Complementary Medicines: the way forward

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According to a recent report published by Grand View Research, Inc., it is expected that by 2026, the global complementary and alternative medicine (CAM) industry will generate over USD 200 billion. The CAM industry, which encompasses at least nine different philosophical approaches to medicine preparation and application, requires a workable regulatory system in order to ensure that products are of a good quality and are safe for use.

Prior to November 2013, there was very little regulation pertaining to CAM in South Africa, however, this position changed after the adoption of revised regulations (General Regulations) and guidelines.

Currently, "medicines" are regulated in terms of the Medicines Act and are classified into basic categories, of which CAM is one. CAM is further classified into sub-categories including discipline-specific medicines and health supplements.

In terms of the provisions of the Medicines Act, no manufacturer, wholesaler or distributor may manufacture, import, export, act as a wholesaler of or distribute any medicine unless the person or entity is the holder of a licence issued by the South African Health Products Regulatory Authority (Authority).

In addition, if a product falls within the broad definition of a medicine, it will be subject to compulsory registration in terms of the Medicines Act if that product is in a class or category of medicines which has been "called up" to registration by the Authority.

Interestingly, the General Regulations included deadlines for submissions in terms of various call up notices, however, these deadlines were later overturned by further changes to the regulatory framework during 2017.

In a recently published guideline (Roadmap), the Authority has sought to establish a new timeline in respect of licensing and medicine registrations (i.e. new notices will be issued in respect of the timelines for registration of unregistered CAM).

In the Roadmap, the Authority details an electronic process to follow in respect of licensing applications, which process is intended to be launched at least 6 months prior to any new call-up notices being published. What this means is that current manufacturers, wholesalers and

distributors of CAM in South Africa, will be afforded a "priority period" within which to submit their applications.

According to the Roadmap, all CAM registration applications that have already been submitted to the Authority, will be processed and finalised as soon as possible.

For all other submissions of CAM registration applications, these must be attended to within the timelines prescribed by the relevant call-up notices issued.

It is proposed that the call-up notices in respect of discipline-specific medicines and health supplements will be staggered over a period ranging from 6 months to 72 months, commencing from April or May 2020.

Although the Roadmap provides guidance to all stakeholders on the intended regulatory pathway with particular insight into the way forward for existing and future CAM registration applications, it remains to be seen how these applications will be dealt with in practice.

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