

Will the new Consumer Protection Act prevent harm to nutritional supplement users?

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Background. There is no clear distinction between the regulation of food, supplements and medicines in South Africa. Consequently, grey areas exist in implementing the legislation, particularly in the supplement industry. The increase in supplement sales in South Africa can be attributed to aggressive marketing by manufacturers whose claims are not always supported by published peer-reviewed evidence. Such claims often go unchecked, resulting in consumers being misled about the role of supplements. As a result of poor regulation, contaminants or adulterants in supplements may also cause insidious effects unrelated to the listed ingredients.

Aim. To assess the regulations, legislation, and claims associated with nutritional supplement products in South Africa.

Method. Peer-reviewed literature and the relevant South African statutes were consulted.

Results. The National Health Act incorporates the Medicine Control Council, which is charged with ensuring the safety, quality

and effectiveness of medicines, and related matters, including complementary/alternative medicines. The South African Institute for Drug-Free Sport and Amendment Act provides for testing athletes for using banned substances, but currently does not concern itself with monitoring nutritional supplements for contaminants or adulterants that may cause a positive drug test, which has implications for sports participants and also the health of the general population. The implementation of the Consumer Protection Act 68 of 2008 (CPA) could protect consumer rights if it is administered and resourced appropriately.

Conclusion. The CPA should promote greater levels of policy development, regulatory enforcement, and consumer education of South Africa's supplement industry.

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There is no clear distinction between food, supplements and medicines in South Africa. As these are regulated differently, grey areas exist in implementing the legislation, particularly in the supplement industry.

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The increase in supplement sales in South Africa can be attributed partly to aggressive marketing by manufacturers. Claims made by the companies selling supplements are not always supported by published peer-review evidence. Such claims often go unchecked, resulting in consumers being misled about the role of supplements. Contaminants or adulterants in supplements may also cause insidious effects unrelated to the listed ingredients. The Consumer Protection Act 68 of 2008 (CPA) could promote greater levels of policy development, regulatory enforcement, and consumer education of South Africa's supplement industry.

Nutritional supplement annual retail sales in the USA increased from \$8.8 billion in 1994 to \$18.8 billion in 2003 – an increase of 115%, of which much was spent on 'sports supplements'.^{1,2} South Africa's supplement turnover was estimated at R1.5 billion per year (Health Product Association Survey 1998 - 2000) and continues to grow rapidly.³ The increase in supplement sales is more probably due to aggressive marketing by manufacturers, rather than the

development of more effective nutritional supplements.⁴ Because of the complex legislation governing supplements in most countries (including South Africa), companies can make unsubstantiated claims about the efficacy of their supplements.⁵ Since the accuracy of product labelling often goes unchallenged, effects of the supplement that could be due to contaminants or adulterants might not be reflected on the label.^{3,6-8} The management of the supplement industry is in stark contrast to the drug industry, which has strict legislation and control. Divergence between food and drug laws has generated grey areas regarding the 'voluntary' declaration of 'all' content in a specific nutritional supplement product. This makes the product manufacture chain difficult to deal with or even subject to appropriate law enforcement. Although some consumer protection and anti-doping agencies have requested stricter report requirements for supplement manufacturers and tougher penalties for repeat offenders, legislation is largely unchanged.⁹

Claims made by companies

Some marketing claims about the efficacy of nutritional supplements are not supported by published peer-reviewed evidence, often leaving the general public confused as they are unable to distinguish between correct and false claims.¹⁰ Container labels also do not always accurately reflect the contents,⁴ which poses health concerns. A competitive athlete risks failing a drug test if a contaminant is on the banned substances list. There are examples of South African-made nutritional supplements containing banned substances that would have resulted in a positive doping test.³

Legislation in South Africa

The regulation of nutritional supplements in most countries, including South Africa, is usually embedded in other forms of legislation than those governing medicine.^{11,12} The Constitution of South Africa Act 108 of 1996 enables, and sometimes obliges, parliament to legislate on certain aspects of nutritional supplements, viz. (i) the Consumer Protection Act (CPA); (ii) the National Health Act 61 of 2003; (iii) the Medicines and Related Substance and Amendment Act 59 of 2002; (iv) the South African Institute for Drug-Free Sport and Amendment Act 25 of 2006; and (v) the Medical Research Council Act 19 of 1969.¹³

The CPA, which is intended to serve the consumer, was implemented on 1 April 2011. It seeks to establish in part (i) national norms and standards, (ii) improve standards of information, (iii) protect consumers from hazards and maintain safety, and (iv) promote a consistent legislative and enforcement framework.^{14,15}

Consumer courts have operated in Gauteng and the Free State for several years, via provincial legislation. In Gauteng, consumer legislation for the court was introduced via the Consumer Affairs (Unfair Business Practice) Act 7 of 1996.¹⁶ However, the jurisdiction of the court did not extend to product liability claims. Furthermore, the creation of the court itself may be subject to constitutional challenge, as only national parliament may create a court – and not provinces.¹⁶

Consumer courts within the context of the CPA will have limited powers and be subservient to common law regarding the interpretation, ambiguity and the best spirit that promotes the CPA.¹⁶ The Act distinguishes a consumer court from a judicial court. A consumer court is a national or provincial court or tribunal specifically established to protect consumers, as opposed to a civil or criminal court.

