



Probiotics — findings challenged

To the Editor: Startling and irresponsible conclusions are drawn in relation to various probiotic products on the South African market by the authors of an article in the February 2004 *SAMJ* entitled 'An evaluation of nine probiotics available in South Africa, August 2003'.¹

The article fails to do justice to the recognised benefits of probiotic products and, arising from its inaccuracies and its apparent subjectivity, issue must be taken with its contents. The authors level various criticisms against the manufacturers/distributors of certain probiotic products, including Pharma Dynamics in relation to its product, *Culturelle*.

Set out below are pertinent facts omitted by the authors of the article (one of whom is medical advisor to, and apparently a shareholder of, Thebe Pharmaceuticals, the sponsor of the study reported in the article and the South African distributor of the probiotic product, *BioPro Reuteri* — a product favourably evaluated in the article).

1. The study, its methodology and its results are severely flawed. The sampled products, which are particularly sensitive to atmospheric conditions and extremes in temperature, were transported from South Africa to Belgium for analysis under uncontrolled conditions ('packed on ice' in the hold of an aeroplane, subject to low levels of oxygen and without any form of monitoring or recording of conditions).

2. The study reported in the article is based on the DGGE (denaturing gradient gel electrophoresis) testing method. The method is fundamentally flawed in that it is unable to quantify the amount of bacteria identified. Thus the quantity of bacteria referred to in the article (based on the method) cannot be verified by the testing method.

3. DGGE is not a recognised international standard for the identification of commercially available probiotic bacteria, and is therefore unreliable in the final identification of the lactic acid bacteria strains, and, on the study researcher's own version, not to be considered optimal in obtaining a 100% reliable result.

4. In respect of its product, *Culturelle*, the manufacturer uses internationally renowned and approved Bergey's Manual to identify lactic acid bacteria strains present in the product. This method remains recognised and internationally approved for the identification of commercially available lactic acid bacteria.

5. The certificate of analysis and the underlying data in respect of the batch of *Culturelle* to which the article refers have been verified and comply with European Pharmacopoeia specifications. Pharma Dynamics conducts repeated periodic stability testing and verification during product storage to ensure the continued stability of *Culturelle*.

6. *Culturelle* is enteric coated to ensure that the bifido-bacteria, which are sensitive to acid, are protected during the

passage through the stomach, the product reaching the intestine before the coating dissolves to release the lactic acid bacteria. The article fails to detail whether an appropriate method, taking into consideration the nature of products tested, was used to release the tested bacteria from the micro-encapsulated particles.

7. The clear association between at least one of the co-authors and Thebe Pharmaceuticals casts serious doubts on the impartiality of the article, the study and its various conclusions.

The above brief comments and observations raised all illustrate the numerous and serious concerns that must be raised in relation to the article and the study to which it refers. For the sake of the reputation of the *SAMJ*, it is essential for the integrity of the journal that a comprehensive peer review process excludes the publishing of what one is ineluctably led to conclude is an 'advertorial' based on the disparagement of competitor products.

Paul Anley

Managing Director: Pharma Dynamics

*Steenberg Office Park
Westlake
Cape Town*

1. Elliott E, Teversham K. An evaluation of nine probiotics available in South Africa, August 2003. *S Afr Med J* 2004; 94: 121-124.

Doctors and the medical aid industry

To the Editor: I would like to add my (slightly humbler) voice to those of my esteemed colleagues Robert Caldwell¹ and N C Lee.²

Doctors are service providers who have/should have absolutely no contractual or other obligations to insurance companies (which, after all, is what medical aids are). Furthermore, doctors should not be required to be businessmen, but we are rapidly being forced in that direction. In this regard surely it must be unethical not to recommend fees to be charged? That great institution, the HPCSA, is strangely silent on this issue. How has it come to be that the medical aid industry has the power to prescribe to us? Above all, what is SAMA as our only representative organ doing about it? Public perception is definitely that we are the baddies (rich, greedy doctors, always wanting more money), and they remain sublimely ignorant as to the real state of affairs. Medical aids have frequently shown that this is not a 'gentleman's fight' and they should be handled accordingly. I have been a SAMA member since my internship and am now a SASA member as well, but more and more colleagues inform