



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

CASE NO: 000149/2023

(1) REPORTABLE: NO.
(2) OF INTEREST TO OTHER JUDGES: NO
(3) REVISED.
DATE: 27 FEBRUARY 2024
SIGNATURE [REDACTED]

In the matter between:

COVID CARE ALLIANCE NPC	First Applicant
TRANSFORMATIVE HEALTH JUSTICE NPC	Second Applicant
FREE THE CHILDREN – SAVE THE NATION NPC	Third Applicant

and

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF THE NATIONAL DEPARTMENT OF HEALTH DR M PHAAHLA	Second Respondent
THE ACTING DIRECTOR GENERAL OF THE NATIONAL DEPARTMENT OF HEALTH DR N CRISP	Third Respondent

**THE SOUTH AFRICAN HEALTH PRODUCTS
REGULATORY AUTHORITY**

Fourth Respondent

THE NATIONAL TREASURY

Fifth Respondent

Summary: *An application for a final order compelling various organs of State to cease and desist from the making available in the widest possible sense vaccinations against Covid19 was refused. The application failed on various grounds including a lack of a sufficient evidentiary basis as well as locus standi and an attempted breach of the separation of powers.*

ORDER

1. The application is dismissed with costs, including the costs of senior and junior counsel, where employed.

J U D G M E N T

This matter has been heard in open court and is otherwise disposed of in terms of the Directives of the Judge President of this Division. The judgment and order are accordingly published and distributed electronically.

DAVIS, J

Introduction

- [1] Every death brought about by the Covid19 pandemic and its consequences remains tragic. This includes those deaths which occurred as a result of attempts to curb the virus by the administration of vaccinations. This case is about the applicants' attempts to stop the further "roll out" of vaccinations and in particular the administering thereof to minors from 12 – 17 years of age.

The parties:

- [2] The first applicant is the Covid Care Alliance NPC [Covid Care] a non-profit company which describes itself as an "*alliance network of various groups and many individuals, professionals like attorneys, advocates, alternative practitioners, medical doctors, scientists and parents representing people and organizations who seek to help and protect persons effected by Covid and Covid19 vaccines....*". The second applicant is Transformative Health Justice NPC (Transformative Health), a similar non-profit company which proclaims that it is "*focused on safe, effective, affordable and necessary access to healthcare, informed consent as a pillar of transparency and democracy and education on the impact of conflicts of interest on human rights*". The third applicant is Free the Children – Save the Nation NPC (Free the Children), another non-profit company whose stated aims and objectives include the promotion, protection and upholding of the best interests and rights "*of the children of South Africa*".
- [3] The first respondent is the President of the Republic of South Africa (the President), the second respondent is the Minister of National Department of Health (the Minister and the Department), the third respondent is the

Acting Director-General of the National Department of Health (the ADG), the fourth respondent is the South African Health Products Regulatory Authority (SAHPRA) and the fifth respondent is the National Treasury.

Relief claimed

- [4] The relief claimed by the applicants were contained in two parts in their notice of motion. It was initially envisaged that Part A would be sought as an urgent application pending the determination of Part B. The application had some procedural history which resulted in it not being heard as an urgent application but as a special application in this division's Third Court. At that time both Parts A and B were before the Court and had been addressed by the parties. Adv. Benson, who appeared for the applicants, conceded however that should the relief in Part A be granted, the relief formulated in Part B would have to be modified and she had advised her clients of this. The relief in Parts A and B were however argued as if separate and independent relief, without modification or amendment.
- [5] In order to understand Adv Benson's concession better and to facilitate the adjudication of the various objections against the formulated relief (principally that it was overbroad and otherwise not competent) I deem it appropriate to quote the relief in full. It is the following:

"Part A:

2. *Pending the determination of Part B of this application the Respondents shall:*
 - 2.1 *forthwith cease and desist from all aspects related to the approval, procurement, promotion, advertising, encouraging, mandating,*

distribution, administration, funding of the Covid19 vaccine in all public and private health facilities;

- 2.2 *forthwith cease and desist from, whether orally or in writing through any media outlet whatsoever making or reporting any allegations, promoting, advertising or giving out any information in any way whatsoever, howsoever reporting that Covid19 vaccines are effective;*
- 2.3 *forthwith cease and desist from inviting anyone to be vaccinated against Covid19;*
- 2.4 *forthwith cease and desist from administering and/or causing to be administered any Covid19 vaccine to any person of any age;*
- 2.5 *forthwith close all vaccination stations whose primary purpose is the administering of Covid19 vaccines;*
- 2.6 *forthwith close and caused to be closed all Covid19 vaccinations sections in all healthcare facilities in South Africa in the private and public sectors;*
- 2.7 *forthwith cease and desist from distributing and/or causing to be distributed any Covid19 vaccines to any vaccination station and/or person or entity regardless of whether such personal entity is the public or private sector;*
- 2.8 *forthwith cease and desist from approving any Covid19 vaccines for emergency or final use to children aged 5 to 11 years of age;*
- 2.9 *forthwith cease and desist from approving any Covid19 vaccines for emergency or final use to persons of any age group whatsoever;*

- 2.10 *forthwith cease and desist from funding, buying and procuring or supplying any Covid19 vaccines for emergency or final use to any age group whatsoever;*
- 2.11 *forthwith make a public announcement detailing the procurement to be followed by people who have suffered vaccine adverse events;*
- 2.12 *Within 48 hours of granting of this order comply with subparagraphs 2.1 to 2.11 above;*
- 2.13 *The Fifth Respondent shall forthwith be interdicted from availing any funds whatsoever or whensoever for purposes of acquisition of Covid19 vaccinations;*
- 2.14 *forthwith make public announcements about this order on all platforms in all languages regularly and their compliance with the terms herein for a period of no less of 14 calendar days ...*

Part B

1. *Compelling the Respondents to conduct detailed joint investigations into:*
 - 1.1 *The medical and scientific safety and efficacy of Covid19 vaccines being administered in South Africa as follows or any other where agreed to by the experts appointed:*
 - 1.1.1 *Directing the Second to Third Respondents to provide the Applicant with:*
 - 1.1.1.1 *50 vials of each different Covid19 vaccine previously and currently used in South Africa or intended to be used including but not limited to*

Pfizer, Pfizer Comirnaty, Johnson & Johnson and Moderna from batches identified and selected by the Applicants within 10 days from date of the order;

1.1.1.2 *Twenty PCR test kits from different batters identified and selected by the Applicants within 10 days from date of this order;*

1.1.1.3 *Directing the Respondents to appoint and identify experts within 30 days from date of this order in the fields of medicine, scientific exploratory investigation and research or experts specifically involved in the testing of vaccines for human use at the Respondents' costs;*

1.1.1.4 *To analyse and test the 50 vials of Covid19 vaccines and the 20 PCR kits referred to above in conjunction with experts to be appointed by the Applicants ...*

1.1.1.5 *Directing the Applicants and the Respondents to each identify 5 persons willing to participate that have been vaccinated and 5 persons that have not been vaccinated to submit themselves to life blood analyses...*

1.2 *The medical conditions self which are rare conditions being witnessed by doctors in South Africa as displayed by people who have been vaccinated against Covid19;*

- 1.3 *The deaths of otherwise healthy people in South Africa after been injected with the Covid19 vaccines;*
 - 1.4 *The appearance of and unexplained found in substances in the blood of vaccinated people in South Africa;*
 - 1.5 *The otherwise healthy young people who, after being injected with the Covid19 vaccines in South Africa display symptoms of myocarditis;*
 - 1.6 *The rare blood clots being witnessed by pathologists in the veins and arteries of vaccinated people in South Africa;*
 - 1.7 *Conflicts of interests among the personnel and/or entities who are in any way for whatsoever or howsoever responsible for or associated with Covid19 vaccines recommendation, promotion, marketing, procurement and administering in the private and public sectors in South Africa;*
 - 1.8 *Spike protein shedding from vaccinated people to the unvaccinated in South Africa;*
 - 1.9 *The administration of the vaccine injury compensation scheme in South Africa ...*
2. *Directing the Respondents:*
 - 2.1 *To disclose and identify all persons and/or entities in South Africa and internationally involving the approval procurement distribution and administration of Covid19 vaccines in South Africa;*

- 2.2 *Not to interfere in any way whatsoever, when so ever or howsoever in the operations of the Team of Experts in the establishment of the terms of reference of the investigations including but not limited to all the requirements needed for the investigations with specific requirements and details of the appointed investigation shall be discussed and determined by the joint experts;*
- 2.3 *That the Fourth Respondent forthwith issue a directive to all relevant parties that autopsies must be done in all bodies who died where:*
- 2.3.1 *the cause of death is expected to be a “Covid death”;*
- 2.3.2 *where the deceased was administered with a Covid19 vaccine at any time before the death...”.*

Certain ancillary relief relating to disclosure of records and costs were also claimed.

