WHAT SAHPRA MAY DO DURING THE PERIOD OF SUSPENSION OF THE CMs REGULATIONS

1. In the SCA judgment, Van der Merwe J said: *"I find no reason in principle to interfere with the suspension order. It was at least justified on the following basis. As I have said, it is widely accepted that there is a public interest need to also regulate complementary medicines and health supplements that are not medicines under the Act. Therefore, it is in the public interest to regulate these substances under the regulations during the interim period of consideration of the appropriate regulation thereof. The cross-appeal must therefore fail."*[1]

2. Read on its own, in a vacuum, this paragraph says exactly what it *prima facie* does. But it cannot be read in isolation – especially not by SAHPRA who has received a raft of complaints and knows full well that the regulations are unworkable. Here it is important that the Medicines and Related Substances Act has NO reference to CMs nor any definition thereof. Not a single word. No definition thereof. Nothing. The definition appeared for the first time in the Regulations.

3. Due to the Reitzer Pharmaceuticals[2] and Treatment Action Campaign v Rath[3] cases, the precursor of SAHPRA already knew what a medicine is. Advocate Marcus, in a junior

[1] *Minister of Health and Another v Alliance of Natural Health Products (South Africa)* (Case no 256/2021) [2022] ZASCA 49 (11 April 2022)
[2] *Reitzer Pharmaceuticals (Pty) Ltd V Registrar of Medicines and Another* 1998 (4) Sa 660 (T)
[3] *Treatment Action Campaign and Another v Rath and Others* (12156/05) [2008] ZAWCHC 34; [2008] 4 All SA 360 (C) (13 June 2008)

capacity, was arguing the self-same point which he sought, unsuccessfully in the appeal referred to above, to oppose, in the Reitzer Pharmaceuticals matter.

4. After the very thorough Kubushi J Judgment SAHPRA knew what a medicine was. It conceded the definition in its answering affidavit already. It conceded it before Kubushi. It conceded it in its Heads of Argument in the SCA. Its counsel, Marcus, now a silk, conceded the definition twice in argument. At no point in time did SAHPRA believe that unscheduled substances or substances without a therapeutic claim was a medicine. In any event, the Minister cannot make regulations in terms of the Medicines Act which do not even mention complementary medicines. The Statute will have to be amended or a new statute will have to be drafted.

5. In pages 484 – 485 of her seminal textbook on Administrative Law, 3rd edition, Juta, Professor Hoexter discusses the repercussions of statutes without regulations and similar scenarios which render the application of an act impossible. The most important cases she refers to are the *Affordable Medicines*[4] case and the *Kruger v President of the Republic of South Africa*[5] cases.

6. As stated by her one is confronted with a Constitutional Rule of Law situation. Legislation may not be vague. I attach the relevant two pages hereto.

[4] *Affordable Medicines Trust v Minister of Health* 2006 (3) SA 247 (CC)
[5] *Kruger v President of the Republic of South Africa* 2009 (1) SA 417 (CC)

7. I use the analogy of a house which has been condemned and which will be demolished within 12 months. However, the landlord may not throw people out on the pavement. It must do its best to making the house as safe as possible for current tenants with as few expenses as possible. Only the bare minimum repair work may be done. Hundreds of new tenants may not be housed in the building, nor may tennis courts and a swimming pool be built at the public's expense.

8. SAHPRA is *mala fide* and is acting recklessly in reading the quoted passage from the SCA judgment in a vacuum and with studied obtuseness. It may not impound further products, issue new guidelines, state that it is "business as usual", call up products, force entities to go through the portal, in the full knowledge that the regulations have been "condemned". That is just downright wrong, and they know it. SAHPRA is flaunting the Rule of Law and its conduct is highly irregular and questionable.

9. A perfect example of what SAHPRA may do is to recall undesirable products in terms of section 23 of the Medicines Act. It can take cowboy operators to court. Most food supplements and complementary medicines have been on the marketplace for decades without any adverse events, but they are being targeted. Traditional African medicines have been sold freely although a large number of deaths have been reported because of, inter alia, poisonous substances. Apparently SAHPRA does not care about a very large percentage of South Africans' health but intend to enforce invalid regulations with vim and vigour. It does not take an active imagination to realise that SAHPRA's blinkered approach is unconstitutional and in contempt of court.

M M JANSEN SC

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