A brief look at a complex matter

Regulation and registration of complementary medicines and health supplements

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"Ethical pharmacists should not sell quackery"

This was the title of an article written by columnist Ivo Vegter for the Daily Maverick in May 2018. The trigger for the article was a bottle of complementary medicine that he saw in a pharmacy. Its label claimed that it contains a "natural antibiotic". The patient information leaflet stated that the product had not been evaluated by the Medicines Control Council (MCC), and concluded by saying that the medicine was not intended to diagnose, treat, cure or prevent any disease. The columnist questioned why an ethical pharmacist would sell products that made contradictory claims (natural antibiotic vs not intended to cure a disease) that had not been evaluated by the MCC.

Why does this affect pharmacist's assistants? Many pharmacist's assistants work in community pharmacies, which frequently stock these products. As registered healthcare professionals, they may also be accused of allowing consumers to buy products that have not been proved to be effective or safe. It is therefore important to understand what is happening in the regulatory background, and to have some understanding of the complementary medicine and health supplement environment.

Regulatory environment

What the columnist did not know is that the General Regulations to the Medicines and Related Substances Act (Medicines Act), 101 of 1965, were amended in 2013 to make provision for complementary medicines.

The 2013 General Regulations were replaced in 2017. There were several significant changes that were necessary in order to implement the amendments that had been made to the Medicines Act. The most important change was that the Medicines Control Council (MCC) was replaced by the South African Health Products Regulatory Authority (SAHPRA).

The work of the MCC will be continued by SAHPRA, but in addition SAHPRA's scope also includes medical devices, including *in vitro* diagnostics, and some aspects of radiation control.

A significant difference between the MCC and SAHPRA is that SAHPRA will operate as a separate public entity outside the National Department of Health.

Definition of a complementary medicine

The definition in the Regulations has three components:

a. What is it? It is a substance that originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or any other substance that SAHPRA may include.

b. What is it used for? It is used, claimed to be suitable for use, manufactured or sold for use for two purposes:
   - maintaining, complementing or assisting the physical or mental state
   - to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal

c. How is it used? It's used either as a health supplement or in accordance with specific allied health professionals.

Allied health professionals

The Allied Health Professions Council controls the education and practice of a number of disciplines in order to ensure the quality of complementary and alternative health care. These disciplines are:

- Ayurveda
- Chinese Medicine and Acupuncture
- Chiropractic
- Homoeopathy

- Naturopathy
- Osteopathy
- Phytotherapy
- Therapeutic Aromatherapy
- Therapeutic Massage Therapy
- Therapeutic Reflexology
- Unani-Tibb

Not all of these disciplines use medicines in their treatments, and some are traditional healthcare practices from around the world.

Registration of complementary medicines

In 2013, the MCC drew up a roadmap for registration of complementary medicines. There were, and still are, literally thousands of medicines that fell into this category and it would have been impossible for all manufacturers to immediately submit applications as well as impossible for the MCC to process all these applications.

It was decided that a simplified registration process should be followed for some of the traditional complementary or alternative medicines that had been in use for a long time within the European Community, India and China or within South Africa. For these particular medicines, it was agreed that both safety and quality issues should be addressed in applications for registration.

The MCC also performed a risk assessment of complementary medicines for which claims were made that they could be used to diagnose, treat or modify particular conditions. It identified priority products that needed to be submitted for registration urgently, but in a phased way.

The first round

The first group of medicines to be called up for registration were those used in any of the complementary disciplines for HIV and AIDS, diabetes, hypertension and cancer. These medicines fell into the pharmacological classifications of antiviral agents, oral hypoglycaemics, cardiac medicines and cytostatic agents respectively.

In April 2016, the MCC published a list of products in this group for which applications for registration had been received. Processing of applications can be a lengthy process, which makes it significant that for these products only, an important concession was made – during the evaluation process, these are the only products in these categories of medicines that may continue to be sold in South Africa. All medicines making similar claims were therefore to be removed from the market immediately.

It is notable that no applications were recorded for medicines claiming to be suitable for use in HIV and AIDS or cancer.

Applications for registration as cardiac medicines

- Cralonin oral drops, Modhomco (Pty) Ltd
- Crataegus Oxy Liquid, Bioforce SA (Pty) Ltd
- Cardio Health, Bell Lifestyle Products SA (Pty) Ltd

Applications for registration as oral hypoglycaemics

- Antagolin, Medical Nutritional Institute (Pty) Ltd
- Patrick Holford Cinnamon, Brunel Laboratoria (Pty) Ltd
- Bioharmony Cinnabalance, Avid Brands (Pty) Ltd

While these medicines may continue to be sold, it is anticipated that a final decision will be made on each when the application has been thoroughly evaluated.

The next stages

The life-style products were considered to be the next priority. This included both slimming or weight reduction products and those claiming to be suitable for use as sexual stimulants.

Other products that were prioritised are those claiming to be immune-boosters, medicines acting on the muscular system and sports supplements making any medicinal claim. Sport supplements that contained ingredients that exceeded the upper limit recommended for vitamins or minerals were also included.

