
PROCLAMATIONS • PROKLAMASIES

PROCLAMATION NO. R. 54 OF 2019**by the****PRESIDENT of the REPUBLIC of SOUTH AFRICA****SPECIAL INVESTIGATING UNITS AND SPECIAL TRIBUNALS ACT, 1996 (ACT NO. 74 OF 1996): REFERRAL OF MATTERS TO EXISTING SPECIAL INVESTIGATING UNIT**

WHEREAS allegations as contemplated in section 2(2) of the Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of 1996) (hereinafter referred to as “the Act”), have been made in respect of the affairs of the South African Health Products Regulatory Authority established in terms of section 2 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (hereinafter referred to as “the SAHPRA”);

AND WHEREAS I deem it necessary that the said allegations should be investigated and civil proceedings emanating from such investigation should be adjudicated upon;

NOW, THEREFORE, I hereby, under section 2(1) of the Act, refer the matters mentioned in the Schedule, in respect of the SAHPRA, for investigation to the Special Investigating Unit established by Proclamation No. R. 118 of 31 July 2001 and determine that, for the purposes of the investigation of the matters, the terms of reference of the Special Investigating Unit are to investigate as contemplated in the Act, any alleged—

- (a) serious maladministration in connection with the affairs of the SAHPRA;
- (b) improper or unlawful conduct by employees of the SAHPRA;
- (c) offence referred to in Parts 1 to 4, or section 17, 20 or 21 (in so far as it relates to the aforementioned offences) of Chapter 2 of the Prevention and

Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004), and which offences were committed in connection with the affairs of the SAHPRA; or

(d) unlawful or improper conduct by any person, which has caused or may cause serious harm to the interests of the public or any category thereof,

which took place between 1 January 2015 and the date of publication of this Proclamation or which took place prior to 1 January 2015 or after the date of publication of this Proclamation, but is relevant to, connected with, incidental or ancillary to the matters mentioned in the Schedule or involve the same persons, entities or contracts investigated under authority of this Proclamation, and to exercise or perform all the functions and powers assigned to or conferred upon the said Special Investigating Unit by the Act, in relation to the said matters in the Schedule.

Given under my Hand and the Seal of the Republic of South Africa at Pretoria this 4 day of October Two thousand and nineteen.

CM Ramaphosa

President

By Order of the President-in-Cabinet:

R Lamola

Minister of the Cabinet

SCHEDULE

1. Maladministration in connection with the affairs of the SAHPRA in relation to—
 - (a) the authorisation of the sale of unregistered medicines or medical devices, including *in vitro* diagnostic medical devices; and
 - (b) licensing,in terms of the Medicines and Related Substance Act, 1965, including the causes of such maladministration.
2. Any unlawful or improper conduct by—
 - (a) employees of the SAHPRA; or
 - (b) any other person or entity,in relation to the allegations set out in paragraph 1 of this Schedule.

PROKLAMASIE NO. R. 54 VAN 2019**van die****PRESIDENT van die REPUBLIEK van SUID-AFRIKA****WET OP SPESIALE ONDERSOEKEENHEDE EN SPESIALE TRIBUNALE, 1996
(WET NO. 74 VAN 1996): VERWYSING VAN AANGELEENTHEDE NA
BESTAANDE SPESIALE ONDERSOEKEENHEID**

AANGESIEN bewerings soos beoog in artikel 2(2) van die Wet op Spesiale Ondersoekeenhede en Spesiale Tribunale, 1996 (Wet No. 74 van 1996) (hierna na verwys as die "Wet"), gemaak is in verband met die aangeleenthede van die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte, ingestel ingevolge artikel 2 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965) (hierna na verwys as "die SARGP");

EN AANGESIEN ek dit nodig ag dat gemelde bewerings ondersoek en siviele geskille voortspruitend uit sodanige ondersoek bereg moet word;

DERHALWE verwys ek hierby, kragtens artikel 2(1) van die Wet, die aangeleenthede in die Bylae vermeld ten opsigte van die SARGP, vir ondersoek na die Spesiale Ondersoekeenhede ingestel by Proklamasie No. R. 118 van 31 Julie 2001 en bepaal dat, vir die doeleindes van die ondersoek van die aangeleenthede, die opdrag van die Spesiale Ondersoekeenhede is om soos beoog in gemelde Wet, ondersoek te doen na enige beweerde—

- (a) ernstige wanadministrasie in verband met die aangeleenthede van die SARGP;
- (b) onbehoorlike of onregmatige optrede deur werknemers van die SARGP;
- (c) misdryf bedoel in Dele 1 tot 4, of artikel 17, 20 of 21 (vir sover dit op voornoemde misdrywe betrekking het) van Hoofstuk 2 van die Wet op die Voorkoming en Bestryding van Korrupte Bedrywighede, 2004 (Wet No. 12 van 2004), en welke misdrywe gepleeg is in verband met die sake van die SARGP; of
- (d) onwettige of onbehoorlike optrede deur enige persoon wat ernstige benadeling vir die belange van die publiek of enige kategorie daarvan veroorsaak het of kan veroorsaak,

wat plaasgevind het tussen 1 Januarie 2015 en die datum van publikasie van hierdie Proklamasie of wat plaasgevind het voor 1 Januarie 2015 of na die datum van

publikasie van hierdie Proklamasie, wat relevant is tot, verband hou met, insidenteel of bykomstig is tot, die aangeleenthede vermeld in die Bylae of wat dieselfde persone, entiteite of kontrakte betrek wat ondersoek word kragtens die volmag verleen deur hierdie Proklamasie, en om al die werksaamhede en bevoegdhede wat deur die Wet aan die gemelde Spesiale Ondersoekeenheid toegewys of opgedra is, uit te oefen of te verrig in verband met die genoemde aangeleenthede in die Bylae.

Gegee onder my Hand en die Seël van die Republiek van Suid-Afrika te Pretoria op hede die 4 dag van Oktober Twee duisend-en-negentien.

CM Ramaphosa

President

Op las van die President-in-Kabinet:

R Lamola

Minister van die Kabinet

BYLAE

1. Wanadministrasie in verband met die aangeleenthede van die SARGP ten opsigte van—

(a) die goedkeuring van die verkoop van ongeregistreerde medisyne of mediese toestelle, insluitende *in vitro* diagnostiese mediese toestelle; en

(b) lisensiëring,

ingevolge die Wet op Medisyne en Verwante Stowwe, 1965, insluitend die oorsake van sodanige wanadministrasie.

2. Enige onwettige of onbehoorlike gedrag deur—

(a) werknemers van die SARGP; of

(b) enige ander persoon of entiteit,

ten opsigte van die bewerings uiteengesit in paragraaf 1 hierdie Bylae.