

**Legal aspects of submitting
application to the medicines
control council (“MCC”): Waiting
for Godot and the Law of Decisions**

**South African Clinical
Researchers’ Association**

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Keep us close

Law of Decisions

**Medicines and Related Substances Act No. 101 of 1965, as amended
and
Medicines and Related Substances Amendment Act No. 72 of 2008**



Law of Decisions

Applications



Decisions

but

Decisions



Administrative Action?



Law of Decisions

Administrative Law

- ▶ Section 33 of the Constitution of the Republic of South Africa, 1996 (“the Constitution”)
- ▶ Common law
- ▶ Uniform Rule 53
- ▶ Promotion of Administrative Justice Act No. 3 of 2000 (“PAJA”)



Law of Decisions

RELIEF?

- ▶ Legalese defines rights:
 - “decisions”
 - “administrator”
- ▶ “Administrative action”
 - procedurally fair administrative action



Law of Decisions

“Decision”

Any decisions of an administrative nature made, proposed to be made, or required to be made, as the case may be, under an empowering provision, including a decision related to –

- a) Making, suspending, revoking or refusing to make an order, award or determination;
- b) Giving, suspending, revoking or refusing to give a certificate, direction, approval, consent or permission;
- c) Issuing, suspending, revoking or refusing to issue a license, authority or other instruments;
- d) Imposing a condition or restriction;
- e) Retaining, or refusing to deliver up, an article; or
- f) Doing or refusing to do any other act or thing of an administrative nature, and a reference to a failure to take a decision must be construed accordingly”.



Laws of Decisions

“Administrative action”

“means any decision taken, or any failure to take decisions, by –

a) an organ of state, when –

- i. exercising a power in terms of the Constitution or a provincial constitution; or
 - ii. excusing a public power or performing a public function in terms of any legislation;
- or

b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision, full extent of the quote which adversely affects the right of any person and which has a direct, external legal effect...”



Laws of Decisions

“Administrator”

“means an organ of state or any natural or juristic person taking administrative action”



Law of Decisions

“A fair administrative procedure depends on the facts of each case.”

Section 3(2) of PAJA



Law of Decisions

**Letter writing competition
to
The inside of a court room**



Law of Decisions

Awareness

- ▶ What is reasonable on your merits?
- ▶ When did you reasonably repeat a decisions?
- ▶ Reasons requested – section 5 (1) of the PAJA
- ▶ No reasons – now what?
- ▶ Reasons obtained – now what?
- ▶ DIY
- ▶ Prescription: 180 day watch period: “without unreasonable delay”
- ▶ “what could I have done to avoid this?”



Law of Decisions

Judicial Review

**Don't promise – don't act
or
Don't take a knife to a gun fight**



Law of Decisions

...reach up and pull the mask downwards...

- ▶ Damages – costs of application
- ▶ Reputation – costs of market freeze
- ▶ Access to healthcare – Constitution
- ▶ Consequences of litigation – suing the MCC?



Law of Decisions

Two folk songs

- ▶ Under pressure – Queen
- ▶ The Happy Wanderer

Which one are you?



Thank you

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