

ISSUES IN MEDICINE

Multiple organ failure – death of consumer protection?

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The enormously profitable complementary medicines, dietary supplements and traditional medicines markets are largely unregulated internationally and in South Africa. Attempts to ensure that consumers are not exposed to harmful or ineffective products have met with varying success around the world.

International perspective

The USA introduced its Dietary Supplements Health and Education Act (DSHEA) in 1994.¹ This was seen as a precedent in many countries, including South Africa. In Canada a Natural Health Products Directorate as part of the Health Products and Food Branch of Health Canada was created.² In 2004, the Natural Health Product Regulations (NHPR), under Canada's Food and Drugs Act, became a reality. Rather than fully regulating these products as drugs, or leaving them virtually unregulated (as is done in the USA), the NHPR were a regulatory compromise: implementing manufacturing quality and safety standards, while significantly relaxing the standards for product efficacy claims.³

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) introduced the Traditional Herbal Registration (THR) certification mark to indicate that a herbal medicine that has been registered under the UK's THR scheme meets the criteria laid down by the Traditional Herbal Medicinal Products Directive.⁴

In New Zealand a 2-month consultation was held in early 2010 because, according to Associate Health Minister Dr Jonathan Coleman, the current legislation governing natural health products is outdated, inadequate and quite restrictive.⁵ The intention in New Zealand is to draft a Natural Health Products Bill during 2010.⁵ In Australia, the Therapeutic Goods Authority's listing system has been widely implemented,⁶ but has been criticised because it does not adequately assess efficacy.⁷

It is difficult to ascertain what the situation is in India, where traditional medicines and 'conventional' or 'Western' medicines have coexisted for many years. Similarly, in China it is difficult to determine the extent of regulation (or not) of traditional Chinese medicines. Unfortunate examples of adulteration of

medicines imported from China – such as Simply Slim in South Africa, containing sibutramine – have cast suspicion on many products imported as complementary medicines or dietary supplements.

In South Africa the consumer of natural health products should be protected from harmful or even useless products by several organs of state: the Medicines Control Council (MCC), the South African Pharmacy Council (SAPC), and the Public Protector. The Advertising Standards Authority of South Africa (ASA) is a body created by the industry to protect consumers from misleading advertising claims. We provide examples showing how each of these organs has failed South African consumers.

The advertising standards authority

The weight-loss product Peel Away the Pounds, declared 'dead' by the USA Federal Trade Commission (FTC), was transplanted by Homemark into the South African market. The scientific panel of the FTC had in 2004 unanimously found that the pilot study was inadequate to support the claims.^{8,9} A complaint laid with the ASA in 2005 by the first author was dismissed following substantiation by a pharmacist, Dr Beverley Summers, who argued that the study was sufficient proof of efficacy, and that a kelp transdermal patch was pharmacologically active (despite no scientific proof).¹⁰ Four internationally recognised experts who evaluated the original study agreed with us that the study was inadequate to support the claims being made for the product.¹¹ Subsequent arbitration by Professor René Blaauw and Dr Edelweiss Wentzel-Viljoen found in favour of the complainant,¹² and the product was removed from the market 3 years after the initial complaint.

Homemark then marketed another product ruled against by an FTC scientific panel: Slim Coffee with the ingredient *Citrus aurantium*,¹³ which contains synephrine. Dr Summers again substantiated¹⁴ the study and supported the weight-loss claims despite the FTC ruling.^{15,16} The research entity and its address could not be verified, not even by the Italian consulate.

Weight-loss products are defined as medicines and were called up in 1972 by the Medicines Control Council for registration.¹⁷ The complementary medicines call-up of 2002 did not specifically exempt products affected by the 1972 call-up.¹⁸ This fact was ignored by Dr Summers, who failed to point out that Slim Coffee should not have been submitted to the MCC for an abbreviated registration (as a complementary medicine), but for 'full' registration as a medicine.

