REPUBLIC OF SOUTH AFRICA

IN THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION, PRETORIA

CASE NO.: 2025 - 051503

(1) REPORTABLE:NO
(2) OF INTEREST TO OTHER JUDGES: NO
(3) REVISED: NO

Date: 7 May 2026 E van der Schyff

In the matter between:

UNICIRC (PTY) LTD	**APPLICANT**
and	
MINISTER OF FINANCE	**FIRST RESPONDENT**
DIRECTOR GENERAL: NATIONAL TREASURY	**SECOND RESPONDENT**
CHIEF PROCUREMENT OFFICER: NATIONAL TREASURY	**THIRD RESPONDENT**
CHIEF DIRECTOR: TRANSVERSAL CONTRACTING, NATIONAL TREASURY	**FOURTH RESPONDENT**
MINISTER OF HEALTH	**FIFTH RESPONDENT**
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, GAUTENG PROVINCIAL GOVERNMENT	**SIXTH RESPONDENT**
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, KWAZULU-NATAL PROVINCIAL GOVERNMENT	**SEVENTH RESPONDENT**
PROVINCIAL MINISTER OF HEALTH AND WELLNESS, WESTERN CAPE GOVERNMENT	**EIGHTH RESPONDENT**
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, EASTERN CAPE PROVINCIAL GOVERNMENT	**NINTH RESPONDENT**

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTHERN CAPE PROVINCIAL GOVERNMENT **TENTH RESPONDENT**

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTH WEST PROVINCIAL GOVERNMENT **ELEVENTH RESPONDENT**

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, FREE STATE PROVINCIAL GOVERNMENT **TWELFTH RESPONDENT**

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, LIMPOPO PROVINCIAL GOVERNMENT **THIRTEENTH RESPONDENT**

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, MPUMALANGA PROVINCIAL GOVERNMENT **FOURTEENTH RESPONDENT**

MINISTER OF DEFENCE AND MILITARY VETERANS **FIFTEENTH RESPONDENT**

CIRCUMQ IP (RF) (PTY) LTD **SIXTEENTH RESPONDENT**

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JUDGMENT

VAN DER SCHYFF J

Introduction

[1] The applicant, Unicirc (Pty) Ltd ("Unicirc"), seeks the review and setting aside of the decision by the National Treasury to award tender RT35-2023 — being a Transversal Term Contract for the supply of a surgical assist device to be used in the provision of voluntary medical male circumcision ("VMMC") services — to the sixteenth respondent, CircumQ IP (RF) (Pty) Ltd ("CircumQ"). The award was made on 20 April 2023 and communicated to CircumQ on 20 August 2023.

[2] The application is brought in terms of section 6(1) of the Promotion of Administrative Justice Act 3 of 2000 ("PAJA"), alternatively under the principle of legality. Unicirc contends that even if the impugned decision does not constitute administrative action, it nonetheless constitutes an exercise of public power reviewable for lawfulness, and for both substantive and procedural rationality. Unicirc seeks to impugn that award notwithstanding the common cause fact that Unicirc neither submitted a bid nor participated in the tender process in its own name.

[3] I pause to note that it was not disputed that the award of the tender constituted an administrative action.

[4] The National Treasury opposes the relief sought and raised two preliminary points *in limine* for determination:

(a) *Locus standi*: Whether Unicirc has the requisite legal standing to challenge a procurement process in which it was not a direct participant; and

(b) Non-joinder: Whether Unicirc has failed to join a necessary party with a direct and substantial interest in the outcome of these proceedings.

[5] A further interlocutory issue raised concerns the admission of additional affidavits. Following the filing of Unicirc's replying affidavit, the National Treasury applied for leave to file a supplementary answering affidavit. While Unicirc initially opposed this, it subsequently sought leave in February 2026 to file a further affidavit of its own, which the National Treasury in turn opposed. On 9 March 2026, the Minister of Health, who had previously indicated an intention to abide by the court's decision, belatedly filed a notice of opposition to Unicirc, submitting a further affidavit. This was followed on 10 March 2026, the day of the hearing, by the filing of an unsigned answering affidavit, with a signed version served later that day. Unicirc vigorously opposed the admission of the Minister's affidavit.

[6] Without determining the merits of the respective objections to these late filings, I directed that the main application proceed to argument, subject to the following procedural directions: (a) Unicirc is granted leave to file a further replying affidavit by

3 April 2026; and (b) all parties are permitted to file supplementary heads of argument by 17 April 2026, a date settled by agreement, specifically addressing the admissibility of the Minister of Health's belatedly filed affidavit.

[7] A further issue not fully ventilated by the parties, but addressed by Unicirc in its founding affidavit, is the effluxion of time between the impugned decision and the institution of these review proceedings. The tender award was made on 20 April 2023, but only communicated to CircumQ on 20 August 2023. Unicirc contends that it only became aware of CircumQ's appointment as the successful bidder some 13 months later. It is Unicirc's further contention that the reasons for the award were only furnished on 10 December 2024, affording it until early June 2025 to institute proceedings. On Unicirc's version, the application was launched well within the prescribed time. Unicirc's contention was not disputed by the National Treasury.

[8] On the merits, and in its supplementary founding affidavit filed after receipt of the record, Unicirc contends primarily that the record discloses that CircumQ's bid ought to have been disqualified for non-compliance with the special conditions of the contract, and secondly, that the safety and efficacy of the CircumQ device have not been established. Of particular concern is the absence of testing of the device on boys aged 10 to 14 years, notwithstanding that this age cohort constitutes a primary target demographic of voluntary medical male circumcision programmes in South Africa.

[9] Unicirc raises the following grounds of review:

(a) Section 6(2)(b) of PAJA, in that the National Treasury was precluded by the Special Conditions of Contract ("SCC" or "special conditions") from making the award:

(i) in respect of a device that is neither prequalified by the World Health Organisation ("WHO"), nor in the process of being prequalified; or properly classified as a class B medical device; or

(ii) in circumstances where the scope of the ISO certificate relied upon is limited to '*In-Vitro Diagnostic Tests for Fertility, Drug abuse and Infectious Diseases*' and does not extend to any other medical devices, including circumcision devices; or

(iii) where the South African Health Products Regulatory Authority ("SAHPRA") licence relied upon does not authorise the importation or distribution of a class B device such as the CircumQ device.

(b) Section 6(2)(d), in that the decision to award the tender for the surgical assist device was materially influenced by at least two errors of law:

(i) the technical requirements relating to WHO prequalification could not properly be assessed without a thorough interrogation of key documents submitted as part of CircumQ's bid, including the Technical Advisory Group ("TAG") report; and

(ii) the tender could not be awarded in respect of a surgical aid in respect of which the WHO confirmed that there is inadequate evidence of safety in adult males, and that there is no evidence of safety in boys aged 10 to 14.

(c) Section 6(2)(e)(iii), in that the National Treasury failed to take the following relevant considerations into account:

(i) the absence of relevant clinical trial data establishing that the CircumQ device is suitable for its primary intended purpose, namely the circumcision of boys aged 10 and above, having regard to both efficacy and safety;

(ii) the risk of harm, including irreparable harm, to boys aged 10 to 14 arising from the use of an unproven surgical aid;

(iii) the risk to the circumcision programme as a whole, and to the broader HIV prevention programme, should boys be harmed as a result of such use.

(d) Section 6(2)(e)(iii), in that the National Treasury took irrelevant considerations into account, such as CircumQ's mere submission of an application for WHO prequalification, unsupported by any evidence that approval was imminent or forthcoming.

(e) Section 6(2)(f)(ii)(cc), in that the impugned decision was not rationally connected to the information placed before the National Treasury, which indicated that:

(i) there was no scientific basis to suggest, let alone establish, that the CircumQ device is suitable for the circumcision of boys aged 10 and above;

(ii) the ISO certificate relied upon by CircumQ is limited to "*in Vitro Diagnostic Tests for Fertility, Drug abuse and Infectious Diseases*" and does not extend to any other medical devices, including, in particular, circumcision devices; and

(iii) the SAHPRA licence relied upon does not authorise the importation or distribution of a class B device such as the CircumQ device.

(f) Section 6(2)(h), in that the award of the tender to CircumQ in these circumstances was unreasonable.

[10] Unicirc throughout contends that 'the evidence unequivocally shows that the use of the CircumQ device places boys aged 10 to 14 at risk of serious harm, including irreparable harm'.

Unicirc's standing

[11] The National Treasury advertised a Transversal Term Contract for the provision of voluntary medical male circumcision services and the supply and delivery of surgical aids to the Department of Health for a period of 36 months.

