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'Remedyless' review – a cautionary tale

An analysis of the recent High Court judgement in *Ilex*

Helen Michael

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TENDERS IN SOUTH AFRICA

- Tenders are often subjected to judicial review
- Procurement of goods and services by the State is highly regulated -
  - Constitution of the Republic of South Africa, 1996 (s217(1))
    - requires all organs of state that contract for goods or services to do so "in accordance with a system which is **fair, equitable, transparent, competitive and cost effective**"
  - PFMA (Public Finance Management Act No. 1 of 1999)
  - PPPFA (Preferential Procurement Policy Framework Act No. 5 of 2000)

TENDERS IN SOUTH AFRICA (CONTINUED)

- PAJA (Promotion of Administrative Justice Act No. 3 of 2000)
  - "action"-
    - **decision** by an **organ of state**, that exercises **public power**, which **adversely affects** the rights of any person and which has a **direct, external legal effect**
  - administrative action must be **procedurally fair** (s3)
  - **review** proceedings and grounds of review (s6)
  - Remedies
    - any order that is "**just and equitable**", including an order **setting aside** the administrative action

THE *Ilex* JUDGEMENT

- Full citation: *Ilex South Africa (Pty) Ltd v National Health Laboratory Service and Others* 2021 (5) SA 587 (GJ)
- 15 September 2020
- Gauteng Local Division
- No Appeal

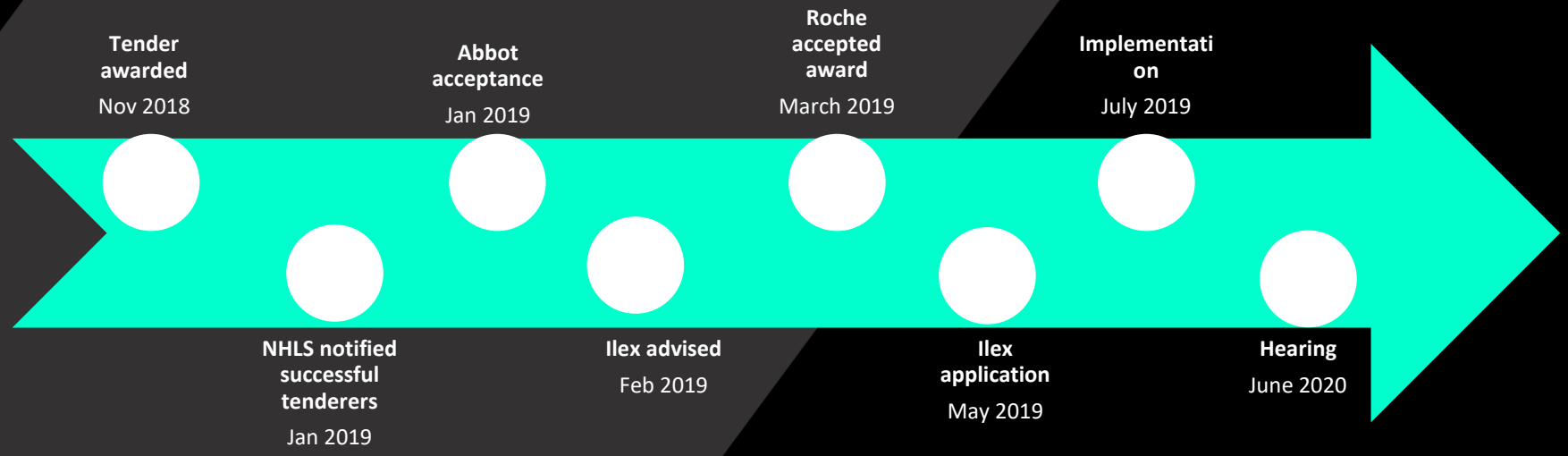
PARTIES

- Applicant: Ilex South Africa (Pty) Ltd (Ilex)
- 1st to 4th respondents:
  - National Health Laboratory Service (NHLS)
  - CEO of the NHLS
  - Abbott Laboratories South Africa (Pty) Ltd (Abbott)
  - Roche Diagnostics (Pty) Ltd (Roche)

