



TRADITIONAL MEDICINES – NO CLEAR OR PRESENT DANGER



Top government researchers and medicines officials have made a concerted bid to reassure the scientific community that the intended dilution of draft laws requiring rigorous testing of complementary medicine poses no threat to the public. Health Minister, Dr Manto Tshabalala-Msimang, caused a stir recently when she said the regulations around the Medicine and Related Substance Control Act were likely to be relaxed to enable less rigorous testing of complementary medicines. While the announcement was greeted with jubilation in complementary circles where many cannot afford expensive, large-scale trials and most products are not patented, it created deep disquiet in the scientific community.

The products referred to by Tshabalala-Msimang include African traditional medicines, homeopathic remedies, Chinese and Ayurvedic medicines, Unani-tibb and nutritional substances, western herbs and anthroposophical remedies. Tshabalala-Msimang said her department 'would like to avoid the pitfall of putting such products in the same regulatory environment as pharmaceutical drugs, whose testing and control is very different'. Responded Janet Welham, co-chairperson of the Complementary and Traditional Medicine Stakeholder Committee: 'It's fantastic news. If what the minister is saying comes to pass, it would be of benefit to everyone in South Africa'. Welham's committee has been in lengthy negotiations with the Health Department and Medicines Control Council.

Safety and efficacy paramount

Approached by *Izindaba*, Dr Gilbert Matsabisa, the director for the indigenous knowledge systems lead programme at the Medical Research Council, explained that only complementary medicines intended for sale to the general public needed to be put forward for registration.

'Basically the protocols for testing will not be as stringent as the so-called FDA protocols, but they will be up to the best and most acceptable international standards while safety and efficacy will be paramount,' he said.

He said anyone who interpreted the minister's statement as 'opening the floodgates for everything', would be fundamentally mistaken. 'Once we can show efficacy and safety and it meets the claims made on its behalf – and only once that is shown, will we recommend that it be sold commercially,' he said. He said the MRC had developed an 'abridged toxicology' that still looked at all the major organs but was different from that required for a new chemical entity. 'It's been shortened simply because we know complementary medicines have been used before,' he said.

Among the tests that would be excluded would be mutagenicity and those for cancer-causing agents, because 'we know that complementary medicine would not do that because if they did it would have been picked up through epidemiology'. He said he hoped the new regulations would compel practitioners to report any instances of harmful side-effects from the use of any complementary medicine in order to increase monitoring efficacy.

Matsabisa said the MRC was not interested in the traditional healer/patient relationship where complementary practitioners dispensed to their own patients. However, if a traditional healer for example wanted to

make the product available through a chemist or to market it widely, 'then we come into the picture'. The only time the government would intervene would be if any cases of toxicity were reported.

So far his group had researched the safety and efficacy of four products. Three clinical trials were scheduled this year, two of them on safety and the third on efficacy. He emphasised that, 'if anything doesn't work, we have an equal responsibility to educate the public and tell them'.

Sources at the Medicines Control Council told *Izindaba* that, with the regulations not yet passed into law, there was 'no framework' to register any complementary medicines.

However one said that she expected this to be in place before the end of the year. She said any complementary medicine found to have significant public health benefits could be fast-tracked 'on a needs basis' to circumvent the usual time frame of 3 - 5 years to registration.

The Traditional Health Practitioners Bill, which sets up a statutory council to regulate and register healers, birth attendants and surgeons is also due to come before parliament for finalisation later this year. The council will have 22 members consisting of traditional healers, a representative each from the Department of Health and the community, a medical practitioner and a pharmacist. The health minister, in 'consultation with the council', will determine what the minimum requirement, training and practice standards are. The health care sector will then learn how traditional medicines will be regulated, medical aid schemes impacted and what status, if any, medical certificates issued by traditional healers will carry. Any traditional healer not registered and found practising will be liable to a fine or imprisonment of up to 12 months.

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