Satahwa wants to thank Anthony Rees and his team for fighting this battle on our behalf.

COMPLEMENTARY MEDICINES REGULATIONS DECLARED UNLAWFUL – SUPREME COURT OF APPEAL

The Supreme Court of Appeal (SCA) in Bloemfontein ruled on 11th of April that the controversial regulations for complementary medicines under the Medicines and Related Substances Act (Act 101 of 1965) are invalid and unlawful.

The SCA dismissed an appeal by the Minister of Health and the South African Health Products Regulatory Authority (SAHPRA) against a previous North Gauteng High Court (Pretoria) judgement in favour of the Alliance of Natural Health Products South Africa (ANHP), by Judge Elizabeth Kabushi on the 1st of October 2020. The verdict follows after the ANHP, a TNHA partner, took the Minister of Health and the SAHPRA to court over contested regulations that would regulate all natural health products, defined as complementary medicines and health supplements as medicines.

According to ANHP, it is not the statutory duty of SAHPRA in terms of the Medicines Act to regulate complementary medicines and health supplements as defined in the regulations, according to the original spirit and intention of the 57 year old Medicines Act. Complementary medicines include products such as vitamins, minerals, amino acids, enzymes, pro and pre-biotics, herbal remedies, homeopathic medicines, sports supplements, etc.

ANHP Chairman – Anthony Rees

The ANHP initially filed for a declaratory order on the lawfulness of the said regulations, in whole or in part, in the High Court on the 19th of February 2018. Our TNHA Chairman Anthony Rees was nominated as Chairman of the ANHP when the organization was founded, and deposed the founding court papers, assisted the legal team and attended all the court hearings.

The ANHP argued that the Minister of Health is only authorized to regulate medicines and scheduled substances within the definition of a medicine in the Medicines Act, and that attempting to regulate substances which do not purport to be medicines was a regulatory overreach. In the SCA, the appellant's Counsel, Adv. Gilbert Marcus SC, twice admitted that only products which purport to diagnose, treat, mitigate, modify or prevent disease will be regarded as medicines as defined in the Medicines and Related Substances Act No 101 of 1965 ("the Act").

Both the High Court and five-seat bench of the SCA unanimously agreed that the SAHPRA have no legal jurisdiction to regulate substances that are not medicines or scheduled substances, and to that extent, the 2017 regulations were / are ultra virus (unlawful). The SCA partially upheld the challenge of the regulations. It was of the opinion that the declaration of invalidity should be suspended for a 12 month period in order for the Minister of Health (and not the SAHPRA) to exercise his prerogative to find an appropriate legal path to regulate the natural health product industry.

All parties agreed in filings that appropriate regulation is needed to regulate the natural health product sector, and the court agreed.

This SCA judgement has reaffirmed that the making of regulations by a Minister acting in terms of a statute constitutes administrative action within the meaning of the Promotion of Administrative Justice Act of 2000. This means that such regulations can be challenged if they are outside the powers of the Minister under the enabling legislation (ultra vires), or if they are irrational or unreasonable in relation to their purpose.

The ANHP was represented by Adv. David Borgström SC, and legal representatives from Cliffe Dekker Hofmeyr (CDH) in the SCA.

The Minister of Health and SAHPRA were jointly represented by Adv. Gilbert Marcus SC and Adv. Nasreen Rajab-Budlender SC

The five seat bench of the SCA was constituted of judges Christiaan Van der Merwe JA, Ashton Schippers JA, Fikile Mokgohloa JA, Caroline Nicholls JA and Moroa Tsoka AJA.

WHAT COMES NEXT?

This judgment has severe ramifications for the SAHPRA which did not cease its enforcement of the 2017 regulations after the Kabushi judgement in 2020, as any prudent regulatory authority should and would have done but, instead, proclaimed on its website that it would continue to enforce its regulations. It went ahead with issuing official guidelines, road maps, scheduling notices and electronic portals for companies to apply for Section 22(c) manufacturing, import, wholesale and distribution licenses, plus instituted an electronic portal for companies to obtain authorization to import products in collaboration with the Port Health Authority. We contend all subsequent guidelines, road maps, portals and the like issued and gazetted in terms of the invalidated 2017 complementary medicines regulations be rescinded immediately as they are the fruit of a poisoned tree. The Minister and SAHPRA are now forewarned to tread lightly and to address the very real problems faced by the sector.

We believe it would not be in the SAHPRA's interests to continue with its wholly illegal electronic Port Health clearance portal and the continued detention of products in light of this unanimous SCA judgment. It would be very unwise to proceed with call up notices for complementary medicines in the knowledge that extending the unlawful regulations for another 12 months will only lead to larger legal entanglements, potentiating more vigorous litigation, including companies suing for reparations after incurring heavy compliance costs since 2017 for non-medicines they sell. Members of SAHPRA are not above the law and may even incur personal liability.

"This monumental case opens a new exciting chapter in the way in which natural health products are to be potentially regulated and sold in South Africa. At last, the industry has clarity on what is, and what is not a medicine. Many companies have spent many millions of Rands in an attempt to comply with the regulations and are continually hitting their heads against a brick wall with an uncooperative regulator. This SCA judgement finally delineates key issues of contention and will provide the natural health products sector much needed clarity on how they wish to proceed marketing their products going forward. They will hopefully have a choice in whether to sell their products as food-like health supplements without health claims purporting to diagnose, treat, mitigate, modify or prevent disease, or as medicines under a dense thicket of costly regulations designed around pharmaceutical medicines.", says Anthony Rees, TNHA Chairman.

"The SAHPRA has itself to blame for its current legal dilemma. It knew full well that a large complement of complementary medicines fell outside the ambit of the definition of a "medicine" as set out in the Medicines Act. In fact we have learned from a former senior official of the former Medicines Control Council which preceded the SAHPRA, that they were warned by the State Attorney's office over 20 years ago, that similar regulatory attempts on the sector would risk being declared be unlawful. In fact, prior to the Kabushi judgement in 2020 finding for the ANHP, two previous cases involving natural health products in the past (TAC v. Rath and others, 2008 [Case No: 12156/05] and Reitzer Pharmaceutical v. Registrar of Medicines, Medicines Control Council, 1998 [Case 10842/98] have been adjudicated where the court found the similar conclusions regarding what are and what are not medicines. How is it that in 2017 and up until this SCA judgement did the Minister and regulatory authority act unlawfully again, knowing full-well that they did not have the legislative jurisdiction?"

"Ultimately, the TNHA would like to see South Africa either regulate no medicinal therapeutic health products as a new 'third category', separate from foods and medicines, under its own legislative instrument (Act) and under its own statutory regulatory authority, or through amendments to the existing Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972). The TNHA will now begin lobbying the Minister of Health and members of parliament to adopt a new inclusive vision for traditional & natural health products. We invite other associations, importers, manufacturers, wholesalers, distributors and retailers of natural health products to join the TNHA, so that we can stand united in a call for fairer, appropriate regulations and to continue to protect the natural health choices of South Africans".

“I wish to thank all our loyal TNHA supporters and other ANHP stakeholders who wish to remain anonymous for their support throughout this four and a half year process. At the end of the day good science, good law and basic common sense prevailed. We will soon unpack this latest judgement and its practical business implications for our members”.