It must also be remembered that although the call-up of these medicines were prioritised, at some stage all complementary medicines must apply for registration. Any new product entering the complementary medicine market, no matter what the pharmacological classification is, is now required to have gone through the registration process.

Information about complementary medicines

Within the context of this article, another important change in the General Regulations concerns professional information for medicines for human use, and the patient information leaflet.

In the past, all products were obliged to be accompanied by a printed package insert. This was in effect a legal document, addressing all the professional aspects of the medicine. The regulation has changed to permit professional information for medicines for human use to be presented either in a printed format or to be available in electronic format.

It was recognised that access to understandable information was essential to aid in informed decision making, and patient information leaflets (PILS) in plain language were introduced. Preparation and production of these leaflets was a lengthy and expensive process that happened gradually.

For complementary medicines, there is a legal requirement to include certain words in both the professional information and the PIL.

- The words “Complementary Medicine” must appear.
- In the Annexure 1 of the regulations, which deals with classes of medicines, complementary medicine disciplines

which specifically use complementary medicines with traditional claims are identified.

- Aromatherapy
- Homoeopathy
- Phytotherapy
- Traditional Chinese Medicine
- Unani Medicine (Unani-Tibb)
- Western Herbal Medicine

In the case of medicines used by a particular discipline, both the professional information and the PIL must include a statement identifying the discipline.

- The same Annexure identifies complementary medicines that are used as health supplements by a number of disciplines.
  - Amino acids
  - Aminosaccharides
  - Animal extracts, products and derivatives
  - Carotenoids
  - Enzymes
  - Fats, Oils and Fatty Acids
  - Minerals
  - Polyphenols (including bioflavonoids)
  - Probiotics
  - Saccharides (including prebiotics)
  - Vitamins
  - Multiple substance formulation

  The professional information and the PIL must include the words "Health Supplement".
- The statement that the columnist questioned in the PIL is actually a legal requirement for complementary medicines that have not yet been registered by SAHPRA. The professional information and the PIL must contain the following disclaimer – "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use." This is a completely factual statement that will be removed if and when the medicine has been evaluated.
- Some complementary medicines contain genetically modified organisms. For those products that contain 5% or more, the information should contain the warning – "contains genetically modified organisms".

What can and should pharmacist's assistants (and pharmacists!) do?

Pharmacy professionals are ethically and legally obliged to ensure that consumers are informed of the safety, efficacy and quality of the products that are supplied.

In an ideal world, only medicines registered by SAHPRA would be provided in pharmacies, but we do not live in an ideal world. Decisions to stock products are also outside the control of pharmacist's assistants and probably most pharmacists.

So what can you do? Make sure that you are knowledgeable about every product that you provide to a patient, including those that do not require professional intervention. At this stage, most complementary medicines would fall into Schedule 0 so they may be sold in outlets that do not employ a healthcare professional. It is however logical to assume that when the same product is sold in a pharmacy, professional staff should at least know all about the products and be able to advise consumers accordingly.

A good start is to read the PILs in complementary medicine products. This may be an enormous and time consuming task, but it will add to your professional credibility. Discuss them with your pharmacist as well. Make sure that you understand the statements that must be included in PILs, and make sure that you can explain them to your customers and patients.

A frequent misconception that consumers have is that if the product is "natural" it must be safe. Remember that even nature produces substances that are not safe – cyanide, arsenic, mercury, anthrax and many other occur naturally. Neither is the production process of products necessarily safe – look at what happened in South Africa with listeriosis in 2018.

The bottom line

It sounds like an impossible situation but there is good news. Unfortunately, it will take time, but both SAHPRA and the involved statutory health councils, e.g. AHPSCA and SA Pharmacy Council, are committed to ensuring patient safety and that all health care, both practices and products, is delivered in the interest of the patient. The fact that the MCC embarked on the epic journey of beginning the registration process for complementary medicines and SAHPRA intends to continue and hopefully complete it, is major progress in this contentious area.

References

1. Vegter I. May 2018. Ethical pharmacists should not sell quackery. Daily Maverick (accessed 2 May 2018)
2. GNR 859 of 2017. General Regulations – Medicines and Related Substances Act, 1965 – http://www.mccza.com/documents/959cb9e1Test.pdf (accessed 22 May 2018)
3. Publication of complementary medicines (Category D) submitted for registration in terms of section 14(3) of the Medicines and Related substances Act, 1965 (Act 101 of 1965) http://www.mccza.com/documents/2ca6c1c29.72_Complementary_medicines_right_to_sale_Apr16_v1.pdf (last accessed 23 May 2018)
4. Complementary medicines – health supplements safety and efficacy http://www.mccza.com/documents/d0f3f80c7.04_SE_Health_Supplements_Jun16_v2.pdf (last accessed 23 May 2018)
5. Complementary medicines – discipline-specific safety and efficacy http://www.mccza.com/documents/8b57b09c7.01_CMs_SE_DS_Jun16_v3.pdf (last accessed 23 May 2018)