[12] It is common cause that Unicirc did not participate in the tender process in its own name. A bid was submitted by an entity styled Access Medical (Pty) Ltd. ("Access Medical"), which intended to utilise a medical male circumcision device supplied by Unicirc. Access Medical was, however, disqualified at the technical evaluation phase for failing to provide WHO pre-qualification documentation or evidence of a pending application in respect of the device.

[13] Unicirc seeks to bridge this gap by contending that Access Medical acted as its agent. This averment is unsubstantiated. No agency agreement, power of attorney, or confirmatory affidavit from Access Medical has been produced. Unicirc has also failed to disclose when Access Medical was informed of the award to CircumQ, a fact it should have been aware of if Access Medical acted as its agent. This is a material omission given its bearing on the timeline of these proceedings. The replying affidavit further undermines the agency's contention, stating:

> "Without Unicirc's consent, Access Medical has no skin in the game. For reasons that needn't be explained here, Unicirc has decided not to rely on Access Medical in any potential future tender for the provision of a surgical aid. In such circumstances, Access Medical has no direct and substantial interest in the subject matter of this application."

[14] This contention is legally irreconcilable with a claim of agency. There is a clear legal distinction between a principal-agent relationship and a commercial arrangement in which a bidder intends to source a product from a third-party supplier. Where the bidder is unsuccessful, the supplier's interest is purely commercial and indirect; it does not, without more, translate into a legal right to impugn the administrative process.

[15] Unicirc further asserts its own-interest standing on the basis that, should the tender be set aside, it would be well-placed to participate in a fresh procurement process. In support of this prospective interest, Unicirc relies on *WDR Earthmoving Enterprises v Joe Gqabi District Municipality (WDR Earthmoving),*[1] and *Proxa South Africa (Pty) Ltd v Trans-Caledon Tunnel Authority (Proxa).*[2]

[16] In my view, this reliance is misplaced. In both *WDR Earthmoving* and *Proxa*, the litigants were unsuccessful bidders who had actually participated in the impugned processes, and their interests were accordingly direct and immediate. Unicirc, as a non-participant, occupies a different position, more properly governed by the principles articulated in *Giant Concerts CC v Rinaldo Investments (Pty) Ltd* (*Giant Concerts*).[3]

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[1] [2018] ZASCA 72 at paras 15-17.
[2] [2024] ZAGPPHC 932 at para 68.
[3] 2013 (3) BCLR 251 (CC).

[17] *Giant Concerts* held that, while a court must assume the challenge to the lawfulness of the tender is well-founded,[4] this does not grant an own-interest litigant an "unqualified capacity" to litigate against illegalities. To escape the characterisation of an "interloper", the litigant must demonstrate that its interests are directly affected by the challenged conduct.[5] Courts do not adjudicate abstract or hypothetical issues at the instance of a party whose interest is merely peripheral.[6]

[18] Unicirc has failed to demonstrate a direct interest beyond being the supplier of a device used for similar medical procedures. It has provided no clarity on its contractual relationship with Access Medical or on the terms of its arrangement with its sister company, the manufacturer of the device in question. Its interest accordingly remains a secondary financial expectation. A party cannot claim own-interest standing merely because it might have derived financial benefit from a contract awarded to a third party.

[19] I am alive to the observation of Cameron J in *Giant Concerts*,[7] that a commercial interest in the subject-matter of the transaction will be sufficient to establish own-interest standing to challenge it. However, Unicirc has furnished scant particulars regarding any prospective participation in the hypothetical event that a fresh tender is called. It asserts that it would submit a bid, but does not explain how it would do so, with whom, if anyone, or on what basis it contends that a new tender would in fact be issued. Its stated interest accordingly remained hypothetical.

[20] While the threshold for own-interest standing under the Constitution is broad, it is not limitless. Just as the law of delict distinguishes between factual and legal causation to prevent indeterminable liability, the law of standing must distinguish between a direct legal interest and a remote economic consequence. A supplier's loss of prospective profit arising from the rejection of a potential customer's bid is insufficient, without more, to bestow *locus standi.*

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[4] Id at para 32.
[5] Id at para 41.
[6] Id at para 37.
[7] Id at para 51.

[21] This is, however, not the end of the *locus standi* enquiry. Unicirc further contends that it acts in the public interest. The Constitution has fundamentally transformed the approach to standing in favour of a more expansive, value-based approach. As Cameron J observed in *Giant Concerts*:

> "[T]he interests of justice under the Constitution may require courts to be hesitant to dispose of cases on standing alone where broader concerns of accountability and responsiveness may require investigation and determination of the merits. By corollary, there may be cases where the interests of justice or the public interest might compel a court to scrutinise action even if the applicant's standing is questionable. When the public interest cries out for relief, an applicant should not fail merely for acting in his or her own interest."[8]

[22] While this broad approach is a cornerstone of our constitutional jurisprudence, it does not dispense with the requirement that the interest asserted must be real, and not merely hypothetical or academic.[9] Public interest standing is not a procedural bypass for litigants who fail to establish own-interest standing by reason of their non-participation in a process. An applicant relying on public interest standing must make out a case that the relief it seeks is motivated by a genuine intention to benefit the public at large or a segment thereof, and not primarily to advance its own interests, notwithstanding that such interests may incidentally be served.[10] The existence of a commercial interest in the subject matter of a review application, whether direct or indirect, does not, without more, disqualify a litigant from acting in the public interest; the inquiry is whether the litigation is genuinely grounded in public interest considerations. An applicant relying on public interest standing must further allege that a right in the Bill of Rights has been infringed or threatened,[11] not necessarily that the rights of the public have been violated, but that the public has a sufficient interest in obtaining the relief claimed.[12]

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[8] Id at para 34.
[9] Id at para 37.
[10] With recognition to the South African Law Reform Commission in its *Report on the Recognition of Class Actions and Public Interest Actions in South Africa* , Project 88, August 1998 para 2.2.1 as quoted in Harms "Civil Procedure: Lower Courts" in *LAWSA* 3 ed (2024) vol 5(1) at para 112 – Actions in the public interest.
[11] Section 38 of the Constitution of the Republic of South Africa, 1996.
[12] *Ferreira v Levin; Vryenhoek v Powell* 1996 (1) SA 984 (CC) at para 168; Freedman *et al* "Constitutional Law: Bill of Rights" in *LAWSA* 2 ed (2012) vol 5(4) at para 44.

[23] As affirmed by the Constitutional Court in *Lawyers for Human Rights v Minister of Home Affairs,*[13] a distinction must be drawn between the subjective position of a person or organisation claiming to act in the public interest and whether it is, objectively speaking, in the public interest for the particular proceedings to be brought.

[24] In making this determination, a court considers all relevant factors, including the degree of vulnerability of those affected, the nature of the said right implicated, and the consequences of its infringement.[14] In his minority judgment in *Lawyers for Human Rights,* Madala J added that the egregiousness of the conduct complained of is a further relevant consideration.[15] The list of relevant factors is not closed.

[25] Importantly, standing is an *in limine* issue, and the court is not at this stage required to determine the merits of the review. It would be sufficient, as *Giant Concerts* confirms,[16] if Unicirc's complaints about the lawfulness of the tender process are justified on the papers. The enquiry of standing is divorced from the substantive merits of the case.

[26] Unicirc alleges that the use of the CircumQ device poses a risk of serious harm to boys aged 10 to 14, and to the credibility and viability of the circumcision programme in the context of HIV prevention. This potentially affected group constitutes a vulnerable class unlikely to approach the court directly. The allegations implicate public health, bodily integrity, and, in particular, the paramountcy of the best interests of the child.

[27] It is accepted for purposes of the *locus standi* inquiry that Unicirc has demonstrated sufficient involvement in the field of male circumcision and possesses the requisite technical expertise to be well-placed to raise concerns relating to the safety and efficacy of circumcision devices within public health programmes.

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[13] 2004 (4) SA 125 (CC) at para 18.
[14] Id.
[15] Id at para 73.
[16] *Giant Concerts* above n 3 at para 32.

[28] Furthermore, the impugned decision concerns the procurement of medical devices for use in public health programmes. Public procurement is a matter of constitutional significance. Judicial oversight of procurement decisions serves an important public function, given that compliance with procurement requirements is fundamental to accountability in the expenditure of public funds.[17]

[29] I accordingly hold that Unicirc has established *locus standi* to act in the public interest.

Non-joinder

[30] The National Treasury contends that Access Medical has a direct interest in the relief sought and ought accordingly to have been joined as a party. I agree, however, with Unicirc that, since the relief sought is limited to the setting aside of the tender award, Access Medical has no direct interests that would be prejudiced if the review application succeeded.

The admissibility of the further affidavits filed

[31] This issue will be dealt with concisely after the content of all the affidavits filed in the application has been summarised below.