AWARD OF TENDER BY NHLS

- NHLS –
  - awarded a tender for the provision of HIV blood sample testing services to Abbott and Roche (the decision)
  - the value of the tender exceeded R1 billion
  - the duration of the contract was 3 years
- Ilex (an unsuccessful tenderer) applied to court for an order -
  - declaring that the tender process undertaken by the NHLS was **illegal, invalid and unconstitutional**; and
  - reviewing and **setting aside the decision**.

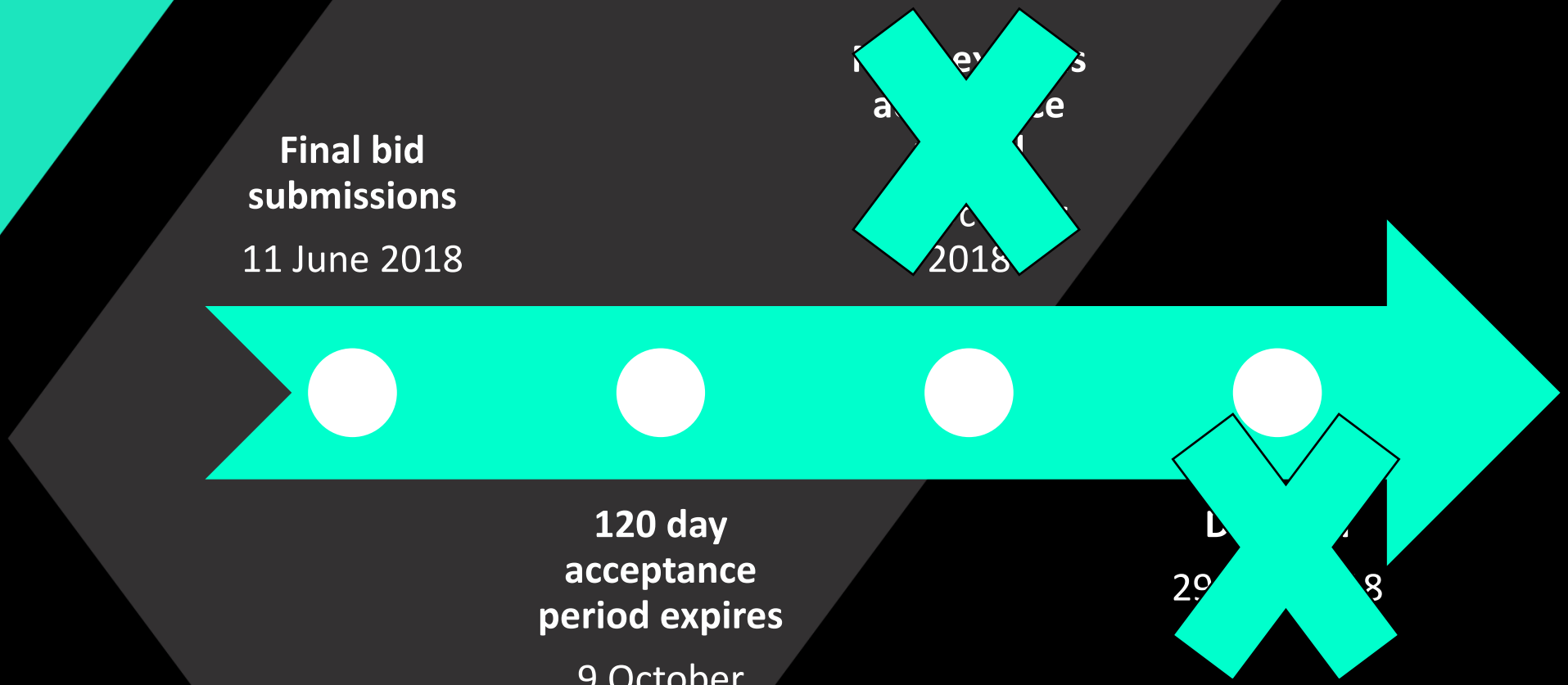
TIMELINE OF MATTER



Ilex ARGUMENTS

- Ilex argued that the award of the tender was invalid on several grounds, *inter alia* -
  - The Bids by Roche and Abbott had **lapsed**
  - Ilex's disqualification was unlawful - vagueness of **pricing criteria**

