

THE SUPREME COURT OF APPEAL OF SOUTH AFRICA MEDIA SUMMARY OF JUDGMENT DELIVERED IN THE SUPREME COURT OF APPEAL

From: The Registrar, Supreme Court of Appeal

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Status: Immediate

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Minister of Health and Another v Alliance of Natural Health Products (South Africa) (Case no 256/2021) [2022] ZASCA 49 (11 April 2022)

Today the Supreme Court of Appeal (SCA) handed down judgment dismissing, with costs, the appeal and cross-appeal against the decision of the Gauteng Division of the High Court, Pretoria (the high court).

The issue in this appeal was whether any review ground of the Alliance was good.

The Minister of Health (the Minister) is the first appellant in this matter. The second appellant is the South African Health Products Regulatory Authority (the Authority). It was established as an organ of state and juristic person by s 2 of the Medicines and Related Substances Act 101 of 1965 (the Act). The respondent is the Alliance of Natural Health Products (South Africa) (the Alliance), a voluntary association with the capacity to sue or be sued in its own name.

After a public consultative process that had stretched over several years and in consultation with the Authority, the Minister, acting in terms of s 35 of the Act, made the regulations that are the subject of this appeal. They are the General Regulations published on 25 August 2017 under GN 859, in GG 41064 (the regulations). It appeared from the evidence that there was a substantial market worldwide and in South Africa for complementary medicines and health supplements. There was no dispute that this market should be regulated in the public interest. That, in the main, was the purpose of the replacement of the previous General Regulations under the Act, with the current ones. The regulations therefore introduced a new category, to wit complementary medicines (Category D).

The Alliance sought declaratory orders as well as the review and setting aside of these regulations, in whole or in part, in the high court. The Alliance contended that the Minister was only empowered to regulate medicines and scheduled substances within the meaning of the Act. However, so it submitted, the regulations purported to regulate substances that were neither medicines nor scheduled substances and, to that extent, they were *ultra vires* (the *ultra vires* ground). The high court partly upheld the challenge to the regulations. It considered that the partial declaration of invalidity in respect of the regulations should be suspended for a period of 12 months. The Alliance cross-appealed against the suspension of the declaration of invalidity.

The SCA held that the regulations purported to regulate substantial numbers of substances that were not medicines under the Act. Therefore, held the SCA, the high court correctly concluded that the regulations were *ultra vires* and invalid. The SCA therefore held that the appeal must fail on the *ultra vires* ground and that it was unnecessary to make a final determination of the other review grounds. In respect of the cross-appeal, the SCA held that there was no reason in principle to interfere with the suspension order.