

# More about: OTCs and alternative medicines

## THE RISK OF HARM OF OTC MEDICINES

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*Mrs Mavis Gumede is one of the many stall owners on the bridge next to the Durban Market. She has a wide selection of traditional herbs and animal-based products which she claims are of tremendous benefit for various conditions including psoriasis, tuberculosis, fever, HIV and asthma. Times have been hard and in recent years, with the increasing number of stall owners now selling traditional medicines and with the depletion of many of the plants and animals that were her main source of medicine, she has had to supplement her 'dispensary' stocks with steroid creams, skin-whitening creams, analgesics containing codeine, aspirin, phenylbutazone and various other 'Western' medicines. She occasionally uses chemicals or crushes the tablets into powders and mixes them with the herbs to improve the potency of some of her remedies. Many people who buy from her have also visited the community clinics or hospital nearby for their prescription medicines. If the medicine they get from the clinic does not work or makes them feel bad, they come to Mrs Gumede to seek her help and advice and hopefully a cure. What happens to them afterwards is not always known...*

The above scenario is fictitious but illustrates a situation that is becoming increasingly prevalent in our country. Vending outlets like Mrs Gumede's medicine stall, the local herbal health shop and supermarket chains are rapidly becoming the largest providers of medicinal products. What this means in terms of patient safety is not well understood, but is likely to give rise to new and possibly unanticipated risks to the patient.

Recent findings regarding the safety of certain over-the-counter (OTC) products and changing trends in the use of medicines by patients and health practitioners in South Africa, indicate that greater vigilance is needed on the part of health care providers to protect the public from the unsafe use of OTC products. There are three myths that need to be acknowledged and dispelled by health care providers (both orthodox and complementary medicine practitioners) with regard to the safety of OTC and complementary medicines.

### **Myth 1. 'No news is good news' – inadequate knowledge about the safety of OTC products**

In 2000 and 2001, drug regulatory authorities around the world, including the South African Medicines Control Council, took steps to restrict and improve the use of OTC cough and cold preparations containing phenylpropranolamine (PPA). This was because a case-control study found that there was an increased risk of haemorrhagic stroke in people taking PPA, especially as a weight loss aid.<sup>1</sup> The products containing PPA

had been used for these indications for several years before the findings were published and regulatory action taken.

A pilot study determining the safety of long-term use of ibuprofen found that at the end of a 12-month period, patients who used ibuprofen for longer than 8 weeks in total (long-term users) were significantly more likely than short-term users (< 8 weeks total use) and non-users to have experienced dizziness, skin rash, itchy skin and wheezing in the previous week (i.e. at the end of the study).<sup>2</sup>

In recent years the number and range of medicines available OTC have increased dramatically. Limited evidence suggests that the general public may respond by increasing self-medication.<sup>3</sup> Little is known about the way in which OTC medicines are used by patients. Do patients actually read, understand and, more importantly, adhere to the recommendations for use and warnings reflected in the package insert? Do patients inform doctors about the OTC products they are taking or even the adverse effects they may be experiencing while taking these medicines? To what extent do patients delay seeking care for serious conditions by self-medicating with OTC medicines?

The findings of the studies described above and the lack of information regarding the nature of use of OTC products by consumers highlight the need for good post-marketing surveillance of OTC products presumed to be safe.

**Myth 2. 'Advertising is about educating' – the need for unbiased drug information to patients**

Direct-to-consumer advertising of OTC as well as prescription medicines is increasingly practised by pharmaceutical manufacturers and suppliers of medicines. Spending on direct-to-consumer advertising has doubled in the USA over the past 4 years in an effort to improve marketing and sales.<sup>4</sup> While it is argued that this may improve patients' understanding and access to drug information, this type of information often lacks reliability, accuracy and balance, and might paradoxically compromise patient care and safety. Although direct advertising of prescription medicines is illegal in South Africa, the Internet makes communication possible across borders, overriding any national regulations about advertising. The purchase of prescription as well as unregistered medicines is facilitated by Internet sales.

With the information obtained from advertisements, patients feel more empowered to make their own therapeutic decisions, without the assistance of the doctor or pharmacist. This has resulted in increasing self-medication and over-prescribing by doctors on patients' demand.<sup>5,6</sup> With increasing self-medication, the risk of drug interactions and adverse effects is likely to increase as well.

**Myth 3. 'Natural equals safe' – cashing in on an old wives' tale**

Feeding on the general misconception held by the public that 'natural' means 'safe', herbal medicines are being aggressively promoted as a safer (and implicitly effective) alternative to Western/orthodox medicines. The need for scientific evidence is superseded by the



belief that a strong and ancient tradition of use of a particular product must imply that it is effective and safe. However, it must be recognised that complementary medicines are being manufactured and sold for global use and have moved well beyond the traditional and cultural paradigms within which they were originally intended to be used. The dangers of widespread indiscriminate and uninformed use of herbal products in 'pretty bottles with shiny labels' is no less significant than the dangers that might be anticipated from medicines used from Mrs Gumede's dispensary. The following are a few examples of natural products that have been shown to have significant risks of adverse effects or drug interactions.