- [6] Apart from various objections raised by the various respondents against the relief which I deal with more fully hereunder, Adv. Benson in argument conceded that much of the relief was indeed overly broad. She however had instructions to persist and she argued that at least the relief set out in paragraphs 2.8, 2.10, 2.13 and 2.14 should be granted and if that relief is granted there would be no real need for the investigative processes contemplated in Part B to be implemented. In the alternative, should it appear that any of the relief in Part A cannot be granted due to a factual disputes disclosed by the papers, it should be postponed and the investigative relief mentioned in Part B should be granted whereafter the

questions related to the relief in Part A could be dealt with either by way of motion or by way of a referral to trial. I shall deal with these aspects and whether it was appropriate in circumstances of the case for the applicants to rely on the various alternatives proposed by Adv. Benson in the fashion that she did without committing themselves to a specific case which the respondents had to meet.

The applicants' case and evidence relied on

[7] Various "joint" practice notes were filed by the parties. From a reading of the applicants' papers, it appears that the most apposite summary of their case can however be found in the "joint" practice note delivered on behalf of the first-, second and third respondents, which summarized the applicants' case as follows:

"11.1.1 The applicants seek broad orders, interdicting and entirely halting the respondents' Covid vaccines programs and the closure of all vaccination sections in all healthcare facilities in South Africa, including the private and public sectors and the effective withdrawal from circulation of the vaccines;

11.1.2 The applicants also seek a consequential order interdicting the approval of vaccines for emergency or final use ..."

[8] A summary of the applicants' grounds for claiming the above is that they, together with some doctors in South Africa, have tried to draw the attention of the respondents to what they have labelled "strange and unusual medical conditions" which they have witnessed occurring in patients who had been administered Covid19 vaccines, but that the respondents were either unwilling or incapacitated to stop the vaccination program or to conduct any investigation into the consequences of the

administration of vaccination and that therefore the court should step in to achieve this.

[9] The applicants in general aver that there are otherwise healthy people who, after receiving the Covid19 vaccines, experience “unexplainable changes” to their blood cell structure or who have “unexplainable foreign substances” in their blood. The allegation is further that some children who have been vaccinated have had their health impaired thereby and have even died as a result of being vaccinated. The applicants also allege that there is no “logic” in administering vaccines to children with or without pre-existing medical conditions where “*damage to health is being witnessed in healthy people, young and old*”. The applicants claim that to safeguard the nation of South Africa, it is imperative to apply a precautionary rule and stop any vaccination.

[10] The first of the practitioners’ evidence relied on by the applicants is that of the deponent to the first founding affidavit. He is Dr De Wet Oosthuizen who conducts a private practice in Tongaat, KwaZulu Natal. The learned doctor (who is also a member of the first applicant) stated that since the introduction of Covid19 vaccines into South Africa he started noticing an increase in the number of his patients with medical conditions that he could “... *not quite relate to as a medical doctor*”. He witnessed symptoms which he had not previously seen in his 42 years of medical experience. The doctor stated that he was not witnessing the same medical “complications”, or at least not of the same magnitude in unvaccinated patients. The symptoms were described as “abnormal” flu-like symptoms and he contended that 70% of the patients who consulted him for various illnesses had either received vaccinations or were in close contact with people who had received vaccinations. The doctor referred

to a “Pfizer report” and a rough survey that he had conducted amongst colleagues in the medical profession. He contended that they had seen the same medical conditions “amongst the jabbed members of society” and concluded that 20 000 primary doctors in private practice or in clinics “*were on the verge of witnessing or have started on a catastrophic medical disaster of a magnitude never witnessed before in South Africa*”. The doctor further averred that he had submitted no less than 125 adverse events following immunizations reports to either the Department and/or SAPHRA without any meaningful response. He averred that of those reports that he have submitted only 33 “seem to have been officially logged” onto the American VAERS platform, being an international Vaccine Adverse Events Reporting System. The doctor also advocates for compensation for “vaccine injured people”.

- [11] The “Pfizer report” on which the doctor relies is apparently an internationally accessible “cumulative analysis of post-authorization adverse events reports” with reference no. FDA-CDER-2021-5683-0000054 entitled “*Cumulative analyses of post-authorization adverse events reports of PF07302048 (BNT162B2) received through 28 February 2021*” prepared by Pfizer itself. Although certain adverse events were listed in the report which might be of special interest, the conclusion was however that the available data confirmed a favourable benefit/risk balance for the vaccine under investigation. The findings of the detection analyses were consistent with the known safety profile of the vaccine and the report concluded that Pfizer will continue the routine pharmacovigilance activities in order to ensure patients safety.

- [12] In addition to the Pfizer report, the doctor relied on analyses conducted by a Dr Zandre Botha consisting of microscopic examinations of the blood of vaccinated patients.
- [13] Dr Zandre Botha has confirmed a report compiled by her by way of a confirmatory affidavit. She describes herself as a “*major scientific multidimensional health practitioner in private practice*” and she has a PhD in alternative medicine. Her speciality is live blood analysis. Dr Botha has performed blood analyses on patients who had received vaccinations and she concluded that she had observed abnormalities in the blood of such patients. Some of those abnormalities she describe as being severe rouleau, where red blood cells form aggregations which she concluded was suggestive of a patient with a chronic degenerative disease or advanced “endobiosis” and advanced colon, liver and small intestine damage. She also observed red blood cell rings, indicating high cortisol levels as well as schistocytes being fragmented red blood cells, mostly related to cardiac and vessel abnormalities. She also referred to other cell abnormalities but in particular observed “artifacts” which is a term used to denote objects that are inorganic. She described these as hereto before unseen dark crystals.
- [14] The applicants also placed reliance on a confirmatory affidavit deposed to by attorney Riekie Erasmus. She is the founding member and director of the first applicant. In her affidavit the learned attorney alleged that she had made an in-depth study of Covid19 since about July 2020 “*...as everything about it did not make sense to me...*”.
- [15] Listing a number of concerns, she concluded that “*the numbers of people dying unexpectedly is shocking, yet we only know of it from reports on social media. We hear of healthy family and friends dying all of a sudden,*

in their sleep, while strolling, cycling or relaxing. Strokes and heart attacks are given as a cause of death without any autopsy being done.” She further confirmed that she had “*participated*” in the drafting of the founding affidavit of Dr Oosthuizen and she confirmed the veracity of references to links made in his affidavit and agreed with his conclusions and opinions “*...and the other experts whose reports are attached to the application...*”

- [16] The attorney then annexed a number of further affidavits apart from that of Dr Zandre Botha and quoted references to two clients of hers, a Ms Oosthuizen and Mrs Oguz to whom the other practitioners also refer. She also relied on a “thesis” prepared by another attorney, Abbygail van Wyk (Lock) and a presentation of a psychologist, Dr Elise Kruger.
- [17] The next of the practitioners specifically relied on was Dr Herman Edeling. He is a neurosurgeon and he has presented a medico-legal report in respect of the aforementioned Ms Oosthuizen. Ms Oosthuizen is a doctor’s assistant and was previously a Dischem Senior Adviser. Both attorney Erasmus and Dr Edeling mentioned that they had Ms Oosthuizen’s permission to disclose her condition and particulars in their papers. Dr Edeling listed a number of pre-existing conditions and procedures relating to Ms Oosthuizen which he labeled “*unrelated*”. These included (in his summary) the following:

“Auto immune disorder – neuropathy – blood clotting disorder – connective tissue disorder – PTSD – diabetes – Addison’s disease – cardiac pacemaker – osteoporosis- CVA – epilepsy – migraine – sacral hemangioma and angiosarcoma – surgery and chemotherapy – colectomy – stoma – reversal of stoma.”