Ilex's LAPSED BID ARGUMENT



COURT ON BID VALIDITY PERIOD

- The court ruled in Ilex's favour -
  - need for **transparency**
  - after bid validity period expired, NHLS could **no longer take any decisions** pursuant to bids
  - the NHLS was required to **readvertise**
  - nothing to extend because the tender process was **concluded**

Ilex's DISQUALIFICATION AND COURT'S DECISION

- Price declaration form reflected **annual costs** and not the **total amount for three years**
- Ilex: disqualification was based on **technicality** and NHLS acted irrationally
- Court held that –
  - Pricing document was **vague**
  - Vagueness and uncertainty are grounds for **review** under s6(2)(i) of PAJA
  - Tender must elicit **best solution** through a fair, equitable, transparent, cost-effective and competitive process – this is not achieved where a tender is vague
  - Ilex's disqualification was arbitrary, irrational and unlawful

THE COURT'S DECISION

- The award of the tender was indeed an **unlawful exercise of state power**

> "The decision is … an unlawful exercise of public power, contrary to the **principle of legality embodied in s 1(c) of the Constitution**; and an unlawful administrative decision which is subject to review in terms of s 6(2)(d), 6(2)(e)(iii), 6(2)(f)(i), 6(2)(f)(ii) and 6(2)(i) of PAJA" (para 80).

SHOULD THE TENDER BE SET ASIDE?

- *Millennium Waste Management (Pty) Ltd v Chairperson, Tender Board: Limpopo Province and Others* 2008 (2) SA 481 (SCA) –

  "The difficulty that is presented by invalid administrative acts … is that they often have been **acted upon by the time they are brought under review**. That difficulty is particularly acute when a decision is taken to accept a tender. A decision to accept a tender is almost always acted upon immediately by the conclusion of a contract with the tenderer, and that is often immediately followed by further contracts concluded by the tenderer in executing the contract. To set aside the decision to accept the tender, with the effect that the contract is rendered void from the outset, can have **catastrophic consequences for an innocent tenderer**, and **adverse consequences for the public at large** in whose interests the administrative body or official purported to act. Those interests must be carefully **weighed** against those of the disappointed tenderer if an order is to be made that is just and equitable."

REMEDIES – CONSTITUTION

172. Powers of courts in constitutional matters

(1) When deciding a constitutional matter within its power, a court:-

(a) must declare that any law or conduct that is inconsistent with the Constitution is invalid to the extent of its inconsistency; and

(b) may make any order that is **just and equitable**, including:-

(i) an order limiting the retrospective effect of the declaration of invalidity; and

(ii) an order suspending the declaration of invalidity for any period and on any conditions, to allow the competent authority to correct the defect.

APPROACH

- Every improper performance of an administrative function implicates the **Constitution**
- Aggrieved party is entitled to **appropriate relief**
- The remedy must **fit the injury** and must be **fair to those affected**

CONSIDERATIONS

- National **importance** of the service
- **Disruption** that would be caused
  - "There can be no doubt that **immense disruption** would be caused, with **dire consequences** to millions of South Africans living with Aids, if the contracts concluded by the NHLS with Roche and Abbott were to be summarily set aside. It is unthinkable that that should occur" (para 84).
- Interests of the **public**

CONSIDERATIONS (CONTINUED)