Background / Context

[32] Tender RT35-2023 was designed to appoint a single supplier of a surgical aid to be used in the provision of circumcision services across the public sector. The tender contemplated a single "Transversal Term Contract", being a centrally facilitated contract arranged by the National Treasury for goods or services required by one or more organs of state.

[33] The special conditions issued for tender RT35-2023 are of central importance to this application. They required, among other things, that the surgical aid to be procured be a non-invasive Class A medical device classified as a surgical aid in terms of the WHO definition; that it either already hold WHO prequalification approval or be in the process of obtaining such approval; and that its manufacturer hold the

[17] *AllPay Consolidated Investment Holdings (Pty) Ltd and Others v Chief Executive Officer of the South African Social Security Agency and Others (Corruption Watch and Another as* amici curiae*)* 2014 (1) SA 604 (CC).

appropriate licence issued by the SAHPRA in terms of section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act"). The SCC further required that the surgical aid be mandatorily used when circumcising boys aged 10 to 14 years.

[34] The tender was evaluated by a Bid Evaluation Committee ("BEC") and thereafter adjudicated by a Bid Adjudication Committee ("BAC"). On 16 March 2023, the BEC concluded its technical evaluation, finding CircumQ to be the only bidder compliant with all technical requirements. The BAC, meeting on 20 April 2023, approved the recommendation to award the tender to CircumQ.

Applicable legal principles: Review of Administrative Action

[35] The constitutional and statutory framework governing review applications is embedded in section 33 of the Constitution, which guarantees the right to administrative action that is lawful, reasonable, and procedurally fair, and the PAJA.

[36] A reviewing court does not sit as a court of appeal and is not concerned with the correctness of the impugned decision, but with its lawfulness. Its function is to ensure that the exercise of public power complies with the Constitution and is not arbitrary.[18] In performing that function, a court must accord due weight to the decision-maker's expertise and the polycentric or technical character of the decision, and must guard against impermissibly usurping the administrator's role.[19]

[37] That restraint does not, however, insulate administrative action from scrutiny: where a decision is vitiated by illegality, irrationality, or procedural unfairness, particularly in matters engaging public power and constitutional rights, a court is duty-bound to intervene. Not every deviation from a prescribed process will, however, warrant invalidation. The applicable enquiry is one of materiality: the irregularity must be of sufficient consequence to have prejudiced the applicant or to have infected the integrity of the decision-making process. A purely technical departure that had no bearing on the outcome will not, without more, justify setting the decision aside.

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[18] *Pharmaceutical Manufacturers Association of SA: In re Ex Parte President of the Republic of South Africa* 2000 (2) SA 674 (CC) at paras 85–86.
[19] *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism* 2004 (4) SA 490 (CC) (*Bato Star Fishing*) at paras 46–48.

[38] A finding of unlawfulness does not carry with it an automatic or inflexible consequence of setting aside.[20] Section 8 of PAJA, read with section 172(1)(b) of the Constitution, confers upon the court a wide remedial discretion to grant any order that is just and equitable. The court's remedial function under section 172 is not merely curative of past unlawfulness; it must be exercised with a view to the ongoing vindication of constitutional rights in the most effective manner practicable. In *AllPay 2*,[21] the Constitutional Court gave effect to that principle by suspending a declaration of invalidity of the impugned contract, notwithstanding its constitutional infirmity, in order to avert serious disruption to the payment of social grants to approximately 15 million beneficiaries.

[39] The present review turns primarily on rationality and reasonableness. These are distinct standards of review that ask different questions, apply in different contexts, and impose different levels of scrutiny on a decision-maker.

[40] Rationality is a minimum threshold requirement. It asks whether there is a rational connection between the decision that was made and the purpose it is supposed to serve. The Constitutional Court in *Pharmaceutical Manufacturers Association of SA: In re Ex parte President of the Republic of South Africa,*[22] confirmed that the exercise of all public power is subject to this requirement, and in *Democratic Alliance v President of the Republic of South Africa,*[23] reaffirmed that rationality review is not confined to the outcome of the decision but extends to the process by which it was reached. A decision arrived at through a flawed or irrational process may be set aside even if the outcome itself might have been defensible.

[41] Reasonableness under section 6(2)(h) of PAJA requires an enquiry into whether the decision is one that a reasonable decision-maker could reach on the available material. It is not an appeal on the merits, and the court does not ask whether the decision was correct or whether it would have preferred a different outcome. The

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[20] *AllPay* above n 17 at para 25.
[21] *AllPay Consolidated Investment Holdings (Pty) Ltd and Others v Chief Executive Officer, South African Social Security Agency and Others* 2014 (4) SA 179 (CC) (*Allpay 2*).
[22] *Pharmaceutical Manufacturers Association of SA* above n 18 at para 90.
[23] 2013 (1) SA 248 (CC) at paras 34-39.

question is whether the decision falls within a range of decisions that a reasonable decision-maker, properly directing itself in law and on the relevant facts, could rationally and defensibly reach.

[42] This standard is inherently context-sensitive and requires a holistic assessment of the decision-making process and outcome. As explained in *Bato Star Fishing*,[24] reasonableness involves a value-laden evaluation that considers "the nature of the decision, the identity and expertise of the decision-maker, the reasons given for the decision, the nature of the competing interests involved and the impact of the decision". The court must evaluate whether, in light of these factors, the decision is justifiable in relation to the reasons given.

[43] Similarly, in *Sidumo and Another v Rustenburg Platinum Mines Ltd,*[25] the Constitutional Court confirmed that the ultimate question is whether the decision reached is one that a reasonable decision-maker could have reached on the material before it. A decision may thus be reasonable even if the court would have reached a different conclusion. Conversely, a decision may fail the standard where material considerations were ignored, irrelevant considerations were taken into account, or the outcome is not rationally connected to the information before the decision-maker, viewed as a whole.

The parties' respective contentions

Unicirc's contentions

[44] The grounds of review advanced by Unicirc, properly distilled, coalesce around three interrelated questions that arise from the SCC and the evaluation process: (a) whether CircumQ satisfied the WHO prequalification requirement; (b) whether the device was shown to be safe and suitable for its intended use, particularly in the 10 to 14 year age group; and (c) whether the evaluation bodies properly discharged their functions in assessing technical compliance.

[45] First, Unicirc contends that CircumQ did not satisfy the WHO prequalification requirement. The SCC required either WHO approval or demonstrable progress

[24] *Bato Star Fishing* above n 19 at para 45.
[25] 2008 (2) SA 24 (CC) at para 110.

toward such approval, supported by substantive documentation reflecting the status of the process. On Unicirc's case, the record — including the WHO TAG report — demonstrates that the application had not progressed beyond a preliminary stage and was characterised by material evidentiary deficiencies. The submission of an application, without meaningful advancement or supporting information, did not constitute compliance with the SCC.

[46] Second, Unicirc contends that the device was not shown to be safe or suitable for its intended purpose. The SCC mandated its use in boys aged 10 to 14 years, yet no clinical data exist establishing safety or efficacy in that cohort. The TAG report itself records that available evidence relates only to adult males and that bridging studies would be required for younger populations. In those circumstances, Unicirc submits that the award was made in respect of a device whose safety in the primary target group was unknown.

[47] Third, Unicirc contends that the evaluation process was vitiated by a failure to engage substantively with the material placed before it. The BEC and BAC, it is said, adopted an unduly formalistic or "tick-box" approach, treating the mere existence of documentation as sufficient, without interrogating its content or implications. This, in turn, led to material errors of law and to the failure to take relevant considerations into account, including the concerns identified in the TAG report and the absence of supporting clinical data.

[48] These deficiencies, Unicirc submits, render the decision both irrational and unreasonable. On the information before the decision-makers, there was no rational basis to conclude that CircumQ met the technical requirements of the SCC, nor that the device was fit for purpose in the context of the tender.

[49] A further, related contention concerns the classification of the device. Unicirc submits that the CircumQ device ought properly to have been classified as a Class B medical device and not as a Class A device, as it was, with the result that the SAHPRA licence relied upon did not satisfy the requirements of the SCC. This issue is advanced as reinforcing the broader contention that the evaluation process failed to interrogate technical compliance with the necessary rigour.

The National Treasury's contentions

[50] The National Treasury opposes the review and advances a series of interrelated contentions directed at the proper interpretation of the SCC, the nature of the WHO prequalification process, and the evaluation undertaken by the BEC and BAC.

[51] First, Treasury contends that clause 6.6.7 of the SCC does not require WHO prequalification to have been finalised. It submits that the requirement is satisfied where a bidder demonstrates that its device is "in the process of being approved". On its case, this threshold was met by CircumQ through the submission of a WHO prequalification application, the TAG report, and supporting documentation reflecting engagement with the WHO process.