- [18] Dr Edeling diagnosed Ms Oosthuizen as suffering from a “*disabling post-vaccine syndrome*” and contended that any reasonable and suitably informed medical practitioner who had taken Ms Oosthuizen’s medical history into consideration would not have recommended her participation in the Johnson & Johnson Covid19 vaccination Sisonke trial. He labelled the administration of such vaccine wrongful “*...as she was at high risk for serious adverse events on the injection...*”
- [19] A further opinion relied on by the applicants was that of Mr S.J. Schmidt who is a gastroenterologist. He produced a report at the request of attorney Erasmus as a result of her own participation in the Sisonke trial although the report deals with the consideration of Dr Edeling’s diagnosis of Ms Oosthuizen. In particular, Dr Schmidt criticized the recruitment and enrolment and participation of Ms Oosthuizen in the Sisonke trial. He concluded that Ms Oosthuizen was incorrectly enrolled in the trial and that major protocol violations had been made by the study team. He further considered Ms Oosthuizen’s deterioration in her health and concluded that “*most*” of the adverse events she had suffered “*...are likely the result of the studied drug...*”
- [20] A further opinion on which the applicants sought to rely was that of Dr Rose-Innes who is also an alternative medicine practitioner. Dr Rose-Innes further stated that she is a “Chief Clinician with a PhD in alternative medicine”. She is in private practice in Pretoria North. The extent of her confirmatory affidavit is that she confirmed that she was “*on a daily basis dealing with patients complaining of ill-health since they had received one of the Covid19 vaccines.*” Based on her own research she has prepared a report which she has annexed to her affidavit bearing the heading *The Western Herbal Medicine Group*. The report expresses a criticism of

mainstream medical practitioners as being “...a panel of experts who do not know or understand allergies, vaccine ingredients and adverse reactions, also referred to as vaccine injuries.” She then furnished a brief exposition of various ingredients referred to in Pfizer, Moderna and Johnson websites. She concluded that patients who participated in clinical trials were not sufficiently and comprehensively informed of risks of possible adverse effects and questioned whether those companies who provide vaccines, the policy makers who make the vaccines available and persons who enforces vaccination accept “...the associated legal financial burdens and liability for adverse reactions and medical costs.”

- [21] The applicants also relied on the opinion of a medical practitioner from Mitchell’s Plain who questioned the efficacy of vaccines. This is a Dr Rapiti who calls the administration of the Covid19 vaccines “...a gross violation of the Nuremberg code”. Dr Rapiti was also of the opinion that those who received the vaccines could not have given informed consent as the possible adverse effects were not sufficiently explained.
- [22] The applicants also relied on the opinions expressed by a retired molecular biologist, Mr Hassang. He has also prepared a report in an affidavit form wherein he analyzed the presentations made to the relevant Parliamentary Portfolio Committee and other statements made by SAPHRA. These were particularly in respect of the annual performance plan of 2019 to 2020 and he expressed concern regarding what he labeled a conflict of interest between “big pharma” and SAPHRA, particularly as the latter is alleged to receive funding from various sources, including the Bill and Melinda Gates Foundation, the Clinton Health Access Initiative and Centers for Disease Control and Prevention.

[23] The second applicant relied on a statement by its founder. She is a Ms Mohamed who styles herself as a journalist, activist and admitted attorney residing in Kwa-Zulu Natal. The second applicant is a “*partner*” of the World Council for Health, being a coalition of 170 health focused groups and organizations “*all across the world*”. The second applicant had apparently launched an “*independent C19 shot reporting platform*” called SAVAERS (“*South African Vaccine Adverse Effects Reporting System*”) in May 2021. The object of the platform was to “*give a voice to victims and survivors*”, to enhance data transparency and to strengthen accountability. The second applicant, according to this founder, decided to become a co-applicant in this matter due to its perception of “*...the Government’s plan to enable the injecting of vulnerable 5 to 11-year old children with unnecessary, ineffective and risky C19 injections*”. She labeled these vaccines as “*devastating*” and “*debilitatingly*” acute with serious and chronic adverse effects and the Government is accused of employing censorship and ignoring people who need support treatments. She also claimed that there was a lack of a proper pharmaco vigilance system in South Africa and that conflicts of interests made blood safety evaluation impossible.

[24] The applicants also relied on similar opinions expressed by certain healthcare practitioners and a substantial volume of internet published articles. I find it unnecessary for purposes of this application to list all of these. Suffice it to say that all the applicants’ papers, including the affidavits, the annexures, the internet content referred to and articles, run to more than a thousand pages. In conclusion, the applicants’ contentions were that the vaccines are harmful, that the “*Government*” is not administering it in a responsible manner and that both it and SAPHRA cannot be trusted.

The respondents' case

[25] The respondents, as can be inferred from their respective citations, fall into three groups. The “*Government Respondents*” comprised of the President, the Minister and the ADG of the Department. SAPHRA as a regulatory authority comprised the second grouping and the National Treasury as the last of the respondents. The Government Respondents made common cause with and relied on the factual allegations made by SAPHRA. It is therefore apposite to commence a summary of the respondents' case with reference to the relevant evidence produced by SAPHRA.

SAPHRA's case

[26] The affidavit delivered on behalf of SAPHRA was deposed to by its Chief Executive Officer. His evidence departed from the premise that the applicants' attempt to prevent the Government from using vaccines to address the Covid19 pandemic was misguided and reliant on hearsay, speculation and inexpert opinion on issues of medical science. In addition, he argued that the disjunctive relief sought in Parts A and B of the applicants' notice of motion would undermine SAPHRA's role and responsibilities. He pointed out that this was not the first attempt by the applicants to stop the use of vaccines. He also raised the issue of non-joinder of Janssen Pharmaceuticals (Pty) Ltd and Pfizer Laboratories (Pty) Ltd as well as the initial non-compliance with Rule 16A.

[27] After raising the aforesaid issues, SAPHRA's Chief Executive Officer set out the statutory obligations of SAPHRA. Its primary objects are set out in section 2A of the Medicines and Related Substances Act¹ (the Act) medicines which are to “*provide for the monitoring, evaluation,*

¹ 101 of 1965

regulation, investigation, inspection, registration and control of medicines, schedule substances, clinical trials and medical devices, IVD's and related matters in the public interest."

[28] SAPHRA's functions are set out in section 2B of the Medicines Act and include "(1) SAPHRA must, in order to achieve its objects, ensure the efficient, effective and ethical evaluation or assessment and registration of medicines medical devices and IVD's that meet the defined standards of quality, safety, efficacy and performance, where applicable."

[29] Although unusual but deemed necessary in the circumstances, the deponent referred to an extract of a judgment by Kriegler AJA (as he then was) in *Administrator, Cape v Raats, Röntgen and Vermeulen*²: "Manifestly the Medicines 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

² 1992 (1) SA 245 at 245B - E

round it out detailed mechanisms for enforcement are created and ancillary measures are authorised." (emphasis added by the deponent)

- [30] SAPHRA further made the point that it was an organ of State as defined in section 239 of the Constitution and as such was bound by the provisions of the Constitution including the Bill of Rights. It was therefore required, together with other responsible organs of State, to comply with the obligations imposed by section 27 of the Constitution which includes the duty to ensure that available medicines meet the requisite standards of safety, therapeutic efficacy and quality. SAPHRA accepted that this duty in respect of Covid19 vaccines was not a trivial one.
- [31] Regarding the process of registration by SAPHRA it was stressed that SAPHRA's function is one of a regulator. It does not conduct its own research or develop its own medicines. It only consider medicines for registration upon applications that meet the requirements of the Medicines Act and in particular section 15(1) thereof.³ In addition, Regulation 16 of the general regulations promulgated in terms of the Medicines Act on 25 August 2017 describes long and detailed requirements for the application for registration of a medicine.⁴

³ "15(1) ... Every application for the registration of a medicine, medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by-
the prescribed particulars;
samples of the relevant medicines;
where the practicable, samples of medical devices or IVD's; and
the prescribed registration fee ...".