- St John's wort has been shown to reduce the efficacy of oral contraceptives, certain transplant medications and antiretroviral medicines through its cytochrome P450 enzyme-inducing properties.<sup>7</sup>
- Kava kava, a plant derived from the South Pacific, used for anxiety, stress and related conditions, has been shown to cause hepatotoxicity which could result in liver failure and death.<sup>8</sup>

- Gingko biloba is known to inhibit platelet aggregation and case reports of spontaneous intracranial bleeding have been reported. Based on the kinetics of the drug, it is recommended that patients should discontinue taking gingko at least 36 hours before surgery.<sup>9</sup>
- Ephedra causes dose-dependent increases in blood pressure and heart rate. Fatal cardiac and central nervous system complications have been reported with products containing ephedra.<sup>9</sup>

**Responsibility of the clinician**

The safety of medicines has in recent years become a very important public health issue. With increasing demands from the public for greater access to medicines, there is a growing concern about the potential risks these medicines may pose to patients and the public as a whole. This is particularly the case with OTC medicines, traditional medicines and complementary medicines since they are used more frequently and more widely than prescription medicines.

A large part of the responsibility for improving the safe use of OTC

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products lies with medical practitioners and pharmacists. The routine practice of the following basic principles by clinicians, pharmacists and other health care providers is likely to significantly improve patient safety and the safe use of OTC products:

- Obtain a comprehensive drug history from the patient including the use of OTC and complementary medicines.
- Rather than demanding that patients stop the use of these products, provide unbiased, evidence-based information about the effects (both positive and negative) of the products patients choose to use. (This implies that clinicians need to be informed about the risks and benefits of commonly used OTC products.)
- Report all suspected adverse drug reactions to OTC and prescription medicinal products to the Medicines Control Council's Pharmacovigilance Programme (Fax: +27-21-448 6181 or Directorate: Medicines Registration: Department of Health: Private Bag X828, Arcadia 0001)

References available on request.

### TREATMENT OF TUBERCULOSIS BY TRADITIONAL HEALERS

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It is estimated that there are about 200 000 traditional healers in South Africa, a figure which is growing daily.<sup>1</sup> This figure gives a ratio of healer:population of 1:200. Despite this large number of traditional healers and the popularity of this health system in most rural areas of South Africa, the SA government has not yet granted them a clear role and there is no proper statutory recognition process in the national health system of the country. The impact of the traditional health system on control and prevention of diseases such as TB, malaria and HIV/AIDS in South Africa is one aspect of assessing the efficacy of the traditional approach to disease prevention. TB is an old disease that has been aggravated by the social and political systems of South Africa.<sup>2</sup> It continues to devastate many communities and families. The sudden emergence of HIV in the last two decades has escalated the magnitude of the problems associated with TB. A survey was performed in 7 provinces of South Africa to understand the role that is played by traditional healers in the prevention and control of diseases and the treatment mode that traditional healers practise, with special reference to TB.

#### Methods of diagnosis of TB

Traditional healers mostly employ visual means of diagnosis for TB. This is supplemented by the spiritual systems such as bone throwing for diviners, prophecy for spiritual healers or information from family members. Most traditional healers use symptoms such as coughing, loss of weight and night sweating in the diagnosis of TB. Their understanding of the cause is different from the conventional knowledge of *Mycobacterium tuberculosis*, which

has influenced the way in which they treat the disease. Most traditional healers prefer to perform the divining before the patient reveals his/her complaint as this shows that the traditional healer has some knowledge of the disease that they are about to cure. The symptoms considered to be diagnostic are persistent cough, weight loss, night sweats and bloody sputum, which correlates with the conventional method of diagnosing TB in modern medicine.

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#### Understanding the cause

Most traditional healers believe that TB is a form of an ancestral way of demanding that a ritual be performed by the unhealthy being. The ancestors would induce the disease in the person in order for the individual to respond by performing the required custom. The healer's role would be to firstly find the type of ritual custom that the sufferer has to perform. The ritual would then be performed as the initial treatment step. Following the performance the person would either recover automatically or the healer would then proceed with the treatment. Some traditional healers believe that TB is a form of poisoning or *idliso*, as it is termed in isiXhosa. This form of poisoning could be through food, water or beer. Others believe in a bad spirit

or witchcraft, known in many parts as *impundulu*. These two beliefs are predominant among the diviners (*izangoma*) and spiritual healers (*abathandazeli*). Still others believe that it is either transmitted through coughs from those who are sufferers or by inhalation.

### Treatment of TB

The treatment of TB with plants varies from one region to another and from one type of traditional healer to another. We have grouped the treatment modes into categories to simplify the understanding of their choices of treatment. The categories are outlined as symptomatic mode, causative mode, diagnostic mode, primary health care mode, and holistic approach.