The World Health Organization (WHO) *Pharmaceuticals Newsletter* reporting on *C. aurantium* warned of, among others, '15 reports ... of cardiovascular adverse reactions, 10 of which were serious and included one report of myocardial infarction' in Canada.¹⁹ Serious adverse reactions to *C. aurantium* have also been published in South Africa.^{20,21} Nevertheless the ASA accepted Dr Summers' substantiation and ruled against

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the complaint. Following a request for arbitration of the ASA ruling dismissing the complaint against Slim Coffee, Homemark stated that they had withdrawn it because of 'safety concerns' and introduced a new formulation of Slim Coffee, now containing guarana and *Caralluma fimbriata* (CF) – again substantiated by Dr Beverley Summers. A new complaint was laid with the ASA with the request that Dr Summers' status with the ASA as a 'credible expert' be revoked. Both aspects of the complaint were upheld. Homemark appealed the 'credible expert' ruling, but this was rejected by the appeal committee. Following a second appeal to the final appeal committee, Judge Mervyn King ruled in favour of Homemark, effectively allowing Dr Summers to substantiate further Homemark products despite the history above.

Dr Summers' substantiation of the new Slim Coffee product was accepted by the ASA's appeal committee in spite of being supported by only two studies,^{22,23} which the European Food Safety Authority 'found ... failed to establish a cause and effect relationship between the ingredient (CF) and the claimed benefit'.²⁴ These were the same studies provided to Dr Summers by Homemark and substantiated by her. Our argument that to reproduce the dose of CF used in the inconclusive CF studies would require a consumer to spend R1 799.40 over 2 months was dodged. The appeal committee ignored previous rulings of the ASA, which stated that a product cannot be substantiated on the basis of ingredients alone but on evidence of the efficacy of the product as a whole.

The South African Pharmacy Council

Because of Dr Summers' persistent substantiation of 'bogus' Homemark products, a complaint of 'unprofessional conduct' was laid with the SAPC in May 2009. The SAPC dismissed the complaint 10 months later, responding that where a pharmacist provides evidence as an expert before an independent judicial tribunal, such as the ASA, Council should not review such evidence on the basis of misconduct, that it is up to the 'independent tribunal ... whether to accept or reject such expert evidence', and that 'the onus rests on the other party to argue whether such expert evidence should be accepted'. The SAPC were concerned that the 'potential would be created that pharmacists would become reluctant to provide expert evidence to independent tribunals and in a court of law should Council adjudicate such matters in terms of unprofessional conduct'.²⁵ The SAPC (a science-based statutory council) therefore did not want to override any decision of the ASA (an industry-based, non-scientific, non-statutory 'authority' and *not* in fact a judicial tribunal). This decision creates a precedent that allows pharmacists to substantiate claims made for unregistered and unregulated products despite insufficient evidence for their claims. Consumers are therefore placed at risk of harm, financially and to their health.

The Medicines Control Council

The most critical organ failure is that of the MCC, which has the statutory responsibility to ensure that all medicines and related substances available to the public meet the criteria of quality, safety and efficacy.²⁶ Inspectors from the Department

of Health (DOH) are responsible for the enforcement of the Medicines Act. The ASA can rule on misleading claims, but cannot prevent any product from being sold, penalise miscreants or rule on product safety. Several letters of complaint submitted about other products to senior members of the MCC/Medicines Regulatory Affairs Cluster of the DOH remain unanswered.

In February 2010 the MCC suspended the sale of Simply Slim, as it had been found to contain sibutramine. The MCC did not 'ban' the product in terms of section 23 of the Medicines Act, but seemingly used a sub-clause of section 15 of the Act. Simply Slim re-launched their product using a local manufacturer and a system for customers to validate that it was a genuine product. It appears that no clinical evidence of the product's safety or efficacy had been provided to the MCC.

The Public Protector

In September 2009, following a complaint directly to the MCC regarding a homeopathic product MODUL8, which claimed to treat AIDS, going unanswered, the Public Protector was approached for intervention. In January 2010 the Public Protector closed the file following the response from the MCC, which stated among other things: 'In February 2008, the Medicines Control Council (MCC) ruled against Canova, a product similar to MODUL8. The Council requested the company marketing Canova to withdraw the product from the market because the product safety profile could not be substantiated. The company has since appealed the decision of Council in terms of the provision of section 24 of the Medicines and Related Substances Act, 1965. The MCC is still awaiting for [sic] the ruling by the appeal committee. The decision of the appeal committee on Canova will be applied to MODUL8.'²⁷ No further information has been received.

Conclusion

Multiple organ failure has clearly resulted in an inability to efficiently clear or reject deleterious medicines and substances, resulting in financial and health trauma to consumers, with possible consequences including unnecessary deaths.

We await with interest the implementation of the Consumer Protection Act²⁸ and wonder whether the National Consumer Council will resuscitate consumer protection in the area of health products, or whether it too will succumb to organ failure.

Conflict of interest: None.

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