⁴ This regulation provides that all available safety data on the safety, efficacy and quality of the medicines as may be determined by SAPHRA must be furnished together with proof of existence of a manufacturing site and detailed particulars of the medicines including proposed proprietary name, dosage form, strength per dosage unit, route of administration, registration status outside the Republic and the approved name of each active pharmaceutical ingredient. In the case where a medicine is or was registered with any regulatory body outside the Republic, further details are required, including the conditions of registration and any other information as may be required by SAPHRA

- [32] In terms of section 15(3) of the Medicines Act, SAPHRA can only register a medicine if it is satisfied that the medicine is suitable for the purpose it is intended, complies with the prescribed requirements and is safe, efficacious and of good quality. A PowerPoint presentation previously made for the industry by SAPHRA highlighting the steps involved, was also annexed to the CEO's affidavit. In brief, the evaluation process involves a review of safety and efficacy data provided by a party seeking registration of a medicine, which includes a vaccine as well as a review of the evidence of the manufacturing quality of the medicine.
- [33] The evaluation is carried out by SAPHRA's technical and subject matter experts who were all qualified scientists with biological science degrees and Bachelors of Pharmacy, either in biotechnology, biochemistry, microbiology or affiliated disciplines. The evaluations are also carried out by external experts appointed by SAPHRA with wide ranging qualifications in fields such as virology, public health, epidemiology, haematology, microbiology, pulmonology, vaccinology and other qualifications in science. SAPHRA also considers reports for studies of other regulatory bodies across the world and the World Health Organisation in assessing the quality, safety and efficacy of the vaccines. This also involves an assessment of other analyses, pre-clinical laboratory research and human clinical trials data in order to determine the risks and benefits of the vaccines. In the present instance this also included a consideration of local epidemiology, specifically with SARS-COV-2 variants circulating in the country at the time.
- [34] The consideration of registration applications often, as in this case, included an assessment of evidence of how the vaccine was manufactured in compliance with good manufacturing practices (GMP). This was one by

an evaluation of the data related to manufacturing processes, including inspections of facilities, manufacturing process validation reports and inspection reports issued by other regulatory authorities. SAPHRA also pointed out that, in respect of the vaccines, the professional information (PI) and patient information leaflets (PIL) and the risk management plans were available on freely accessible links.⁵

- [35] SAPHRA also stressed that it was not unusual that a medicine or vaccine exhibited some side effects. Even a Schedule 0 medicine like Panado has a side effect profile but it was the severity and frequency of the side effects that was important in determining whether a medicine was safe or not.
- [36] SAPHRA conceded that in general, evaluation of medicines for registration or approval take some time, up to 20 months. It stated however that in response to the pandemic and in order to ensure that South Africa had all “*weapons*” available to fight the Covid19 pandemic, SAPHRA introduced a mechanism to facilitate the review of Covid19 applications, which was labeled a “rolling review process”. This created a mechanism that facilitated the submission of data as it became available. A media statement in this regard had been issued in July 2021 explaining that process. This did not detract from the evaluation of the vaccines against the applicable standards of safety, quality and efficacy.
- [37] SAPHRA mentioned that its approach was supported by evidence from other regulatory authorities such as the World Health Organisation, the European Medicines Agency and the United States Food and Drug

⁵ https://pi-pil-repository.saphra.org.za/wp-content/uploads/2023/Final_approved-PI_Comiranty-concentrate-for-dispersion-for-injection-28_deck_2022.pdf or https://pi-pil-repository.saphra.org.za/wp-content/uploads/2022-04-PI-approved_-_COVID-19-Janssen-suspension-for-injection-ZA-English-shelf-life-extension-transverse-myelitis-apr2022.pdf

Administration (FDA). The reports of these regulatory bodies were publicly available.⁶

- [38] SAPHRA made the point that the applicants have not explained why SAPHRA, or the Court, should not have regard to the evidence produced by the aforementioned expert bodies. All the evidence available from these bodies support SAPHRA's decisions. In addition, the evaluation process followed by SAPHRA in evaluating the vaccines had been found to be proper by a scientist, Professor Anton du Plessis Heyns who found that the evaluation process complied with SAPHRA, WHO and EU guidelines and procedures. I shall refer to Prof Heyns' opinion and his Curriculum Vitae later.
- [39] SAPHRA accepted that its role was also to ensure that members of the public are not harmed by medicines or vaccines which extend beyond scientific evaluation of safety efficacy and quality of vaccines which it approves. After the approval of a vaccine, SAPHRA activates its monitoring role in ensuring that the medicine or vaccine that it has approved continued to be efficacious and safe to the public. For this purpose SAPHRA monitors two types of events in relation to vaccines namely: "*Adverse Events Following the Immunization (AEFI)*" which refers to a medical event following immunization and "*Adverse Events of Special Interest*" (*AESI*) which refers to certain events that have been flagged by the World Health Organisation. For purposes hereof SAPHRA

⁶ https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf; <http://extranet.who.int/pqweb/key-resources/documents/recommendation-emergency-use-listing-covid-19-vaccine-janssen-submitted>; www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf; <https://www.fda.gov/media/150386/download>; <https://www.fda.gov/media/151733/download>; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attached_data/file/1112667/COVID19_mRNA_Vaccine_BNT162b2_UKPAR_PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf; https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1.

has established an adverse events reporting portal on its website.⁷ SAPHRA also requires each vaccine manufacturer to record and report side effects of the vaccines throughout the full cycle of the vaccine roll-out process including the submission of clinical data from ongoing studies to monitor the safety of the vaccines within timelines set out in approved risk management plans.

[40] In order to put the purported events into perspective, SAPHRA indicated that during the period of 17 May 2021 to 31 December 2022 (termed “the relevant period”) SAPHRA received a total of 7 546 AEFI reports made up of 5 989 AEFI reports in relation to the Comirnaty Pfizer-BioNTech doses (Pfizer) and 1 557 AEFI reports in relation to Covid19 vaccine Janssen doses (Janssen). The total number of Pfizer doses administered during the relevant period was 28 901 031 and the total number of Janssen doses administered during the same period was 8 622 339. The AEFI reports in relation to Pfizer therefore represented 0,0207% of all doses administered and in respect of Janssen the percentage was 0,0181% of all doses administered. For the period 17 May 2021 to 30 November 2022 a total of 37 523 370 doses of vaccine had been administered in South Africa and 232 reports of deaths among people who had receive Covid19 vaccines were received by SAPHRA and the National Immunisation Safety Expert Committee (NISEC). This represented 0,00062% of the administrated doses. Of these reported deaths, SAPHRA contended that only two turned out to be causally linked to the vaccines.

[41] Reports of serious and severe AEFIs and AESIs are investigated by a multi-disciplinary team from each relevant district or Province. Once all information had been gathered by such a team, NISEC conducted causality

⁷ AEFI – reporting.saphra.org.za

assessments to determine whether the event may have been caused by the vaccine or whether it was coincidental. NISEC is an independent Ministerial Advisory Committee which comprises of experts appointed by the Minister and which sits once a week. To date of the affidavit NISEC had conducted 436 causality assessments and the outcomes thereof showed that the majority of reported adverse events were not serious, could not be causally linked to the vaccines or were either coincidental, unclassifiable or due to underlying pre-existing conditions. SAPHRA provided a spreadsheet of the causality outcomes as an annexure to the affidavit.

- [42] In instances where NISEC had determined that an ASEI is causally connected with a particular vaccine, SAPHRA promptly evaluated the safety evidence of that particular vaccine in relation to the risks of severe adverse events and whether that exceeded the benefits of vaccination. In other words, a determination was made whether it could still be safe to continue with the administration of the vaccine and whether that would be beneficial to the public.
- [43] In relation to the appearance or prevalence of Guillain Barré syndrome (GBS) mentioned by the applicants, the appearance of this syndrome formed part of the cases reported to SAPHRA. GBS accounted for only 2 incidents of fatalities following vaccination with Covid19 Janssen vaccine. NISEC had conducted a causality assessment and found that the events reported in the vaccine recipients were consistent with the case definition of GBS and no other likely cause was identified at the time of illness. After review of available evidence on the safety of the vaccine SAPHRA determined that the benefits of the vaccine are outweighed by the very low risk of severe adverse events, including GBS.