[52] Treasury emphasises that the WHO prequalification process is incremental and staged. It submits that progression through the process necessarily entails preliminary evaluation, the identification of deficiencies, and the requirement of further studies. The fact that the TAG report identified limitations and called for additional data does not, on its own, detract from the fact that the device had entered and progressed within that process.

[53] Second, Treasury contends that the SCC does not require proof of safety and efficacy in every conceivable user cohort as a condition of compliance. It submits that WHO prequalification is directed at the general safety and performance of a device, and is not cohort-specific. On this basis, the absence of clinical data in respect of males aged 10 to 14 does not constitute non-compliance with the SCC.

[54] Treasury further submits that the purpose of the tender was to procure devices capable of being deployed within an established public health programme, and that questions relating to operational deployment, including clinical protocols and training requirements, fall within the domain of implementation rather than procurement compliance.

[55] Third, Treasury contends that the evaluation process was conducted in accordance with a structured, multi-phase methodology. It submits that, during the technical evaluation phase, bidders were required to submit specified documentation, including proof of WHO prequalification or progression toward it, and that CircumQ complied with these requirements.

[56] It denies that the BEC adopted a formalistic or "tick-box" approach. On its version, the BEC considered the documentation placed before it, including the TAG report, and was entitled to conclude that the requirements of the SCC had been met. It emphasises that the Court should be slow to interfere with such technical evaluations, particularly where they fall within the expertise of the decision-maker.

[57] Treasury also contends that Unicirc's case impermissibly invites the Court to substitute its own assessment of the merits for that of the decision-maker. It submits that the review is, in substance, an attack on the correctness of the decision rather than its lawfulness, and that it seeks to impose requirements not found in the SCC.

[58] In sum, Treasury maintains that the decision to award the tender to CircumQ was rationally connected to the information before the BEC and BAC, fell within the range of reasonable outcomes, and does not meet the threshold for interference under PAJA.

Unicirc's reply

[59] In reply, Unicirc largely reiterates the grounds advanced in its founding papers and does not materially extend the factual or legal basis of the review.

[60] Its principal emphasis is that the purpose of the tender — the provision of high-volume circumcision services to males aged 10 years and above — required a proper assessment of whether the device was safe and suitable for that use. It maintains that, in the absence of clinical data relating to the 10-to-14-year age group, the mandatory use of the device in that cohort is irrational.

[61] Unicirc further relies on the TAG report to underscore that the WHO prequalification process had not progressed beyond a preliminary stage and that

significant evidentiary gaps remained. It reiterates that the mere submission of an application does not constitute being "in the process of approval" as contemplated by the SCC.

[62] Beyond this, the replying affidavit does not introduce new grounds. The submissions concerning device classification, the implications of suturing, and the alleged deficiencies in the evaluation process amount to a restatement of the case advanced in the founding affidavit.

[63] The reply accordingly serves primarily to reinforce Unicirc's central thesis: that the procurement of a device not shown to be safe and effective for its intended use, particularly in a vulnerable population, is irrational and unreasonable.

The Department of Health's explanatory affidavit

[64] The Department of Health filed an explanatory affidavit deposed to by the Director-General. The affidavit is expressly tendered from the perspective of the implementing department and is directed primarily at the operational context within which the tender is situated, rather than at the legality of the procurement process itself.

[65] At the outset, the Department emphasises the scale and importance of the voluntary medical male circumcision programme. It records that the tender forms part of a national HIV-prevention strategy aimed at high-volume, cost-effective service delivery across multiple health districts, with a particular focus on males aged 10 years and above.

[66] The affidavit underscores that VMMC is a recognised intervention in reducing HIV transmission, and that the programme is designed to operate at scale, with significant public health implications. It further records that disruption to the programme may adversely affect service delivery and the attainment of national HIV-prevention targets.

[67] Importantly, the Department does not oppose the review. It adopts a non-partisan stance and indicates that it will abide by the decision of the Court. Its purpose,

as stated, is to place information before the Court relevant to the implementation of the programme and the potential consequences of disruption.

[68] In relation to the use of the CircumQ device, the Department places before the Court implementation data from Gauteng Province. This includes the number of procedures performed and reported adverse events. The data reflect that, over the reported period, adverse events were limited in number and were classified as mild.

[69] The Department also records that the implementation of the device is accompanied by training protocols, clinical oversight, and ongoing monitoring mechanisms, including adverse event reporting and quality assurance processes.

[70] The affidavit further emphasises that the programme is already underway, and that continuity of implementation is important to avoid disruption to service delivery. It cautions that delays or uncertainty may impact the effective rollout of VMMC services.

Unicirc's reply to the explanatory affidavit

[71] Unicirc delivered a supplementary replying affidavit in response to the explanatory affidavit filed on behalf of the Department of Health. The affidavit is directed at the weight to be attached to the Department's evidence and at what it contends are material mischaracterisations of both the relief sought and the issues for determination.

[72] At the outset, Unicirc takes issue with the characterisation of the explanatory affidavit as non-partisan. It submits that, notwithstanding the Department's stated intention to abide by the decision of the Court, the affidavit advances substantive opposition to the relief sought and seeks to defend the continued use of the CircumQ device.

[73] Unicirc further contends that the explanatory affidavit is procedurally irregular in that it was delivered outside the prescribed time periods without an accompanying application for condonation. While it does not seek to exclude the affidavit, it submits that this is a factor to be taken into account, particularly in relation to costs.

[74] A central focus of the reply is the implementation data relied upon by the Department, in particular, the Gauteng provincial report. Unicirc contends that the report is of limited probative value. It points out that the data provide only high-level figures relating to the number of procedures performed and recorded adverse events, without the necessary underlying detail. In particular, it does not disclose: the age distribution of patients; whether boys aged 10 to 14 were included; the clinical context in which procedures were performed; or the nature and severity of the reported adverse events beyond broad categorisation.

[75] On this basis, Unicirc submits that the report does not provide a reliable foundation upon which to assess the safety or suitability of the device, particularly in relation to the 10 to 14 age cohort. It further contends that the data reflect relatively limited uptake of the CircumQ device when measured against overall circumcision volumes, and therefore does not demonstrate widespread or established use.

[76] Unicirc maintains that the central concern in the litigation relates to the use of the device in boys aged 10 to 14. It submits that the explanatory affidavit fails to engage with this issue in any meaningful way. In particular, it contends that the available data does not establish safety in this cohort; the implementation evidence does not demonstrate that the device has been used in that group, or, if so, with what outcomes; and the absence of such evidence underscores the risks associated with deployment in that cohort.

[77] Unicirc accepts that the VMMC programme serves an important public health purpose. It submits, however, that this does not justify the use of a device in circumstances where there is a risk of serious or irreparable harm, particularly to minors.

Further affidavits filed

[78] Several further affidavits were filed in the course of the litigation leading up to the hearing date. Unicirc filed an application in terms of rule 6(5)(e) for the admission of an affidavit by Ms. CG Yeko. This affidavit prompted the National Treasury to file an opposing affidavit, to which Unicirc felt inclined to reply. The Department of Health, at a very late stage, filed an opposing affidavit. No explanation was proffered for the

lateness of this filing. As indicated above, I allowed Unicirc to reply and reserved my ruling on the admissibility of the further affidavits.

[79] It is well established that a party is not entitled to file a further affidavit or one out of sequence as a right.[26] The admission of such material lies within the discretion of the court, to be exercised judicially upon a consideration of all relevant circumstances. In exercising that discretion, the Court must have regard to the nature of the issues raised in the further affidavits, the explanation tendered for their late filing, and the extent to which their contents are relevant to the proper determination of the dispute.

[80] To establish good cause, a party must provide a full and satisfactory explanation for the late filing or the need for further affidavits. The explanation must negate any inference of *mala fides* or culpable remissness.[27] Furthermore, the court must be satisfied that the information contained in the additional affidavits could not have been included earlier and that it is relevant to the proceedings.

Unicirc's application to file the affidavit of Ms. Yeko

[81] Unicirc brought an interlocutory application in terms of rule 6(5)(e) and seeks the further affidavit deposed to by Ms. C.G. Yeko ("the Yeko affidavit") to be admitted. The founding affidavit was deposed to by Mr. Vermeulen.

[82] Mr Vermeulen identified the applicable considerations governing such an application, namely: whether a proper and satisfactory explanation has been provided for the failure to place the information before the Court at an earlier stage; whether the admission of the affidavit would occasion prejudice that cannot be cured by an appropriate costs order; and whether the evidence is relevant and of sufficient importance to the issues in the main application. Reliance was also placed on rule 27(3) in relation to the condonation of the departure from the ordinary sequence of affidavits.

