



Normalisation of deviance and medicines regulation

Normalisation of deviance is a concept from sociology that describes situations where an error or an omission has become standard practice, usually through unchecked repetition.¹ The most dramatic examples of this were the Challenger and Columbia space shuttle explosions. Perishing O-rings were overlooked in the case of the Challenger, and foam debris strikes were not considered hazardous in the case of the Columbia.² According to the Columbia Accident Investigation Board (CAIB) report, in both disasters an initial decision 'established a precedent for accepting, rather than eliminating, these technical deviations'.³

Although the explosion of complementary medicines available in South Africa is not as dramatic or lethal as the space shuttle incidents, the cause of their exponentially uncontrolled deluge onto the South African market can probably be traced back to a regulatory decision made in 2002. This decision, which fits the description of 'normalisation of deviance', was that the Medicines Regulatory Affairs Cluster of the Department of Health (MRA) continued to accept documentation for complementary medicines well after the date specified in the complementary medicines 'call-up' had expired.⁴ Rather than a 6-month 'audit' of complementary medicines, a 7-year regulatory hiatus was created, and continues. Estimates of the number of products submitted to the MRA range from about 20 000 products in 2006⁵ to a possible 60 000 products currently.

The technical deviation contributing to the normalisation of deviance in the regulation of complementary medicines in South Africa is that none of these medicines have had to provide independent evidence of their quality. This essentially means that none of the unregistered complementary medicines on the market have had any independent South African regulatory validation of their quality. These medicines could contain only inactive ingredients, or a variety of toxins – from heavy metals to bacterial toxins. They could be adulterated with 'conventional' medicines and scheduled substances. No one can be sure. This surely fits the 'serious public health risk' description of complementary medicines in the Department of Health's Strategic Plan for the next few years.⁶ It can also be considered a deception on a massive scale of the citizens of South Africa, for if the quality of complementary medicines cannot be guaranteed, no claims about safety or efficacy are possible.

Manufacturers' claims to be adhering to current good manufacturing practice (cGMP) guidelines are insufficient evidence of the quality of the product that is purchased by the consumer. As with registered medicines, certificates of analysis should be available for each and every batch. If there is significant variation from the original data submitted to the Medicines Control Council (MCC) for purposes of registration,

that batch cannot be distributed, or must be recalled if already distributed. No such safeguards exist for complementary medicines at present.

The MCC is the statutory body mandated to ensure that the availability of any and all medicines and related substances is in the public interest and meets satisfactory criteria of quality, safety and efficacy. According to the Medicines Act, all medicines and related substances that have been called up are liable for registration.⁷ A series of call-ups (extending from about 1968 to 1985) based on the actions of the products rather than the origin of their constituents were gazetted. For example, an anti-inflammatory substance, synthetic or natural, would have been called up as an anti-inflammatory irrespective of the source of the active ingredients. Complementary medicines falling under any of the categories in Regulation 25 to the Medicines Act would therefore also already have been called up in these categories.

The 2002 call-up of 'medicines frequently referred to as complementary medicines' went a step further: (i) it defined various categories of complementary medicines that had not yet been defined in gazetted regulations; (ii) it granted 'exemption' to applicants from having to complete various components of a 'full' registration – this so-called exemption made no reference to section 36 of the Medicines Act, which is the only mechanism by which an exemption can be made; and (iii) it superseded various previous call-ups including the 1985 call-up of vitamin and mineral products whether medicinal claims were made or not.

It is little wonder that Judge Zondi in his judgment of Matthias Rath and others – including the Chairperson and Registrar of the MCC – stated that '[t]he 2002 call up notice, unlike the 1985 call up notice, is inelegantly worded and appears to be self contradictory in terms'.⁸

The 1985 call-up is significant in that it required oral preparations containing vitamins, alone or in combination with other pharmacologically active ingredients, including minerals, whether medicinal claims are made or not, to be registered. This category could broadly be referred to as 'dietary/nutritional/food supplements'. Here the confounding factor is the 1994 Dietary Supplement Health and Education Act (DSHEA) promulgated in the USA.⁹ It appears that many marketers and distributors of products in South Africa may have erroneously assumed that this Act applied equally to South Africa.

Many consumers are putting themselves at risk as a result of inadequate information being made available about complementary medicines. Drug interactions are increasingly likely to occur and increasingly likely to remain undetected. The adverse drug reaction 'lack of efficacy'¹⁰ is also increasingly likely to take place, and not be reported as such.



The time has come for the regulatory authority to fulfil its statutory obligations and uphold the Medicines and Related Substances Act. The 2002 complementary medicines call-up should be rescinded before the new South African Health Products Regulatory Authority is established. (At the time of writing the Amended Act has been signed by the President, but not yet proclaimed.¹¹)

The Medicines Regulatory Affairs Cluster of the Department of Health urgently needs resources and infrastructure to begin the gargantuan task of actually assessing all the unregistered medicines on the market – initially for their quality at least. While they're at it, they might as well include all the so-called 'old' medicines that were registered many years back, supposedly on the basis of a grandfather clause. Most of the old medicines have not been rigorously evaluated to anything close to the extent of evaluation of medicines currently being registered.

Short-cuts and the acceptance of technical deviations (including the deviation of not insisting on evaluable data) by the regulatory authorities have led to an untenable situation in the regulation of complementary medicines in South Africa. This is an insidious normalisation of deviance causing a serious public health risk⁶ which may yet be shown to have severe consequences for the health of our citizens.

The author is a PhD candidate ('Marketing and advertising of medicines in South Africa') and has no financial or other links to the complementary medicines or pharmaceutical industries.

Roy Jobson

*Faculty of Pharmacy
Rhodes University
Grahamstown*

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