- [44] In discharging its monitoring functions, SAPHRA also noted concerns expressed about cases of myocarditis and pericarditis reported in the United States and other countries after administration of the Pfizer vaccine Comirnaty. However, no causal relationship could be identified between the vaccine and the adverse events at the time.
- [45] In addition to the evidence of Professor Heyns, SAPHRA also relied on opinions expressed by a Professor Pohl and a Dr Msomi in response to the evidence presented by the applicants, in particular that of Dr Zandre Botha and the “*spike protein shedding*” referred to in an article by a Dr Robert Malone which was contained in one of the evidence references referred to by the applicants (but not supported by affidavit evidence).
- [46] In respect of Dr Botha, SAPHRA’s deponent pointed out that she did not hold herself out as an expert. She is not a medical doctor and has no qualifications in haematology. Although she has a qualification in alternative medicine she doesn’t explain what that degree means or where she obtained it. The blood analysis report presented by Dr Botha was criticized as having been obtained by an unreliable method. Although sensational, it was not a report by a pathologist and was not a peer reviewed scientific study.
- [47] In this regard Professor Pohl opined as follows in his expert opinion.⁸

⁸ Professor Pohl is a medical doctor and haematological pathologist. He holds the degrees MBChB and M Med (Haematology) which he obtained *cum laude*. In addition, he has a certificate of clinical haematology obtained in 2002 and he was the former head of the Department of Haematology at the University of Pretoria. He had undertaken post-graduate training at the Royal Marsden Hospital in London, Adenbrooks Hospital in Cambridge and the Department of Surgery at the University of Witwatersrand. He was a previous counsel member of the South African Society of Haematology, a member of the Scientific and Organising Committee of the Federation of South African Societies of Pathology and has furnished an extensive *Curriculum Vitae* indicating his research activities and academic publications spanned more than 2 decades.

- “5.2 *Dr Botha has made use of neogenesis systems live blood analysis. According to the company website, the training for confidence in this methodology is obtained through online training course lasting 12 weeks.*
- 5.3 *Neogenesis is not a gold standard in interrogating changes in the peripheral blood of a patient. The standard method to do is by means of a full blood count and peripheral blood film made from a finger prick or taken from an EDTA tube which is dried stained with a Romanowsky type stain and fixed. It is then examined under light microscope using ten XIP’s and 4X, 10X and 50X objectors.*
- 5.4 *The statements at times make no sense – such as the statements regarding “black matter”.*
- 5.5 *Dr Botha advances several possible diagnoses based on the images in her submission but she is not qualified to make a medical diagnosis.*
- 5.6 *No references are provided for any of the statements made in her notes.”*

[48] In similar fashion SAPHRA attacked the basis relied on by the applicants for demanding an investigation into “spiked protein shedding”. For this purpose, the applicant relied on views expressed by a Dr Robert Malone referred to earlier (of which no evidence but only internet references were

presented). SAPHRA's attack was based on an opinion expressed by Dr Nokukhanya Msomi⁹ who opined as follows:

- “8. *The Applicants also refer to the views of Dr Robert Malone. They do so to make the claim that vaccinated individuals can infect others in their vicinity through shedding of infectious material.*
9. *The assertion that vaccinated individuals shared infectious material and can cause infection in unvaccinated individuals is not factual. The mRNA vaccine only contains instructions to make spike protein and not infectious virus. There is no shedding of infectious virus.*
10. *Likewise, the Johnson & Johnson (also referred to as Janssen) vaccine is based on a replication-defective adeno virus, which means the adeno virus itself is incapable of reproducing.*
11. *Dr Malone's assertion that spiked protein shedding occurs following vaccination has also been checked and debunked.”*

[49] One of the other references contained in the applicant's vast referenced literature was a video clip of a Dr Sucharit Bhakdi. This has been circulated amongst what is called “*anti-vaxxers circles.*” Dr Msomi commented on this as follows:

- “5. *I have read and considered the aspect of the applicant's case that relies on the opinion of certain experts based in the United States of America. Their views cannot be regarded as scientifically credible.*

⁹ Dr Msomi is a medical doctor and a clinical virologist. Amongst other qualifications she holds the degrees MbCHB, FC Path (SA) (Viro), MMed (Virology); PhD and she is the Head of Department in the Discipline of Virology at the University of Kwa-Zulu Natal. She has also provided the Court with a confirmatory affidavit and an extensive Curriculum Vitae

6. *The applicants provide a link to a video by a Dr Sucharit Bhakdi. Dr Bhakdi is a retired Micro Biology Professor. His video has been fact-checked and debunked. I refer the court, for example to the following article: <https://healthfeedback.org-claim-review-unsubstantiated-claims-by-michael-Palmer-Sucharit-Bhakdi-don't-demonstrate-Covid-19-vaccines-harm-organs/>.”*

[50] In conclusion, SAPHRA states that there would be no irreparable harm to the applicants or their members or the members of the general public arising from the rollout of vaccines. No person, whether a member of the applicants or the public are compelled to take the vaccine. In contrast, should the interdict be granted, it would have an adverse impact on public health as the pandemic would not be kept in check through vaccination and it would expose vulnerable people to the risk of contracting Covid19. The granting of the interdict would be a violation of the right of access to healthcare services and those who wish to take the vaccine will not be able to do so which would also constitute a violation of the dignity of those who would be denied their choice of vaccination.

[51] Lastly, SAPHRA contended that the granting of an interdict would prevent SAPHRA from discharging its statutory and Constitutional obligations. Such relief would therefore be incompetent.

The Government Respondents' response

[52] The deponent to the Government respondents' answering affidavit was Dr Nicholas Crisp. He is the Deputy Director General of the National Department of Health. The Director General of that Department has delegated the authority of overseeing the Covid vaccination programme and the procurement of strategic pharmaceuticals to Dr Crisp. Dr Crisp has

confirmed that he is a medical doctor and a public health specialist with years of experience in health management consulting on the African continent and has attached an extensive Curriculum Vitae to his affidavit.

- [53] At the inception of their opposition the Government Respondents and Dr Crisp pointed out that the applicants' application had been preceded by two regulatory appeals and a previous interdict application. The first of the regulatory appeals was one launched by Free the Children in terms of section 28(A)(1) of the Medicines Act, against SAPHRA's decision dated 10 September 2021 authorizing the use of the vaccine known as Comirnaty Pfizer/BioNtech for use for children aged 12 to 18 years of age. This appeal has not been pursued to its conclusion and therefore an available alternate internal remedy has not been exhausted.
- [54] The second regulatory appeal was dated 24 February 2022, also by Free the Children, in terms of the same section of the Medicines Act and was against SAPHRA's decision dated 25 January 2022 to approve an application to register and/or issue a certificate of registration in terms of section 15 of the Act, also for the use of Covid19 vaccine known as Comirnaty including its use in children of any age. This internal remedy has also not been exhausted.
- [55] A previous interdict application was launched by the same three Applicants under case number 55070/2021 whereby the applicants also sought to interdict the then ADG from rolling out the Comirnaty vaccine. That application was postponed at the applicants' costs, including costs of two counsel in April 2022 and which application was subsequently withdrawn together with a tender for costs on 26 May 2022. The reason why Dr Crisp referred to the previous interdict application was because it contained much of the same allegations that have been made in the present

application, and that alternate remedy had not been pursued, but abandoned.

- [56] A further principal objection by the Government Respondents to the applicants' application, prior to dealing with the allegations of fact made therein, was that Part A and B were clearly sought disjunctive from each other despite the wording used in the notice of motion. The relief sought in Part A was not dependent on the relief sought in Part B, nor *pendente lite* thereof.
- [57] On the issue of non-joinder Dr Crisp makes the point that the grant of the interdict would manifestly directly and materially affect the interests of *inter alia* the manufacturers of the vaccines and for this reason, apart from the allegations of impropriety made against them, they should have been joined.
- [58] Dr Crisp also set out extensively why the initial application was not urgent by referring to the number of vaccines administered (which was at the end of January 2023 in excess of 38 million) and referred to various vaccination programmes of the Department initiated in collaboration with SAPHRA to oversee vaccines, safety monitoring and reporting of adverse events following immunization. As the matter was at the hearing thereof no longer dealt with on the urgent roll and, in order not unduly burden this judgment, I deem it unnecessary to deal with the issue of urgency.
- [59] The issue of statistics at the time that the answering affidavits have been deposed to, however go beyond the issue of urgency and are also relevant to the merits. The statistics available have been referred to above as part of SAPHRA'S case.