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[26] *The National Credit Regulator v National Consumer Tribunal* [2023] ZASCA 133 at para 55.
[27] *Standard Bank of SA Ltd v Sewpersadh* 2005 (4) SA 148 (C) at para 10.

[83] The Yeko affidavit, which runs to five pages, is deposed to by a registered nurse. It relates to an incident in which the deponent was consulted regarding a 10-year-old boy who allegedly suffered a serious complication following a circumcision performed using the CircumQ device.

[84] Unicirc contends that the affidavit is relevant for three reasons: it demonstrates that the risk of urethral fistula is real; it raises concerns regarding the adequacy of practitioner training; and it supports the contention that the use of the device requires medical oversight, particularly where complications arise.

[85] Mr Vermeulen further sets out the circumstances in which the information came to Unicirc's attention and submits that the respondents would suffer no prejudice if the affidavit were admitted. As to the concurrent filing of the affidavit with the application for leave, he submits that this was necessitated by the proximity of the hearing date and that good cause exists to condone the departure from the ordinary procedure.

The Yeko affidavit

[86] Ms Yeko is a clinical professional nurse and midwife, registered with the South African Nursing Council, and a trainer in voluntary medical male circumcision procedures. She describes being consulted by a colleague regarding a severe postoperative complication in a 10-year-old boy following a circumcision allegedly performed using the CircumQ device.

[87] Based on a photograph provided to her and the accompanying account, Ms Yeko diagnosed a urethral fistula and advised that urgent specialist intervention was required. She expresses concern regarding the safety of the device in young boys, the adequacy of practitioner training, and the sufficiency of clinical oversight.

[88] The central difficulty with the Yeko affidavit lies in its evidentiary foundation. The critical allegation — that the procedure in question was performed using the CircumQ device — rests entirely on information conveyed by an unidentified third party. The deponent has no direct knowledge of the procedure, did not witness it, and is unable to verify the account.

[89] The identity of the practitioner is not disclosed, the patient is unidentified, and no corroborating documentation — such as medical records, referral notes, or incident reports — is placed before the Court. The evidence is, therefore, hearsay in its essential respects and lacks the particularity necessary to render it reliable.

[90] While the affidavit raises concerns of a serious nature, those concerns cannot be properly tested on the information before the Court. In the absence of confirmatory evidence from the practitioner involved or any independent corroboration, the affidavit does not meet the threshold required for its admission.

[91] In these circumstances, the application to admit the Yeko affidavit must fail.

The Department of Health's belatedly filed answering affidavit

[92] The Department of Health belatedly filed a notice of opposition and an answering affidavit. No application for condonation accompanied the filing, nor was any explanation provided for the delay. In the absence of any explanation, it cannot be said that good cause has been shown for the late filing. The affidavit is accordingly not admitted. It follows that it is unnecessary to deal with Unicirc's reply thereto.

Costs

[93] The application to admit the Yeko affidavit set in motion the sequence of further affidavits. In the circumstances, a fair costs order is that Unicirc is to pay the costs of the first to fourth respondents in relation to the interlocutory application.

[94] Unicirc must bear its own costs in relation to its reply to the Department's affidavit. The Department of Health, having filed its affidavit out of time without explanation, is to bear its own costs.

Review on the merits: Discussion

[95] If regard is had to the grounds of review raised by Unicirc, I find it peculiar that CircumQ, the successful bidder, chose not to oppose or even participate in the review proceedings.

[96] All the parties involved understand the public health benefits associated with medical male circumcision, and in particular, the benefit of reducing a man's risk of acquiring HIV. In addition, they agree that circumcising boys in the 10 -14-year age group offers several notable advantages. From a public health perspective, this age window is considered strategically important, as it precedes sexual debut for many adolescents, meaning the protective benefits against HIV and other sexually transmitted infections are in place before potential exposure occurs. Motivated by the WHO warning on the adverse effects associated with the traditional and current dorsal slit method of circumcision, the National Treasury and Department of Health called for the bid to enable health professionals to move away from the current method of circumcision.

[97] One of the mandatory technical requirements or conditions of the tender was that only surgical aids approved by the WHO, or in the process of being approved, would be considered. The manufacturer or supplier of the device had to state the status with the WHO prequalification process. The result could be one of two scenarios. Scenario 1 – WHO prequalification was confirmed. Scenario 2 – Progress was made towards prequalification. To indicate the extent of progress made, the manufacturer or supplier had to refer to the prescribed studies completed, the application submitted to WHO, and the status of correspondence with WHO.

[98] So rather than a simple "pass" or "fail", the bid acknowledged that full WHO-qualification might not yet be in place and allowed bidders to demonstrate progress along the pre-qualification pathway. A bidder who had submitted their application to WHO and had active correspondence, even without final approval, could still satisfy this requirement by providing documentary evidence of their status in the process. The National Treasury did not set a fixed standard document that had to be completed to show that the WHO pre-qualification requirement was met. Bidders had to supply whatever evidence of WHO status they held. In short, the bid measured WHO pre-qualification on a spectrum of progress rather than as a binary requirement, with full approval as the ideal but documented progress also acceptable.

[99] It cannot be disputed that an application was submitted to the WHO for the prequalification of the CircumQ device. The WHO TAG Report dated 29 June 2021 is

evidence enough of submission. One gleans from the introductory paragraph of the report that the purpose of the meeting of the WHO TAG was "to determine if the evidence available on the CircumQ male circumcision surgical assist device is adequate, and the device-based method is efficacious and safe, thus permitting it to move forward in the prequalification (PQ) process."

[100] When the WHO TAG Report is studied, certain strengths and weaknesses in the pre-qualification context were identified. Of importance, however, is the fact that the TAG's conclusion was conditional and guarded. While it is correct that the device was not outright rejected, the device was not cleared to move forward in the process. The TAG advised that –

(a) the current safety data must be expanded with additional high-quality data from a comparative trial or a case series of at least 2 000 placements, conducted independently of the manufacturer;

(b) a follow-up TAG review would be required after that data was available, before any prequalification decision could be made;

(c) a formal IFU must be developed; and

(d) bridging studies for males under 18 prior to or after prequalification to demonstrate safe use among males aged younger than 18 years.

[101] The TAG report essentially acknowledged that the device showed promise and that clinical studies met most of the WHO requirements for evaluation. Several issues with the quality of the studies and the data were, however, raised. The TAG identified specific outstanding obligations, particularly around data quality and the IFU, that had to be fulfilled before prequalification could proceed. The manufacturer was placed as primarily responsible for commissioning the required studies and developing the IFU.

[102] There is no indication of whether CircumQ accepted the invitation to provide the required information to move the prequalification process forward. The TAG report is dated June 2021, the bid was advertised in December 2022, with a closing date of 24 January 2023. There is no indication in the record that CircumQ was, at that time,

still in the process of seeking WHO prequalification, or that the CircumQ device was being assessed.

[103] The only evidence that WHO prequalification was sought is an application that was submitted at least two years before the tender was advertised. The SCC specifically required that the bidder must submit the status of the application or correspondence with the WHO. The only reason for this additional requirement can conceivably be to allow a determination that the prequalification process is still in progress. No such status or correspondence was provided by CircumQ. To date, the CircumQ device remains unapproved, and there are no public records indicating that the required additional studies have been completed or that the device is being assessed. The record contains no evidence that, at the time of the bid evaluation, the prequalification process remained active or that the deficiencies identified by the WHO TAG had been addressed. In circumstances where the SCC required bidders to disclose the status of the process and ongoing correspondence with the WHO, the absence of such evidence means that the BEC lacked a rational basis to conclude that the device was "in the process of being prequalified".

[104] The tender RT35-2023 is not a routine procurement exercise. Its stated purpose is to appoint a service provider to deliver high-quality, high-volume VMMC services to males aged 10 years and above across 40 health districts nationwide, as part of South Africa's HIV prevention strategy. Section 5.3 of the SCC makes clear that the bid aims to provide services that are both clinically safe and cost-efficient. Section 5.1.1 expressly identifies the avoidance of adverse events as a primary consideration, specifically noting that only organisations meeting the stipulated conditions are permitted to bid precisely because of the elevated risks associated with high-volume surgical procedures. The protection of patients undergoing a surgical procedure, many of whom are children, is therefore not incidental to the tender's purpose; it is its foundational rationale.

[105] Against that backdrop, the WHO prequalification requirement must be understood not as a bureaucratic formality but as a direct expression of the patient safety objective. Section 6.6.7.1 of the SCC is explicit: only surgical aids that have been approved by the WHO or for which an application is actively in progress will be

considered. The provision is framed in unequivocal language — "only" such surgical aids "will be considered". The requirement is peremptory rather than merely directory. This is reinforced by the technical specification in Annexure A, which requires bidders to state with particularity their WHO prequalification status, including confirmed prequalification, the progress of prescribed manufacturer studies at the country of origin and neighbouring country level, confirmation that an application has been submitted to the WHO, and the status of ongoing correspondence with the WHO. These are not aspirational requirements; they are conditions of participation.