In the **symptomatic mode** approach the symptoms observed from the patient influence the type of treatment that a traditional healer would give to a patient. In this instance the treatment is mainly plant medication. An example of this is when loss of weight is the main symptom. The traditional healer prescribes medication to enhance appetite and thereby elicit weight gain.

In the **causative mode** the traditional healers would first treat or address the cause of the disease as they understand it. An example of this is when the traditional healer believes that the reason the patient is ill is the need for a ritual is performed; the healer would request the family of the ill person to perform the ritual and would also advise on what type of ritual is required. This form of healing is sometimes accompanied by medication to fight the invading disease. However, in some instances, ritual cleansing takes place first and then the patient is referred to

another healer who deals with herbal remedies.

Another highly prevalent example is when a patient is given medication to induce vomiting when poison or evil spirit (*idliso*) is suspected to be the cause of illness. In this case the assumption is based on the argument that once the bad spirit or poison is released the patient will recover.

### The level of understanding and the interpretation of TB by most traditional healers differs vastly from orthodox medicine.

In the **diagnostic mode**, the traditional healer would treat the cause while trying to repair any damage to the body. An example of this is where a bacterial infection is diagnosed to have caused a scar in the lungs, resulting in bleeding when coughing. The traditional healer gives medication to treat the scar while eradicating the bacteria with another medication or to 'cleanse the blood', as most traditional healers would term it. Sometimes these processes follow each other.

The **primary health care approach** is the most prevalent form of healing in most rural areas. The traditional healer would engage the whole family in the healing process. This sometimes becomes a lengthy and expensive process, as it requires certain practices such as slaughter of sheep or cattle. This is termed the primary health approach in the sense that

the healer considers the history of the patient, his surroundings and family. In some instances the healer would involve other members of the community. Another example of this is an understanding of the cause, such as cross-infection among family members and inherent causes (*ufuzo*) of low immunity.

Through the **holistic treatment approach** an intensive treatment system is used to treat the symptoms, the causes, and the anatomical deformation that resulted from the disease. This form of treatment is prevalent in many parts of the country.

### Discussion

#### *Traditional healers' perspectives*

The level of understanding and the interpretation of TB by most traditional healers differs vastly from orthodox medicine. The understanding of TB by traditional healers is explained rather in the context of culture than methods of conventionally trained Western medical personnel. The symptoms observed are used to guide the treatment regimen of patients. The culture and background of both the traditional healer and the patient are influential factors in the treatment of the disease. As explained by Airhihenbuwa, culture influences the way people understand and interpret diseases.<sup>3</sup> In the case of TB, traditional healers believe that the individual's cultural background needs to be considered when diagnosing diseases. A traditional healer gave one example when he argued that 'TB is a form of communication by ancestors to an individual who has not performed some of his customs. Without that problem being addressed, the patient will constantly experience episodes of TB.'

From the Western-trained medical practitioner's point of view, this disease persistence could either be recognised as reinfection, relapse or reactivation of latent TB. The issues of culture and customs are relevant tools to use to understand TB and how traditional healers perceive it.

In the process of incorporating culture in the treatment course, some traditional healers even go to the extent of tracing the history of the family to understand the cause of the disease. Whether the direct treatment that accompanies the ritual performance plays a role in the treatment of the disease, requires further investigation. Another dimension to explaining the recovery process is the role of medication taken by patients who attend practitioners of both the traditional and the Western forms of health care. One traditional healer stated that she does not stop patients from attending clinics while they are consulting with her.

In this situation, the effect of the traditional healing cannot be measured, as there is another system of medication being used for the same disease. This combination has the potential of being seriously misinterpreted by scientists if they do not include the cultural aspect of each community in their investigation of the use of traditional medicines.

### Conclusions

Traditional healers have one main aim in their practice, which is improving the health status of their communities. This can be achieved through a number of ways, namely: community wellness, disease prevention, disease control, and patient care. These aims could be furthered if the National Department of Health and other professional health bodies could work together with traditional healers by providing the necessary resources to enable them to be involved in the education of communities about issues such as TB, HIV/AIDS, smoking, alcohol abuse, family violence and many others. Through this primary health care approach, a better scheme of integration of the traditional health system into the main health policies of the country can be achieved. The understanding of the disease and the role of cultural interpretations of the disease by the traditional healers could be used by the Western trained practitioners in understanding the traditional perspective of the disease. Furthermore, this would also help in regulating the collaborative efforts between the government and the other institutions that have interest in working together with traditional healers.

### Acknowledgements

The author would like to thank The Lord Sainsbury/Linbury Trust scholarship and the Medical Research Council, whose generous donations have made this research possible. The study was conducted at the South African Traditional Medicines Research Group, housed in the Division of Pharmacology at the University of Cape Town.

Thanks also to all the traditional healers whose views contributed to this work.

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