- [60] The latest statistics in respect of serious adverse events in respect of injury or deaths were that in addition to the two confirmed fatalities that were adjudicated to have been caused by the J&J vaccine, both from Guillain Barre syndrome, there was a third under review. The total number of serious injuries that have been assessed through a full investigation and the NISEC adjudication process and which have been found to be causally linked to the vaccine, were 44.
- [61] Regarding the causes of adverse events following vaccinations (AEFI), these stemmed from 5 broad categories as per the WHO classification. The categories could be found on <https://aefi-reporting.saphra.org.za/> and are vaccine product related reactions, vaccine quality effect reactions, immunization related reactions, immunization anxiety reactions and coincidental reactions or events.
- [62] The applicants have been accused of being aware of these statistics and outcomes and despite this they were accused of having not placed any credible scientific evidence before the Court to demonstrate that the use of the vaccine is unsafe and against the best interests of the public, including minors.
- [63] Dr Crisp also provided factual context to the Covid19 pandemic which, despite its partially historical nature, I deem apposite to summarize in order to assist with the evaluation of the applicants' contentions and for the benefit of the readers of this judgment. This is also necessary to put the applicants' accusations of a lack of concern by the Department into perspective.
- [64] Dr Crisp pointed out that South Africa, like the rest of the world, faced an unprecedented crisis caused by the Covid19 pandemic. This was as a result

of severe acute respiratory syndrome Corona virus 2 which was a previously unknown Corona virus. The virus, SARS-COV-2 caused the Covid19 disease. Its generic sequence was shared globally making it possible to test patients presenting with symptoms on a worldwide scale. The pandemic and especially its rapid rate of transmission resulted in a global health crisis, particularly due to the fact that Covid19 defied the existing body of scientific knowledge gleaned from pre-existing SARS-COV-2 viruses, such as the SARS virus which broke out in China in 2003 or the MERS virus outbreak in Saudi Arabia. The reason for this was that the Covid19 disease did not follow the expected behavioural patterns of viruses. Numerous new variants were also detected since the initial emergence of the virus. This included the Delta variant.

- [65] Age proved to be the greatest predictor of severe infection which was why South Africa first targeted the provision of the vaccines to older persons. Any immune compromised condition, however raises the bar so that any such individual would need repeated exposure to the antigen to mount a strong immune response. Cellular immunity occurs much later with further exposure to the antigen. The data showed a very high level of community immunity from a combination of vaccination and wild virus exposure.
- [66] In respect of Covid19, vaccine development evolved at an unprecedented pace and on an unprecedented scale. Dr Crisp illustrated this by way of the Department's Covid19 rollout strategies which involved a national rollout in close coordination with Provincial Health Departments and the private health sector.
- [67] Closer to the topic of the applicants' concern, namely administration of vaccines to minors, on 14 September 2021, the NICD published a report titled "Covid19 in Children's Surveillance Report". The report highlighted

statistics of the impact of Covid19 in the under 19 age group. The NICD reported in this regard that as of 28 August 2021, particularly as a result of the Delta virus, individuals under 19 made up 14,2% of SARS-COV-2 positive tests and constituted 4,7% of hospital admissions and 0.7% of Covid19 associated in-hospital deaths.

- [68] The NICD went on to note that the Covid19 disease in individuals below 19 years was more likely to be asymptomatic or mildly symptomatic and less likely to result in hospital admission compared to the disease in adults. There were still however concerns about the possible limited testing in children as well as concerns regarding possible transmission within and outside schools and other congregate settings. The under 19 age group constitutes just over a third of the population of South Africa and includes the entire compulsory school going age, considered to be 7 to 15 years.
- [69] As part of its decision that vaccines should also be administered to adolescents, the department also had regard to the views of prominent organizations in pediatric medicine. One example is the South African Pediatric Association who recommended that children at risk of severe Covid19 in the age group 12 to 17 be vaccinated. The WHO as a strategic advisory group of experts has also concluded that the Pfizer vaccine was suitable for use by people aged 12 years and above and that children aged between 12 and 15 may be offered the vaccine. Incidental to the clinical benefits that supported the rollout of the vaccine, the decision to vaccinate was also underpinned by ethical considerations. In terms of the Constitution, the State was obliged to put programmes in place to protect the best interests of the children. Insofar as the pandemic was concerned, Dr Crisp stated that this meant providing evidenced-based prevention and

early intervention programmes to protect children against severe illness from Covid19.

[70] In opposition to the applicants' attempts to interdict the rollout of vaccinations in respect of administrative decisions which had already been taken and which had not been reviewed or set aside, Dr Crisp attacked the nature of the evidence relied on by the applicants, querying its expertise. In broad terms he stated that the applicants' deponents lack both the qualifications and impartiality necessary to qualify as experts for the purposes of the application. In dealing with the pandemic, an expert in the management thereof would be a registered medical practitioner with specific expertise in either a combination of or at least the disciplines of virology, public health or epidemiology. None of the various deponents to the applicants' various affidavits were suitably qualified and therefore Dr Crisp asserted that their opinion evidence should be disregarded. A number of the sources cited by the applicants also form part of a worldwide disinformation campaign led by what is commonly known as "anti-vaxxers". I do not deem it necessary for purpose of this judgment to express judicial views on the criticism expressed by Dr Crisp in respect of the various campaigns and shall restrict myself to the issues of evidence.

[71] Dr Crisp dealt with the evidence of Dr De Wet Oosthuizen who had, as already mentioned, deposed the founding affidavit of Covid Care Alliance. From paragraph 30 of his affidavit Dr Oosthuizen dealt with the allegation that "*Since the introduction of Covid19 vaccines into South Africa I noticed that I was receiving patients with medical conditions that I could not quite relate to as a medical doctor.*" Dr Crisp responded thereto by complaining that these allegations are so obscure and abstract in their meaning as to be incapable of being meaningfully addressed. The same,

he said, applied to the symptoms which Dr Oosthuizen claimed to be “*unusual*”. Any trend which Dr Oosthuizen alleged existed was denied by Dr Crisp and he further denied any link between these unspecified symptoms and the administration of the vaccines. Similarly, the alleged “screening” of patients by Dr Oosthuizen could not be commented upon as no particularity of the screening procedure had been supplied. Dr Crisp therefore concluded that the applicants has failed to established that Dr Oosthuizen or anyone else on whose allegations the applicants rely, have done a proper, systematic, methodical test or analysis of the relationship between the Covid19 virus, the effects of the vaccination programme and the reporting of any adverse incidents that might have some connection or correlation between the administration of the vaccine and reported adverse events.

- [72] The applicants referred to a Pfizer report which they annexed to their founding affidavits. That document however runs to many pages and contains detailed, technical and specific data and there was no specification as to what part or which section of that report was questioned. There was also no evidence to support or corroborate the allegation that “*Pfizer had sought to withhold the document from the public for a period of no less than 75 years.*”
- [73] In respect of the issue concerning adverse events following immunization, Dr Crisp pointed out that such an event is any detrimental health event which happens chronologically after a person has received a vaccine. Such a health “event” is a symptom which in turn is something which a person experiences or of which a person complains, for example a headache or difficulty to see or something that a health practitioner observes in a patient, for example raised blood pressure. The health event may or may

not be caused by the vaccine and once such an adverse event has been reported using the Med Safety App, available for downloading from SAPHRA or the Department or the NICD website, the processes described by Dr Crisp and which I shall refer to herein later, are set in motion. These aspects are mentioned because Dr Oosthuizen referred to e-mail reports without having stated to which department of the Ministry it had been referred to or without furnishing detail thereof. Reporting to SAVAERS, which claims to be a public interest reporting system of transformative health justice, does not constitute proper reporting. The documents attached to Dr Oosthuizen's affidavit as an annexure run to over a 100 pages. They do not, however establish any link between the administration of the vaccine and any adverse event and the reason for that is because they've been completed in what Dr Crisp calls in a "*less than compliant manner*". To support this allegation, it is pointed out by Dr Crisp that on the forms Dr Oosthuizen compiled, no particular date of vaccination is indicated and there is no indication of the time of vaccination, batch lot or manufacturer of the vaccination. The particularity of the alleged adverse events is also absent. Some of the adverse events also appeared months after the alleged administration of the vaccine. These deficiencies in reportage are repeated during the remainder of the annexure. Many of the alleged supporting affidavits by patients contain inadmissible hearsay evidence indicating their own perception of the causes of health complaints.