[106] The rationale for the requirement is self-evident from the nature of the devices. The surgical aid is classified as a Medical Device and In Vitro Diagnostic under the Medicines Act and bidders are required to hold a SAHPRA licence accordingly. WHO prequalification of the device itself provides an independent layer of international assurance that the surgical aid is safe, effective, non-invasive in the correct clinical sense, disposable, and auto-destructing so as to prevent cross-infection, and suitable for transient use during the circumcision procedure — all requirements expressly stated in the SCC. Without that assurance, the National Treasury and the Department of Health have no internationally validated basis for confidence in the safety of the device that will be used on hundreds of thousands of patients, including children as young as 10 years of age.

[107] The rationality enquiry is not whether the device may ultimately prove to be safe or effective, but whether, on the information before the BEC, there existed a rational basis to conclude that the peremptory requirements of the SCC had been met. Where those requirements function as safeguards for patient safety, a failure to establish compliance severs the logical connection between the award and its purpose.

[108] In my view, no such rational connection exists, for the following reasons:

(a) First, the WHO prequalification requirement is the mechanism by which the State satisfies itself that the surgical device meets international safety standards. To award the tender in the absence of evidence that this process is engaged is to strip the procurement of the very safeguard the State has chosen to impose on itself. The award would not advance the patient safety objective; it would directly undermine it.

(b) Second, the requirement is not merely aspirational. Section 6.6.7.1 of the SCC does not say that WHO prequalification is desirable or preferred. It says that only surgical aids approved by, or in the process of, WHO prequalification will be considered. To award the tender to a bidder who cannot demonstrate that the device is progressing toward WHO prequalification is inconsistent with the express terms of the bid document, which itself constitutes the framework within which the procurement power was to be exercised.

(c) Third, the broader regulatory architecture of the tender reinforces this conclusion. The SAHPRA licensing requirement, the ISO 13485 quality assurance certification requirement, the adverse events monitoring obligations, and the clinical algorithm compliance requirements all point to a procurement framework that places patient safety at its centre. An award to a bidder who cannot demonstrate that it is in the process of obtaining WHO prequalification compliance is inconsistent with the tender's regulatory logic.

(d) Fourth, the requirement cannot be cured by post-award compliance undertakings. The requirement must be met at the closing date of the bid (section 6.6.7.1 of the SCC), and at a minimum, the prequalification process must demonstrably be in progress. A bidder who submits no evidence of this has not merely fallen short of an aspirational standard; it has failed to satisfy a condition of participation.

[109] The inescapable conclusion, on a rationality analysis, is that an award of this tender to a bidder who has produced insufficient evidence that the WHO prequalification process is underway would bear no rational connection to the legitimate governmental objective of providing safe, internationally-compliant surgical circumcision services. Such an award would moreover constitute a material departure from a requirement that, on its face, is peremptory: the language of section 6.6.7.1 — "only... will be considered" — does not admit of discretionary relaxation.

[110] It was furthermore expressly required that the device in question must be a class A medical device in accordance with the GHTF/IMDRF. The BEC merely accepted the manufacturer's classification.

[111] The technical specification in Annexure A is unambiguous in what it demands of the surgical aid. Item 3 of the detailed specification requires that the device be classified as a Class A medical device in accordance with the Global Harmonization Task Force / International Medical Devices Regulators Forum ("GHTF/IMDRF") Principles of Medical Devices Classification. This requirement does not stand alone. It is embedded in a cluster of related technical requirements that together define the acceptable safety profile of the device: it must be non-invasive in the WHO clinical sense, it must be transient and remain on the body only for the short duration of the circumcision procedure, it must be classified as a surgical aid in terms of the WHO Framework for Clinical Evaluation of Devices for Male Circumcision, and it must prevent cross-infection by being disposable and auto-destructing.

[112] The GHTF/IMDRF classification framework classifies medical devices on a risk-based spectrum. Class A represents the lowest risk category — devices that are non-invasive, have low or no energy input, and do not interact with the body in a manner that creates significant clinical risk. Classes B, C, and D represent progressively higher risk profiles. The significance of the Class A requirement in the context of this tender is therefore not merely technical nomenclature. It is the State's chosen mechanism for ensuring that the surgical aid falls within a defined and internationally recognised safety envelope. A device that is in truth Class B or higher carries clinical risks — particularly in respect of adverse events, tissue interaction, and infection — that are fundamentally inconsistent with the tender's stated objective of minimising adverse events and delivering safe high-volume surgical services, including to children as young as 10 years of age.

[113] The bid documents impose several mechanisms by which the BEC is expected to satisfy itself that a bidder's technical representations are accurate. These are not incidental provisions; they are integral to the procurement design.

[114] Section 6.6 of the SCC deals expressly with Technical Specification Compliance. Section 6.6.1 states that non-compliance with any evaluation requirement in that phase will result in the disqualification of the line item being evaluated. Section 6.6.3.1 requires bidders to adhere to the Medicines and Related Substances Amendment Acts in respect of the classification of medical devices, which is a regulatory obligation that exists independently of the bid process. Section 6.6.4.1 requires ISO 13485 quality assurance certification, with the holder being the original manufacturer of the finished product — a requirement that in itself presupposes that the device has been manufactured and quality-assured in accordance with its stated classification.

[115] Crucially, section 6.1.1 of the SCC expressly preserves the right of the State to conduct supplier due diligence at any stage of the evaluation process, including pre-announced and non-announced site visits, specifically for the purpose of confirming the information provided by the bidder. Section 8.7.1 repeats this right in broader terms. Section 8.7.3 goes further still and provides that the BEC reserves the right to subject item samples to applicable clinical evaluations and tests at any State facility to verify compliance with the technical specifications. These provisions make clear that passive acceptance of a bidder's self-assessment is not the intended approach. The procurement framework contemplates that the BEC was required to critically evaluate the available material.

[116] The question is whether there is a logical connection between accepting a manufacturer's unverified assertion that its device is Class A and the procurement objective of ensuring that only safe, internationally-compliant surgical devices are used in high-volume circumcision procedures on a vulnerable patient population.

[117] That connection does not exist, for the following reasons:

(a) The GHTF/IMDRF classification of a medical device is not determined by the manufacturer's labelling. It is determined by the application of objective classification criteria to the device's design, intended use, duration of body contact, degree of invasiveness, and biological interaction profile.

(b) Where a bidder asserts Class A classification but has no proven active WHO prequalification in progress, and where the BEC does not critically engage with the material, the award rests on nothing more than the manufacturer's *ipse dixit*. An award so based bears no rational connection to the objective of patient safety because it provides no assurance whatsoever that the device is what the bidder says it is. A device that is in truth Class B or higher — because it is, for example, more than transiently invasive, or because it interacts with body tissue in a manner inconsistent with Class A — poses clinical risks that the procurement framework was specifically designed to guard against. To award the tender without verifying the classification is to ignore those risks entirely.

[118] The difficulty is not that the BEC accepted the manufacturer's classification per se, but that it did so in circumstances where no independent *indicia* of correctness were evident from the record, and where the procurement framework itself allowed for verification. In a context where classification determines risk, uncritical acceptance of a bidder's assertion cannot constitute a rational or reasonable discharge of the evaluation function.

[119] The test under section 6(2)(h) of PAJA, as elaborated in *Bato Star Fishing*,[28] requires that the decision be one that a reasonable administrator could have reached in the circumstances. The circumstances here include the following. First, the device will be used in surgical procedures on patients, including children, giving the safety question exceptional weight. Second, the bid documents themselves contemplate active verification and expressly preserve the right to conduct clinical evaluations of samples. Third, the WHO prequalification requirement exists precisely to provide independent validation of the classification. Fourth, no reasonable BEC could be indifferent to the question of whether a device being deployed at scale in a national health programme is correctly classified when the classification directly determines the risk profile of the device. Fifth, and perhaps most significantly, section 6.6.1 of the SCC makes technical non-compliance a disqualifying event — which means the stakes of

[28] *Bato Star Fishing* above n 19 at paras 44–48.

incorrect classification are not merely administrative but are directly connected to whether the bidder should have been in the evaluation at all.

[120] A BEC that simply accepts the manufacturer's assertion, does no more, and proceeds to recommend an award is a BEC that has abdicated its responsibility to engage critically with all the material and apply its mind fully to the issues at hand. That abdication is not a permissible exercise of discretion; it is a failure to perform the function that the procurement framework assigns to it.

