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THE ALLIANCE OF NATURAL HEALTH PRODUCTS (SOUTH AFRICA) / THE MINISTER OF HEALTH AND ANOTHER (CASE NO. 11203/18)

The controversial Complementary Medicine Regulations purport to submit natural health products to the stringent regulatory requirements applicable to 'medicines' and 'Scheduled substances' (pharmaceutical drugs). This will have far reaching consequences for manufacturers, importers, retailers, practitioners and consumers associated with these products across South Africa.

On 19 February 2018 the Alliance of Natural Health Products (South Africa) launched an application challenging the General Regulations published by the Minister of Health under the Medicines and Related Substances Act, No 101 of 1965 on 25 August 2017. Those regulations attempt to regulate natural health products on the same basis as conventional pharmaceutical drugs. The Alliance operates across the complementary-medicine, traditional-medicine and health-supplement sectors and its members include traditional healers, natural-health advocates, manufacturers, retailers and concerned members of the public. In the Alliance's view, the Regulations' definitions of "complementary medicines" and "health supplements" are unlawfully and unworkably broad, with the result that the definitions include a range of products and substances that are neither "medicines" nor "Scheduled substances" as defined in the Medicines Act. In other words, all nutritional supplements, vitamins, minerals and food supplements are now subject to the same stringent and costly manufacturing, assessment and registration requirements as pharmaceutical drugs.

The implications of this inclusion are significant. If a substance or product is defined as a medicine, or is specified in one of the schedules to the Medicines Act, certain consequences arise. If the substance is defined as a medicine, it becomes subject to specific limitations concerning its labelling/packaging, supply, marketing and sale, as well as having to have the same clinical research to support health claims related to their known health-promoting benefits. A scheduled substance is also subject to labelling/packaging and advertising requirements, in addition to onerous restrictions regarding its possession, sale and manufacture.

These requirements make sense in relation to conventional pharmaceutical drugs that have a 'therapeutic purpose' (i.e. the prevention or treatment of a malady) and generally have a high risk base. However, health supplements do not perform a therapeutic purpose, catering instead for ordinary human nutrition or sustenance, and so should not be treated as medicines under the Medicines Act. The regulations have also been so broadly phrased that they subject complementary medicines (such as aromatherapy) to a host of ill-suited and ill-considered requirements, which most manufacturers cannot afford without significantly increasing the costs of their products. The regulations fail to make any of the necessary distinctions between conventional pharmaceutical drugs, on the one hand, and natural health products, on the other hand.

Complementary medicines and health supplements are recognisably and materially different to "medicines" and "Scheduled substances": they have different purposes and different effects. They also have a well-established low risk base, and are categorised elsewhere in the world as "Generally Regarded as Safe". The

two forms of treatment should therefore not be subject to the same regulatory requirements: this is irrational and impermissible under the Medicines Act. In fact, the Medicines Act does not mention complementary medicines or health supplements at all.

Since the Medicines Act regulates conventional pharmaceutical drugs, as expressly intended by law-makers in Parliament over half a century ago when the Act was passed into law, and not complementary medicines or health supplements, the regulations are *ultra vires* in terms of the Medicines Act and are therefore unlawful.

The parties cited as respondents in the Alliance's review application are the Minister of Health and the South African Health Products Regulatory Authority (SAHPRA), the successor to the Medicines Control Council (MCC). The Minister is responsible for the administration of the Medicines Act and made the regulations in question. The Authority is responsible for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines and scheduled substances, among other duties, and had to be consulted in the process of making the regulations. It remains to be seen whether the Minister and the Authority will oppose the review.

In launching the review the Alliance is not only protecting its own interests, but also those of the public at large. The effect of the regulations is that the majority of popular and trusted natural health products will become more expensive for consumers and beyond the means of many South Africans, or will disappear from the shelves of health stores and pharmacies, and from direct selling catalogues. Health Practitioners who prescribe and dispense natural health products will also have far fewer natural health products to provide to their patients who choose a natural means to promote health and wellness. Further still, many businesses in the industry will be forced to close operations, contributing to the country's growing number of job losses.