- [74] Similar concerns have been raised in respect of the opinions expressed by Dr Zandre Botha. She is neither a pathologist nor a doctor. It is unclear, Dr Crisp says, what her qualification as a "*scientific multi-dimensional health practitioner*" encompasses. The contents of her affidavit also contain nothing more than argument by analogy. In particular, any similarity

between events which occurred at a particular food factory in South Africa and the Covid19 pandemic are denied. Similarly, any connection between the alleged swine-flu outbreak of 1976 and the nature of the Covid pandemic is denied.

[75] Insofar as Dr Botha attempted to establish a link between the virus vaccines and an alleged “*catastrophic situation, by way of reliance on ‘video evidence’*”, Dr Crisp argues that such evidence is both inadmissible and comes from biased and partisan sources. The Dr Malone referred to by the applicants is a known “anti-vaxxer” and his profile includes “*an embracing denial of vaccines*” which has been set out in an article, a copy of which has been produced by the respondents.

[76] Insofar as the applicants alleged that vaccination or monitoring of the pandemic is no longer required and that Covid19 no longer posed a public health risk, Dr Crisp stated the following:

“Presently, the Covid19 virus variant in South Africa is Omicron with several sub-variants circulating, notably BA.4 and BA.5. There were also instances of variant XBB.1.5 circulating in 50 countries and which has caused illnesses in the United States of America. Vaccines are effective in preventing severe infection but do not prevent transmission. Boosters given from time to time to remind the immune system of exposure to the antigen helps developing longer lasting immunity. Unvaccinated people therefore remain at risk and will definitely get Covid19 infections but they may now partly be protected by the level of community immunity”. For this reason, he mentioned that, given the number of people who have and will be infected with Covid virus, even a low incident mortality rate of less than 1% could translate into hundreds of thousands of deaths. This would particularly be so if the coordinated response to the Covid19 pandemic

would be halted. Dr Crisp contended that the allegations therefore that the mortality rate from Covid is low enough that no vaccines should be needed is not only misleading but callous in the extreme.

- [77] Dr Crisp also vehemently denied the allegation that no proper investigations into the effectiveness and safety of the vaccines have been conducted and that there is no provision for persons to consent to the vaccine. These statements are labeled “*untrue*” and “*vitriolic*” by him. In addition, he with equal vehemence disputed the so-called evidence which the applicants have attached in support of their assertion that the respondents are “*in the pockets of their funders*”. There not only is no evidence of this but the existence thereof was denied.
- [78] In respect of the alleged dire need to appoint a Commission of Enquiry (which was mooted in the papers but which did not feature specifically in Part B of the notice of motion), Dr Crisp denied the applicants’ allegations that vaccines have caused harm (and have killed) South African children under the age of 12. At the stage when these allegations were made, not a single vaccine had been administered to children in the under 12 age group.
- [79] The further allegation that “*protein shedding*” is a real thing and is caused by the administration of vaccines, has been denied as false science being presented under the guise of a “*pseudo medical veneer*”.
- [80] In respect of the affidavit of Riekie Erasmus, Dr Crisp pointed out that as an attorney she is not qualified to give opinion evidence on the merits of the application or of the efficacy of the vaccines. Her entire affidavit is labeled as being replete with hearsay and argumentative allegations and should be entirely struck out or disregarded. Insofar as allegations of fact had been attempted and with reference to consultation notes of Dr Kruger,

these have been made without any particularity and therefore cannot be specifically or scientifically investigated or responded to.

- [81] In respect of the medico-legal report of Dr Edeling, Dr Crisp opined that this report had, on the face of it, been prepared for use by the patient who is the subject thereof, Ms Oosthuizen, for litigation purposes or for purposes of receiving compensation from an administrative or regulatory body. Despite this, Dr Crisp denies that the report correctly indicated or established a causal link between the vaccine and a serious injury sustained from the administration thereof. The basis of the report contained other irrelevant allegations or opinion evidence which Dr Edeling was not qualified to give in regard to the efficacy of the Covid19 vaccination programme.
- [82] In respect of the report of Dr S.J. Schmidt, Dr Crisp also pointed out that it was also replete with irrelevant or uncorroborated hearsay evidence.
- [83] Dr Crisp also denied the evidential value of the "*live and dry blood analysis report*", prepared by Dr Zandre Botha, both in general and with reliance on SAPHRA'S evidence.
- [84] In respect of the affidavit of Maria Rose-Innes, Dr Crisp points out that she is not a qualified expert and not even a medical doctor. As an alternative medicine practitioner, her opinion should constitute impermissible evidence but in any event it had not been presented with reliance on any proper scientific investigations to support the conclusions reached by her.
- [85] In similar fashion Dr Crisp dealt with the affidavits of Dr Rapiti, Dr Olivier and Dr Van Rensburg. In respect of the affidavit of Mr Hassang, it was

pointed out that that affidavit contained scurrilous and vexatious falsehoods regarding the unspecified allegations that the Respondents were in the hands or the pockets of vaccine manufacturers. No evidence has been produced supporting these allegations.

- [86] In respect of the affidavit of Shabda Mohammed, which runs over some 269 pages of irrelevant and tendentious argument, Dr Crisp pointed out that no reliance could be placed thereon, due to the nature of the vitriolic content and the lack of factual particularity. As an example, Dr Crisp refers to paragraph 70 of the affidavit where Ms Mohammed says that she has discovered that SAPHRA “*is covering up*” her discoveries with “*false statistical data*”. The fact that no vaccines have been administered to children in the age group 0 to 11 years old, indicate that Ms Mohammed’s allegations of cover-up of data regarding administration of such vaccines is devoid of a factual basis. The applicants have also referred to affidavits of a Mr John Taylor and a Ms Abigail van Wyk, which I have not referred to above as these merely confirm the affidavits of other vaccine deniers and Dr Crisp states that the contents thereof are irrelevant and incorrect.

Evaluation

- [87] As can be seen from the summaries and extracts from the evidence presented by the parties, the Court was faced with a vast volume of documents, some referred to in passing by the applicants and some incorporated by reference only but without specification. This is an improper form of litigation¹⁰. I shall attempt hereunder to distill the

¹⁰ See: *Swissborough Diamond Mines (Pty) Ltd v. Government of the Republic of South Africa* 1999 (2) SA 279 (TPD) at 323F-G.

conclusions reached based on all of the above, including the arguments presented, both in writing and orally, on behalf of the parties.

- [88] It is accepted that there are members of the public who had received vaccinations and either experienced adverse health events or symptoms which they perceive were related to or caused by the administration of vaccines. The respondents have not denied this. The denial is however that, despite those linked instances referred to by SAPHRA'S Chief Executive Officer and Dr Crisp, no causal link between these symptoms or adverse events and the administration of the vaccine leading to the catastrophic events alleged by the applicants have scientifically and medically been found to exist. Insofar as there had been "*vaccine related*" deaths, these were in such a miniscule percentage of a total administered vaccines, that they can rightly be labeled "*extremely rare*". It is clear from the bulk of evidence that the benefits of administering vaccines and obtaining community immunity by far outweigh those instances of adverse events.
- [89] What is also of great importance, is that none of the rollout programmes for the administering of vaccines proposed by the Government respondents are mandatory or compulsory. No-one is forcing any person or any parent of a minor to receive further vaccines or to subject children to vaccination. This alone is a fatal defect in the applicants' application. But the issue of having vaccines available goes further, the point is well made that, should any interdictory relief be granted in respect of the applicants' application, that would deny those members of the community who would wish to exercise their own rights of access to healthcare and bodily integrity from opting for vaccination. The applicants have no right to do so.
- [90] In respect of any of the relief which might impact on the sale, supply or distribution of vaccines by any named manufacturer, it is clear that those

manufacturers have a direct and substantial interest in any such interdictory relief. To have not joined them as parties result in a fatal non-joinder. In addition to the direct consequences of the interdictory relief sought by the applicants, various allegations of an extremely serious nature have been made against certain vaccine manufacturers and it is manifestly unfair and against all principles of *audi alteram partem* to not have joined those manufacturers to the application. That non-joinder had denied them the right to deal with these accusations and this also amounts to a fatal non-joinder.