[121] In summary — The award of this tender to a bidder who merely asserts Class A classification without the BEC conducting any investigation into the accuracy of that classification would be both irrational and unreasonable. It would be irrational because no logical connection exists between uncritical acceptance of an unverified manufacturer's label and the objective of ensuring that the surgical aid is safe, compliant, and fit for use at scale in a public health programme. It would be unreasonable because no reasonable BEC, properly performing the verification function assigned to it by the bid documents and properly conscious of the patient safety stakes, could have regarded passive acceptance of such an assertion as an adequate discharge of its obligations. The failure would moreover be material — not a technical deviation from a directory requirement, but a departure from the very mechanism by which the State was to satisfy itself that the device met the peremptory clinical and regulatory standards that the tender was designed to enforce.

[122] I considered whether the SAHPRA license and ISO 13485 certificate could serve as a proxy for classification verification, thereby absolving the BEC of its verification requirement. Can it be argued that the BEC, upon sight of CircumQ's SAHPRA licence, was entitled to rely on that regulatory endorsement as confirmation that the device was correctly classified as a Class A device? The difficulty with such an argument is, however, significant. SAHPRA licensing and GHTF/IMDRF classification are related but distinct processes. A SAHPRA licence authorises the manufacture, importation, distribution, or wholesaling of a medical device; it does not necessarily constitute an independent verification of the device's GHTF classification. In the same vein, ISO 13485 certifies the quality management system, not the correctness of any particular regulatory classification. A manufacturer can hold ISO

13485 certification and still misclassify a product, whether deliberately or through an erroneous application of the classification criteria. The certificate is evidence of process, not outcome. The SAHPRA licence and ISO 13485 certificates might establish parallel, but not equivalent, verification of the classification question.

[123] The BEC is a technical committee with procurement expertise. I accept that its judgment that the documentation presented was adequate to support the classification of the device attracts a measure of curial deference. However, where the classification question is the gateway to patient safety, and particularly, the safety of boys aged 10 to 14, the proposition that the BEC had an unfettered discretion to accept unverified representations is difficult to sustain. I hold the view that the BEC conflated documentary compliance with substantive technical compliance.

[124] It thus stands to be found that the award of tender RT35-2023 to CircumQ was unlawful and invalid.

Appropriate remedy

[125] The finding that the award of tender RT35-2023 to CircumQ was unlawful does not conclude the enquiry. Although Unicirc deliberately did not seek any just and equitable relief in addition to the review and setting aside of the award to CircumQ, the Department of Health, in particular, advocated for just and equitable relief.

[126] Section 8(1) of PAJA confers upon this Court a wide remedial discretion to grant 'any order that is just and equitable'. Section 172(1)(b) of the Constitution similarly empowers a court to 'make any order that is just and equitable' when it declares conduct to be inconsistent with the Constitution. These provisions operate in tandem and are to be read generously and contextually.

[127] The Constitutional Court's seminal guidance in *AllPay 2* affirmed that a declaration of invalidity does not carry with it a mandatory corollary of immediate and complete setting aside.[29]

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[29] *AllPay 2* above n 21. Also consider *President of the Republic of South Africa v Speaker of the National Assembly* 2025 (9) BCLR 994 (CC).

The just and equitable standard: relevant factors

[128] The content of the 'just and equitable' standard in the remedial context was elaborated on by the Constitutional Court in *Bengwenyama Minerals (Pty) Ltd v Genorah Resources (Pty) Ltd.*[30] The Court held that in crafting an appropriate remedy, a court must weigh a range of competing considerations. These include the nature and gravity of the unlawfulness; the degree of prejudice to the parties directly affected; the extent to which third parties have acted in reliance on the impugned decision; the extent to which the decision has been performed or acted upon; and the implications for the public interest of the relief sought. No single factor is determinative.

Application: Why complete and immediate setting aside is not just and equitable

[129] Several considerations, assessed cumulatively, militate decisively against the complete and immediate setting aside of the tender award.

[130] The first and most significant factor is the substantial passage of time and the advanced stage of performance of the contract. The Transversal Term Contract is a 36-month contract, awarded on 20 April 2023. As at the date of delivery of this judgment, the contracted term has run to, or is near, its natural expiry. Declaring the award void ab initio and requiring the unwinding of a contract at or near its natural end would not restore a fair procurement process but would produce administrative disruption, fiscal uncertainty, and potential harm to service providers who contracted in reliance on the award, without any corresponding benefit to the constitutional values the procurement framework exists to protect.

[131] The second consideration is the nature and degree of the unlawfulness itself. The grounds on which the award fails are, as found above, serious: the failure to verify whether the CircumQ device was still in active pursuit of WHO prequalification at the time of the bid evaluation, and the BEC's uncritical acceptance of an unverified Class A device classification, represent material departures from a safety-orientated procurement framework. They are, however, irregularities in process and verification, not findings that the CircumQ device is, in fact, clinically dangerous, or that its use has caused systemic harm in all segments of the patient population for which some level

[30] 2011 (4) SA 113 (CC) at paras 84-86.

of evidence exists. The Gauteng provincial implementation data, while arguably methodologically incomplete — in particular, its failure to disaggregate adverse event data by age group — reflects a total adverse event rate of 0.65% across 3,560 procedures, with all recorded adverse events classified as mild. This is not evidence that the procedural unlawfulness of the procurement has not, at least in respect of the broader patient population, produced the scale of harm that would compel immediate and total invalidation.

[132] The third consideration is this: no case has been made out on the papers that the CircumQ device is more harmful, or carries materially greater clinical risk, than the traditional dorsal slit method of circumcision, the very method from which this tender was expressly designed to move away from. The Director-General of the Department of Health records that the bid was developed specifically in response to a WHO report warning of the adverse effects associated with the dorsal slit method. To set aside the entire contract would necessarily revert all circumcision procedures across the VMMC programme to the dorsal slit method. That outcome would not advance the health and safety of the beneficiaries of the programme; in respect of the 15-and-above cohort, it may do the contrary.

Declaration of invalidity and the scope of the operative relief: a two-step approach

[133] It is necessary at this point to address with precision the jurisprudential basis upon which the operative relief is limited. The approach taken in this judgment differs from an analysis grounded in the doctrine of severability, and it is important to articulate why.

[134] A severability analysis asks which portion of an impugned decision is invalid and which is valid, and then preserves the valid residue. The doctrine presupposes a logical correspondence between the unlawfulness and the portion excised. It cannot, however, be applied in the present case to confine the relief to the 10-14 age cohort. The grounds of unlawfulness found above are not confined to a particular age group. The CircumQ device either met the peremptory requirements of the SCC, or it did not, regardless of the age of the patient on whom it is used. There is accordingly no valid residue to identify and preserve in the severability sense; the award is invalid in its entirety.

[135] That full declaration of invalidity does not, however, determine the scope of the operative relief that flows from it. Section 172(1) of the Constitution draws a clear and deliberate structural distinction between two sequential steps.[31] The first, under section 172(1)(a), is the declaration: a court must declare conduct that is inconsistent with the Constitution invalid to the extent of its inconsistency. That declaration is total and unrestricted in the present case. The second step, under section 172(1)(b), is the remedy: a court may make any order that is just and equitable. That discretion is separate from the declaration of invalidity. The scope of the operative relief is governed by what is just and equitable, not by the ambit of the invalidity.

[136] The question for this Court is therefore not whether any part of the award is "valid" and capable of being preserved through severance. The question is whether it is just and equitable, in the exercise of the section 172(1)(b) discretion, to grant relief that is more narrowly calibrated than the full ambit of the invalidity. The answer, for the reasons that follow, is yes — and the appropriate calibration is one that gives immediate operative effect to the declaration of invalidity in respect of the most constitutionally acute application of the contract, namely the mandatory use of the CircumQ device on boys aged 10 to 14, while allowing the remainder of the contract to exhaust its natural term rather than being wound back at significant cost and disruption.

Why the operative relief is directed at the mandatory use of the CircumQ device on boys aged 10 to 14

[137] Three features of clause 5.10.1 distinguish the 10–14 cohort from the remainder of the patient population for the purposes of the just and equitable discretion, even though the underlying unlawfulness is shared across the whole award.

[138] The first is the complete removal of clinical discretion where boys aged 10 to 14 are concerned.[32] Clause 5.10.1 of the SCC is unambiguous: circumcision for males aged 10 to 14 *must* be conducted using the surgical aid provided by the participating

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[31] *AllPay 2* above n 21 at paras 61-67.