- Interest of the **innocent successful bidders**
- Financial effect on the **public purse** in the event of the award being set aside
  - Would a retender, and the subsequent award of the tender to Ilex, cost the NHLS more than it is currently paying for the service?
  - NHLS noted that even if Ilex was not disqualified, it would have scored the least number of points
  - Unlikely that that process would result in the state entity receiving a more cost-effective solution
  - Probable that setting aside the award and contracts would have no financial benefit to the public purse

DECISION

- At paragraph 95 –

"In my judgment the circumstances of the present case, as outlined above, are such that it falls within the category of those cases where, by reason of the **effluxion of time** and other considerations, notably the fact that there is a real possibility that, if the defect is remedied, by the completion of the tender process **the result would be the same**, therefore an invalid administrative act must be permitted to stand. I am of the view that I should exercise my discretion in favour of **declining to set aside the awards**".

DECISION (CONTINUED)

- Decision to award the tender and conclude the contracts –
  - was **constitutionally invalid**
  - was **not set aside**

- Order for **costs** was granted against Ilex in favour of the respondents

CONCLUSION

- When a public tender is awarded unlawfully, the right to just **administrative action** of the unsuccessful tenderers is infringed
- For a tenderer who, but for the unlawful award, would have received the tender, the wrong or harm is particularly **tangible**
- In deciding what constitutes a just and equitable remedy, however, the court **does not focus solely or even primarily on the interests of any wronged tenderer**
- Courts take into account broader **public interests** that stand to be affected by any interruption

CONCLUSION (CONTINUED)

- The setting aside of an unlawful government tender award therefore does **not automatically follow upon a finding of invalidity**

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The status of the regulation of complementary medicines in the current legislative landscape

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CONTENTS

1. The establishment of Category D of medicines in terms of the General Regulations and the implications thereof.
2. Current status of the General Regulations.
3. Regulation by guidelines.
4. The revised Roadmap and transitional process for the regulation of complementary medicines and the implications thereof on manufacturers, importers, exporters and wholesalers of those medicine.

THE ESTABLISHMENT OF "CATEGORY D" OF MEDICINES

- On 25 August 2017 the Minister of Health published the General Medicine Regulations, promulgated in terms of the Medicines And Related Substances Act No. 101 of 1965 ("Medicines Act") under *Government Gazette* No. 41064 ("the Regulations").

- The Regulations introduced the definition of "complementary medicines" and "health supplements", which are both listed in regulation 9 of the Regulations as "Category D" medicines, intended for use in humans and animals and which are, without further manipulation, ready for administration.

- The implications of the Regulations is drafted so broadly so as to incorporate complementary medicines and health supplements that do not fall within the ambit of "medicine" as defined in the Medicines Act, which in turn has various implications for manufacturers, importers and sellers of complementary medicines in terms of provisions of the Medicines Act and the Regulations.

CURRENT STATUS OF THE REGULATIONS

- The implications of the Regulations were discussed by the High Court of South Africa, Gauteng Division, Pretoria in the matter *of Alliance of Natural Health Products (South Africa) v The Minister of Health and Another* (Case No. 11203/18) ("the *ANHP* judgment") were Kubushi, J held that –
    - the Medicines Act does not empower the Minister of Health to regulate all complementary medicines;
    - for complementary medicines to fall within the proper contextual definition of "medicine" in the Medicines Act, only those products that purport to be suitable for use, manufactured or sold for use for a therapeutic purpose, that is, for the prevention and treatment of "a malady", may be regulated;
    - the broad definitions of "complementary medicines" and "health supplements" in the Regulations, may, however, be interpreted to include complementary medicines and health supplements that do not purport to address the prevention, diagnosis, treatment, mitigation or modification of physical or mental diseases; and

CURRENT STATUS OF THE REGULATIONS

- the Regulations are, accordingly, *ultra vires* to the extent that the Regulations apply to "complementary medicines" and "health substances" that are not medicines or Scheduled substances as defined in section 1 of the Medicines Act and are, therefore, declared invalid and unlawful.