Consumers may have redress via Chapter 3 of the CPA, which gives protection of consumer rights and attention to the voice of

the consumer. This section specifically covers consumer rights, commission investigations, redress by the court, and civil society support.¹⁴ The CPA further introduces consumer courts to achieve protection and speedy enforcement of consumer rights, specifically in Section 69 of the Act.¹⁴ This is outlined by referring (i) the matter directly to the tribunal, (ii) to the applicable ombudsman with jurisdiction, (iii) to another alternative dispute resolution agent, (iv) applying to the consumer court of the province with jurisdiction over the matter, (v) filing a complaint with the commission, or (vi) approaching a court with jurisdiction over the matter.¹⁴

In the event of harm (no-fault liability) being suffered as a result of the supply of any unsafe goods, product failure or inadequate instructions or warnings pertaining to hazardous use of any goods, the producer/importer/distributor/retailer is liable, irrespective of whether there was negligence on the part of any of those persons.^{16,17} This is particularly applicable to the manufacturer of medical products e.g. pharmaceuticals. There will, however, be no liability on unreasonable grounds, e.g. on the part of a distributor or retailer if they discover an unsafe product, and had no part in its marketing.

For nutritional supplements, continuous batch-to-batch independent evaluation is important to provide contamination detection for good-quality products, and early warning of products that are contaminated and pose risk to consumers. Short- and long-term adverse effects and events owing to product contamination can so be brought to the attention of the consumer and authorities. Production monitoring further amplifies the importance of independent contaminant screen testing procedures to determine unsafe products, safety monitoring, and recall of products, as presented in more general terms and not necessary for nutritional supplements specifically, in Section 60 and 61 of the CPA.¹⁴ While the CPA is intended to serve consumers' interest, its intention will become meaningful only when court challenges are lodged through intensified and vigilant activism.^{16,17}

Alternative approaches for consumer concerns in South Africa are to solicit support via the National Consumer Forum (NCF) and the South African National Consumer Union (SANCU). These consumer protection organisations act in the best interests of consumers to achieve a wholesome environment, a fundamental quality of life, and good quality in the goods and services provided by the private and public sectors. The CPA, in Section 77 and 78, provides for such accredited consumer protection groups.^{14,15}

The National Health Act incorporates the Medicine Control Council (MCC), which is charged with ensuring the safety, quality and effectiveness of medicines, and related matters, including complementary/alternative medicines. This requirement has met with complexities as the MCC has registered less than half of the medicine applications it received over the past 7 years.¹⁸ The situation has become a life-threatening risk to patients and is under legal threat from stakeholders, who claim the MCC is dysfunctional. Pharmaceutical companies and activists have expressed 'intense frustration' with the current process.¹⁸ The MCC is grossly understaffed, resulting in inefficiency and paucity of registrations. Its law enforcement division is also under fire for failing to stem the flood of unscrupulous practices.¹⁸ This point is further supported by considering that nutritional supplements may be tainted with conventional drugs ('medicines'), as in the case of the claimed natural supplement *Simply Slim* that contained the prescription substance sibutramine.^{19,24}

The Medicines and Related Substance and Amendment Act in part ensures the provision of registration of medicines intended for human or animal use, and provides licences to persons who wish

to manufacture, compound and dispense, or act as a wholesaler or distributor for, medicines. The South African Institute for Drug-Free Sport and Amendment Act provides for an independent sample collection and testing programme that may subject any sportsperson to dope testing. The provision is therefore specifically intended for testing athletes, and does not concern itself with monitoring nutritional supplements for tainting or contaminants that may adversely affect the general population. The Medical Research Council Act provides for the establishment of the Medical Research Council (MRC), which has a mandate to promote the improvement of the health and quality of life of South Africans.

Conclusion

The South African system of Acts and Bills lacks specificity regarding nutritional supplements, which could compromise enforcement, accountability and responsibility by the respective authorities.²⁰⁻²² Marketed nutritional supplements could compromise the health of consumers, owing to potential contamination and absence of appropriate labelling of products, if not properly tested or monitored.²³ Consumer structures must play a greater role in the development of a sound nutritional supplement management system, to ensure the maintenance of quality products and to promote knowledge awareness. Consumer forums should also contribute, and ensure that appropriate legislation and regulation are developed and enforced on a sustainable basis, in line with the CPA. South Africa needs an appropriate agency, or intensified enforcement, for ongoing monitoring of the overall quality of nutritional supplements, and also to assess them for contaminants and undeclared prohibited substances on a batch-to-batch basis. Such initiatives should be in the best interests of consumers, especially as there is increased production, marketing and use of nutritional supplements, in a predominantly self-regulatory environment.

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And as the water bore him off
Some said Greg was heard to scoff:
"I view the prospects with dismay
If this is politics today;

Yes, now it's plain for all to see
That things aren't as they used to be;
I'll stick to where the greener grass is
Up the Working Class's asses".

Maurice Kibel
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