[91] In adjudicating the factual allegations on which the applicants sought to rely for interdictory relief which is to a large extent final in nature, those allegations must be dealt with in accordance with the trite principles encompassed by the *Plascon-Evans* rule¹¹. In short, this rule provides that in applications for final interdictory relief, an applicant can only secure relief if it would be entitled thereto based on the factual versions disclosed by the respondents to such an application together with the allegations of the applicants which had not been denied. In the present instance, each and every allegation or conclusion made by the applicants that the administration of vaccines have led and will lead to catastrophic medical consequences for a vast number of recipients, have been denied on a number of levels, least of which is that the alleged expertise relied on by the applicants are of such a nature that they constitute inadmissible opinion evidence.

[92] The position regarding opinion evidence is that, subject to certain exceptions, it is inadmissible¹². One of the exceptions is an opinion

¹¹ After *Plascon Evans Paints Ltd v Van Riebeeck Paints (Pty) Ltd* 1984 (3) SA 623 (A).

¹² Zeffert & Paizes, *The South African Law of Evidence*, 2nd Ed, at 309.

expressed by an expert. The reason why such an opinion would constitute admissible evidence would be when a person, by reason of his or her special knowledge and skill is better qualified to draw inferences from certain facts or tests or analyses conducted by such a person¹³. “Knowledge” or “skill” in this context would refer to medical and scientific qualifications and experience in dealing with matters relating to vaccinations administered to prevent the spread of a particular disease.

[93] Our courts have identified three functions performed by expert witnesses. These are (1) to give evidence of facts they have observed, (2) to provide the court with abstract or general knowledge concerning their discipline that is necessary to enable the court to understand the issues arising in litigation and (3) to give evidence concerning their own inferences and opinions on the case and the grounds for drawing those inferences and expressing those conclusions¹⁴.

[94] Of particular importance is the fact that the opinion of an expert must be based on a correct observation and interpretation of underlying facts and that it must assist the court in adjudicating a matter¹⁵.

[95] It goes without saying that even an experts’ opinion evidence should be reliable. Therefore it is part of the function of a court in weighing up such evidence that it has to determine whether the “expert” expressing such opinion has the necessary qualifications and experience to enable him to express reliable opinions. A general medical practitioner would, for example not be qualified to speak authoritatively on the significance of

¹³ See: *P v P* 2007 (5) SA 94 (SCA).

¹⁴ *JA obo DA v MEC for Health Eastern Cape* 2022 (3) SA 475 (ECB)

¹⁵ *R v Vilbro and Another* 1957 (3) SA223 (A) and *Gentrico AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 616H.

findings or the validity of opinions expressed in specialised fields of medicine by those who are qualified in those fields and practice therein¹⁶.

[96] Courts frequently have to weigh up competing expert opinions against each other. This matter is an example of such an instance. The conflicts or disputes indicated in the reports or opinions of experts generally fall in the following categories: (1) disputes about assumed facts, (2) differences of analyses and inferences from established facts, (3) competing scientific theories and (4) accepted professional standards of conduct¹⁷.

[97] In the present instance, the qualifications and knowledge of the experts relied on by the applicants have seriously been placed in doubt. They appear to be either general practitioners or not suitably qualified in the specialised fields of medical science required to express opinions the subject matter, principally viruses, vaccinations and blood analysis. In some instances, such as the founder of the first applicant, evidence by a lay person (an attorney) in the field of science and medicine was tendered. There are also grave doubts about the factual bases for the applicant's conclusions and their research methodology. Even if one were to ignore the accusations of possible bias as a result of some of the applicants' witnesses clearly aligning themselves with so-called "anti-vaxxers" here are abroad, their opinions, if not unreliable, are not as weighty as those of the experts produced by the respondents. I therefore accept the expert opinions relied on by the respondents and reject those relied on by the applicants.

[98] Apart from the lack of proper or admissible evidence, the applicants' case for interdictory relief suffers from further deficiencies. It is trite that, in

¹⁶ *Mahomed v Shaik* 1978 (4) SA 523 (N).

¹⁷ *JA obo DA v MEC for Health, Eastern Cape* 2022 (3) SA 475 (ECB)

order to succeed with final interdictory relief, a party must demonstrate a clear right, an act of interference with such a right and that the party has no other remedy¹⁸.

[99] I have already indicated that the applicants do not have the right to prevent others who do not share their beliefs or opinions from being vaccinated. Insofar as the applicants claim that they have a right to protect others, such as minors, it has not been established that the harm which the applicants aspire to prevent, actually exists and even if it may exist in rare or exceptional cases, the benefit of vaccination far outweighs that harm. There is therefore no “interference” which justified any protection by the applicants or by way of a court order. Section 38(d) of the Constitution has therefore not been satisfied¹⁹. Should the applicants otherwise wish to have vaccinations deregistered and thereby prevent their use in the country, they have the alternate remedies available to them in terms of the Medicines Act which remedies they have not pursued on exhausted. Having regard to the nature of the relief sought, despite the initial wording thereof, it is in substance final and not interim²⁰. The applicants have therefore not satisfied the requirements for the relief sought in Part A of their notice of motion.

[100] In respect of Part B of the relief claimed by the applicants, the usurping of the role of SAPHRA and NISEC would not only undermine their statutory obligations but would also cause the court to cross the line delineating the separation of powers. That cannot be permitted. At some stage, the

¹⁸ Prest, *The Law and practice of Interdicts*, Chapter Four.

¹⁹ Section 38: “Anyone ... has the right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened ... The persons who may approach a court- are ... (d) anyone acting in the public interest ...”

²⁰ See: *Gool v Minister of Justice* 1955 (2) A 682 (CC) subsequently considered in *Tshwane City v Afriforum* 2016 (6) SA 279 (CC) and *National Treasury v Outa* 2012 (6) SA 223 (CC) at par 41

appointing of a commission of enquiry was proposed as an alternative but that, of course, is the prerogative of the President. A claim for such relief need only to be stated to indicate that the applicants have no right in law to such relief.

[101] It follows that the application, both in respect of the relief claimed in Parts A and B, must fail.

Costs

[102] All of the respondents have argued that the applicants' application was from the start unmeritorious and that, having regard to the manner in which the applicants and their various deponents have expressed their claims to stop vaccination, the application was vexatious and relied on scurrilous and unfounded accusations. Not only did the respondents claim a costs order in their favour but argued that a Court should order such costs to be on a punitive scale.

[103] On the other hand, the applicants claimed that they were acting *bona fide* and out of care and concern for members of the public, including minors and that the issues raised impacted on Constitutional rights²¹. They should therefore not be mulcted with costs and the *Biowatch* principle should be found to be applicable²².

[104] It is trite that the award of costs is in the discretion of the Court. Whilst I agree with many of the accusations leveled against the applicants' deponents by the respondents, I still gained the impression that there may be a large number of the applicants' members who might be anti-vaxxers out of genuine concern and who may be *bona fide*. In addition hereto, the

²¹ They did so by broadly alleging that their case is covered by the provisions of section 38(d) of the Constitution.

²² After *Biowatch Trust v Registrar of Genetic Resources* 2009 (6) SA 232 (CC).

application has ventilated issues which have been in the public domain and which may have concerned a large number of members of the public. Even if the relief sought might not have been in the public interest, the ventilation of the issue was.


[105] However, the manner in which the applicants have conducted their litigation, including the vague approach to both the relief sought and the manner in which evidence had been presented, caused difficulties for the respondents in discerning exactly what the case is that they have to meet. It also presented difficulties for the court in dealing with the matter and its alleged Constitutional implications, to such an extent that a departure from the *Biowatch* principle is merited. It is impermissible for a litigant to deploy a “shotgun approach” and, upon being unsuccessful in hitting a target, hide behind the shield of Constitutionality allegations.

[106] Despite the manner in which the applicants have launched their application, justifying a costs order against them, I find that the award of punitive costs is not merited but that costs should otherwise follow the event in accordance with the general rule, on a party and party basis. The applicants should also have foreseen the extent of the litigation and the justification of the employment of multiple advocates, including senior counsel. This should be reflected in the cost order.

Order

[107] The following order is made:

The application is dismissed with costs, including the costs of senior and junior counsel, where employed.


N DAVIS
 Judge of the High Court
 Gauteng Division, Pretoria

Date of Hearing: 4 September 2023

Judgment delivered: 27 February 2024

APPEARANCES:

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