[32] In *Minister of Health v Treatment Action Campaign (No2)* 2002 (5) SA 721 (CC) the Constitutional Court emphasised that the State's policy should not prevent medical practitioners from exercising their clinical judgment as it will unjustifiably limit access to healthcare services, particularly for vulnerable groups.

provincial departments. No exception is made for clinical judgment; no discretion is afforded to the treating healthcare provider to depart from this mandatory requirement, even where the particular circumstances of the patient might require a different approach. By contrast, clause 5.10.2 imposes no equivalent compulsion for males aged 15 and above: for that cohort, the surgical aid is offered as an option based on patient preference. The character of the two provisions is qualitatively different. Where the State mandates the use of an unproven surgical device and simultaneously strips the treating clinician of any discretion to depart from that mandate, no residual exercise of professional judgment can intervene between the unlawful procurement decision and the patient.

[139] The second feature is that the evidence gap in relation to boys under 18 is not a matter of degree; it is absolute. For adult males, the procurement decision was informed by clinical data — albeit data the WHO TAG found to be insufficient to satisfy the prequalification requirements: the manufacturer's studies, the Gauteng implementation report, and an adverse event rate within broadly acceptable limits. That data was not adequate to meet the peremptory conditions of the SCC, which is why the award is unlawful; but it represents some evidentiary basis for the use of the device in adult patients. For boys under 18, there is no clinical data whatsoever. The TAG report was unambiguous and unqualified on this point: current evidence relates only to males over 18 years of age, and bridging studies will be required before safe use in males younger than 18 can be demonstrated. That finding had not been addressed in any respect at the time of the bid, nor has it been addressed in the years that have elapsed since. The State has accordingly not merely procured a device on the strength of insufficient evidence; in respect of boys aged 10 to 14, it has mandated the use of a device in the complete absence of evidence. The distinction matters for the framing of the remedy.

[140] The third feature is the independent constitutional imperative created by section 28(2) of the Constitution, which provides that 'a child's best interests are of paramount importance in every matter concerning the child.' The Constitutional Court, in *S v M*

(Centre for Child Law as Amicus Curiae),[33] confirmed that section 28(2) creates a free-standing and justiciable right, not merely a directive principle. It requires that the best interests of the child be given substantial weight in any matter concerning children, and may not be subordinated to administrative or fiscal convenience.

[141] The paramountcy of the best interests of the child under section 28(2) is not simply one factor to be weighed in a general proportionality analysis. It is a self-standing constitutional injunction that requires dedicated and context-sensitive consideration, and which assigns substantial weight to children's interests. While not absolute, it may decisively influence the outcome where competing administrative or commercial considerations cannot be justified in view of its demands. In the present case, section 28(2) is directly engaged. The CircumQ device was mandated for use on boys as young as 10. The WHO's own advisory body identified the complete absence of safety data for that age group. That was disregarded in the procurement process. A remedy that leaves the mandatory-use obligation for children intact, even for whatever period remains of the contract term, would fail in its constitutional obligation to give paramountcy to the best interests of the children concerned. The section 28(2) imperative constitutes an independent and sufficient basis for the operative relief directed at clause 5.10.1, over and above the proportionality and just and equitable considerations that inform the broader remedial exercise.

[142] Taken together, these three features justify the asymmetry in the operative relief. Although the unlawfulness attaches to the award as a whole, the remedial enquiry is distinct. The question is not what is invalid, but what relief is just and equitable in view of that invalidity. In circumstances where the evidence discloses an absence of clinical data in respect of a vulnerable cohort, coupled with a mandatory deployment requirement that removes clinical discretion, it is just and equitable to afford immediate operative relief in respect of that cohort, while permitting the remainder of the contract to run its course to avoid systemic disruption.

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[33] 2008 (3) SA 232 (CC) at para 25. Also consider *Director of Public Prosecutions, Transvaal v Minister of Justice and Constitutional Development* 2009 (4) SA 222 (CC) and *De Reuck v Director of Public Prosecutions, Witwatersrand Local Division, and Others* 2004 (1) SA 406 (CC).

Costs

[143] The principle that costs follow success finds application. In determining the appropriate costs order, I had regard thereto that the applicant brought these proceedings in the public interest and has substantially succeeded on the merits. The *Biowatch* principle requires that an organ of state that unsuccessfully opposes an application brought in vindication of constitutional rights should ordinarily bear the costs of the successful litigant. The first to fourth respondents, as the organs of state principally responsible for the impugned procurement decision and its defence, bear the costs of Unicirc's success.

[144] The fact that operative relief is limited to the 10 to 14 age cohort rather than extending to the complete setting aside of the contract does not diminish the applicant's substantial success. The declaration of invalidity and the interdiction in respect of the most constitutionally acute application of the impugned award — the mandatory use of an unproven surgical device on children — represent the primary relief the applicant sought in substance.

[145] The fifth respondent initially indicated an intention to abide by the decision of this Court and played no substantive role in the defence of the impugned procurement decision. The fifth respondent's explanatory affidavit assisted the court in deciding on the extent of the just and equitable relief. No costs order is made against the fifth respondent.

ORDER

As a result, the following order is granted:

A. Preliminary rulings

1. The applicant, Unicirc (Pty) Ltd., has established *locus standi* to bring these proceedings in the public interest.
2. The *in limine* point of non-joinder raised by the first to fourth respondents in respect of Access Medical (Pty) Ltd is dismissed.

B. Interlocutory application: further affidavits

3. The application by the applicant for leave to file the further affidavit of Ms. Yeko is refused;

4. The answering affidavit filed by the fifth respondent, the Minister of Health, on 10 March 2026 is not admitted into evidence;
5. The applicant's replying affidavit to the fifth respondent's affidavit referred to in paragraph 4, above, falls away as a consequence of the fifth respondent's answering affidavit not being admitted.

C. Costs of the interlocutory applications

6. The applicant is ordered to pay the first to fourth respondents' costs incurred in opposing the application to file the further affidavit of Ms. Yeko;
7. The applicant is to bear its own costs in relation to the interlocutory application, including the costs occasioned by the preparation and filing of its replying affidavit, and heads of argument, to the fifth respondent's belated filed answering affidavit;
8. The fifth respondent is ordered to bear its own costs arising from the filing of its answering affidavit on 10 March 2026 and its notice of opposition filed on 9 March 2026;

D. Review: Declaration of invalidity and just and equitable relief

9. The decision of the National Treasury to award Tender RT35-2023 to the sixteenth respondent, CircumQ IP (RF) (Pty) Ltd, taken on 20 April 2023, is declared unlawful and invalid.
10. Subject to 10.1, 10.2 and 10.3 below, the declaration of invalidity is suspended until expiry of the contract term;
    10.1. The respondents are interdicted and restrained, with immediate effect from the date of this order, from giving effect to, implementing, or enforcing section 5.10.1 of the Special Conditions of Contract for Tender RT35-2023, insofar as that provision requires the mandatory use of the CircumQ surgical assist device in the circumcision of males aged 10 to 14 years.
    10.2. The respondents are directed, with effect from the date of this order and for any remaining period of the contract term, not to require, direct or obligate any healthcare provider operating under the VMMC programme to use the CircumQ surgical assist device when performing circumcision procedures on males aged 10 to 14 years.

10.3. Where voluntary medical male circumcision services are required for males aged 10 to 14 years during any remaining period of the contract term, the relevant provincial departments of health are directed to ensure that the treating healthcare provider is free to apply whichever clinically appropriate method that provider determines to be in the best interests of the individual patient, including the use of the dorsal slit method or any other method in respect of which the relevant department, having regard to available clinical evidence, considers appropriate.

11. Notwithstanding the declaration of invalidity in paragraph 9 above, the Transversal Term Contract concluded between the National Treasury and the sixteenth respondent pursuant to the award of Tender RT35-2023 shall remain in force insofar as it governs the provision of voluntary medical male circumcision services to males aged 15 years and above in terms of section 5.10.2 of the Special Conditions of Contract, and shall continue in that limited respect until the earlier of:

(a) the natural expiry of the 36-month contract term commencing on 20 April 2023; or

(b) such earlier date as the contract is lawfully terminated.

E. **Costs of the main application**

12. The first, second, third and fourth respondents are ordered to pay the applicant's costs of the main application on scale C, jointly and severally, the one paying the other to be absolved, including the costs of two counsel where two counsel were employed.

[redacted]

E VAN DER SCHYFF
JUDGE OF THE HIGH COURT
GAUTENG DIVISION, PRETORIA

For the applicant:	Adv. JM Berger
Instructed by:	Von Seidels
For the first to fourth respondents: With:	Adv. H Rajah Adv. K van Heerden
Instructed by:	State Attorney, Pretoria
For the fifth respondent: Instructed by:	Adv. M Mpya State Attorney, Pretoria
Date of the hearing: Date of filing of heads of argument regarding the filing of further affidavits: Date of judgment:	10 March 2026 17 April 2026 7 May 2026