- The court ultimately elected to strike down the Regulations in so far as they relate to complementary medicines and health supplements that are not medicines as defined in section 1 of the Medicines Act or do not contain Scheduled substances.

- The declaration of validity was, however, ultimately suspended by Kubushi, J for period of 12 months in order to allow SAHPRA and the Minister time to take steps to determine the best manner to regulate and categorise complementary. Accordingly, the *ANHP* judgment largely preserves the *status quo* in respect of the regulation of complementary medicines in South Africa for, at least, 12 months or until the Regulations are amended.

- The Minister of Health lodged an appeal against the *ANHP* judgment to the Supreme Court of Appeal ("SCA") and the appeal is due to be heard on 7 March 2022. Judgement can, thus, be anticipated in the second half of 2022.

CURRENT STATUS OF THE REGULATIONS

- Pending the determination of the appeal, All products that fall within the definition of "complementary medicines" and "health supplements" in the Regulations must, therefore, continue to comply with the current iteration of the Regulations and the Medicines Act, which includes compliance with –
  - the licensing requirements set out in section 22C(1)(b) of the Medicines Act;
  - the provisions of regulations 10, 11 and 12 of the Regulations;
  - section 20 of the Medicines Act and regulation 42 of the Regulations, which deal with advertising and marketing of complementary medicines; and
  - the requirement to submit applications of applicable medicines for registration as complementary medicines in term of call-up notices issued in terms of section 14 of the Medicines Act.

GUIDELINES PUBLISHED BY SAHPRA

- It is currently unclear which products will be classified by SAHPRA as "complementary medicine" and or "health supplements" for purposes of the Regulations.
- The only guidance that we have is the publication by SAHPRA entitled "Complementary Medicines – Health Supplements Safety and Efficacy" ("the Health Supplements Guideline").
- The Health Supplements Guideline provides, in annexures "A" to "N" ("Annexures") to the Health Supplements Guideline, a list of substances that may typically considered to be a health supplement.

GUIDELINES PUBLISHED BY SAHPRA

- In terms of the Health Supplements Guideline, the following substances are excluded from being regarded as a health supplement for purposes of the Regulations -
  - injectable substances;
  - substances scheduled 1 or higher (when indicated for any listed purposes in the schedule);
  - substances not specified in the lists of included substances, unless duly motivated for inclusion as a health supplement as per Annexure "B" to the Health Supplements Guideline; and/or
  - isolated active ingredients not provided for in the Annexures.

Given that the law relating to complementary medicines and health supplements in South Africa is currently in a state of flux, we cannot, with absolute certainty, predict how the regulator will classify specific products.

THE REVISED ROADMAP AND IMPLICATIONS

- SAHPRA initially published a guideline ("the Roadmap") entitled "Roadmap and Transitional Process for the Regulation of Complementary Medicines" in November 2013 in order to establish a new timeline in respect of licensing and registration of complementary medicines.

- The Roadman may be revised further, particularly in light of the outcome of the appeal proceedings in the SCA.

- The Road has since been updated in December 2021 and provides the following timelines -

February 2020 to December 2021	Finalising Annexures and amending and updating guidelines
February 2020 to February 2022	Priority period for application for licenses
1 March 2022	Relevant licenses will be required by SAHPRA prior to the manufacturing, importing, exporting or distribution of complementary medicines
July 2022	Existing applications for registration will be finalized Call up-notices for category D will be published over a period between 6 months and 72 months
1 March 2023	Compliance with labelling requirements at point of submission.

Questions and general discussion

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National Health Insurance Scheme - What are we expecting in 2022?

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National Health Insurance

- What the National Health Insurance Bill says about its future – Clause 57

National Health Insurance

- The current status of the Bill and associated processes

National Health Insurance

- NHI – Phase 2 – Clause 57(5)

National Health Insurance

- NHI – next steps – public participation

National Health Insurance

- The future and the legislative process

Conclusion and questions

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