reasonably have been expected to have become aware of the action and the reasons"

Section 9(1)(b) provides that the period of 180 days may be extended for a fixed period by agreement between the parties or failing such agreement by a court on application by the person or administrator concerned.

(2) ....where the interests of justice so required

[24] It was contended for the first, second and fifth respondent that the application was launched after an unreasonable delay and that what had to be determined was whether such delay should be condoned. Further, it was contended that no basis and or reasons had been proffered for the delay except that knowledge of the unlawfulness of the registration came after date of the renewal, and that even after 1 August 2017, the applicant failed to institute the review proceedings within a reasonable time and not later than 180 days. Further, the first and second respondent contended that no basis was given why the decision was taken contrary to the provisions of the Act.

[25] It was contended for the applicant that the delay was not unreasonable in that there was no knowledge of the unlawfulness of the registration until the renewal and specifically the conditions on the certificate which indicated that the requirements had not been met at registration and neither at the time of renewal, which was followed by the enquiry to the second respondent in January 2018. The application was triggered by the knowledge of unlawfulness. It was contended that the renewal was conditional and that if the merits were good there was no merit in the point *in limine* and that it was unfair to the applicants to deal with it in isolation.

[26] It was also argued for the applicant that the principle in Municipal Manager Quakani v F V General Trading 2010 (1) SA 356 SCA was applicable. It related to the consequences of invalidity and unlawfulness of an administrative decision where an state organ had failed to adher to legislated procurement requirements. It was disputed that Quakana was relevant to the issue dealt with *in limine.*

[27] The issue of delay has to be determined first before the merits are to be considered. The failure to bring a review application within a reasonable time may be prejudicial to the respondent and there is public interest in the finality of administrative decisions, Gqwetha v Transkei Development Corporation Ltd and Others 2006 (2) SA 603 (SCA). Public interest in this respect is within the interests served by competing parties with regard to the use of stock remedies in the feedlot industry. In Opposition to Urban Tolling Alliance and Others v Sanral and others [2013] 4 All SA 639 (SCA) at para 26 the following is stated:

> *"Before the effluxion of 180 days, the first enquiry in applying s7(1) is still the delay (if any) was unreasonable. But after the 180 day period the issue of unreasonableness is pre-determined by the legislature: It is unreasonable per se. It follows that the court is only empowered to entertain in terms of s9. Absent such extension the court has not authority to entertain the review application at all. Whether or not the decision was unlawful no longer matters. The decision has been 'validated' by the delay…. That of course does not mean that after the 180 day period an enquiry into the reasonableness of the applicant's conduct becomes entirely unreasonable. Whether or not the delay was unreasonable is still a factor to be taken into account in determining whether an extension should be granted or not."*

[28] Important is the question, when is it that the applicants might reasonably have been expected to be aware of the registration of Salbutamate 10%. The main object of the applicant as asserted in the founding affidavit was to "*promote, preserve and*

advocate for the safety of product registered for use in food producing animals .....safeguard against the registration of products harmful for human consumption." The fifth respondent had identified members of the applicant who had been actively involved in preparatory work that preceded the registration of Salbutamol 10% and had knowledge of the registration thereof. It was argued for the applicant that the fifth respondent cast aspersions on its members which were irrelevant to the issue sought to be determined. I would not describe them as aspersions, but would say in that event there was a duty to disclose their involvement whether for or against to allow for proper ventilation. The applicant had not refuted such allegations in reply. It was contended that in as far as their activities were not disclosed in the founding papers, in terms of the Plascon Evans Rule, it must be accepted that they became aware of the registration of the product shortly after 10 April 2014 or at least during July 2014.

[29] In my view, besides having relied in this application on experts to opine on the registration and use of the product as a stock remedy, the members are practitioners and academics in the field of the manufacture, registration and supply of stock remedies to feedlots and distribution in the market. They were and presently are aware of the wide use of the product in the market. They have not refuted the evidence of such as given in answer by the fifth respondent that the product has been in use since 2015 and that no adverse effects on humans resulting from long term use have been recorded since registration. Having been involved in the process they would have been aware of any untoward conduct on the part of the fifth respondent in the registration process.

[30] In my view although it is not expected for a new case to be made in reply, no attempt whatsoever was made in reply to explain the involvement of members of the applicant preregistration and shortly thereafter with the product. No explanation is given why it was not necessary to disclose the nature of their activity with the product. No explanation was proffered why they would not have had knowledge of the irregularity, they being actively involved in the feedlot industry. This explanation is

necessary for me to consider the next step, whether there are good grounds in the interests of justice to grant condonation. I am in agreement that in the circumstances of this case it should be accepted that the applicants or some of its members were aware and, if they had any misgivings, they were dilatory in addressing their concern if any. In exercising a discretion to condone or not I am of the view that a period of four years or even more than 180 days is unreasonable and that where there is a total absence of an explanation or good cause shown for the entire period, the merits of the application cannot be entertained.

[31] In conclusion, while the issue of prejudice to the fifth respondent was touched upon, what is important is to ask whether it is just and equitable to entertain the merits where no condonation has been addressed. In the circumstance the interest of justice do not permit condonation for the delay.

Tlhapi

TLHAPI VV

(JUDGE OF THE HIGH COURT)

MATTER HEARD ON	:	**28 JANUARY 2021**
JUDGMENT RESERVED ON	:	**29 JANUARY 2021**
ATTORNEYS FOR THE APPLICANTS	:	**JACOBS LIEBENBERG ATT.**
ATTORNEYS FOR THE 1ST & 2ND RESP	:	**THE STATE ATT.**
ATTORNEYS FOR THE 5TH RESPONDENT	:	**BIELDERMANS ATT.**