PHARMA LAW
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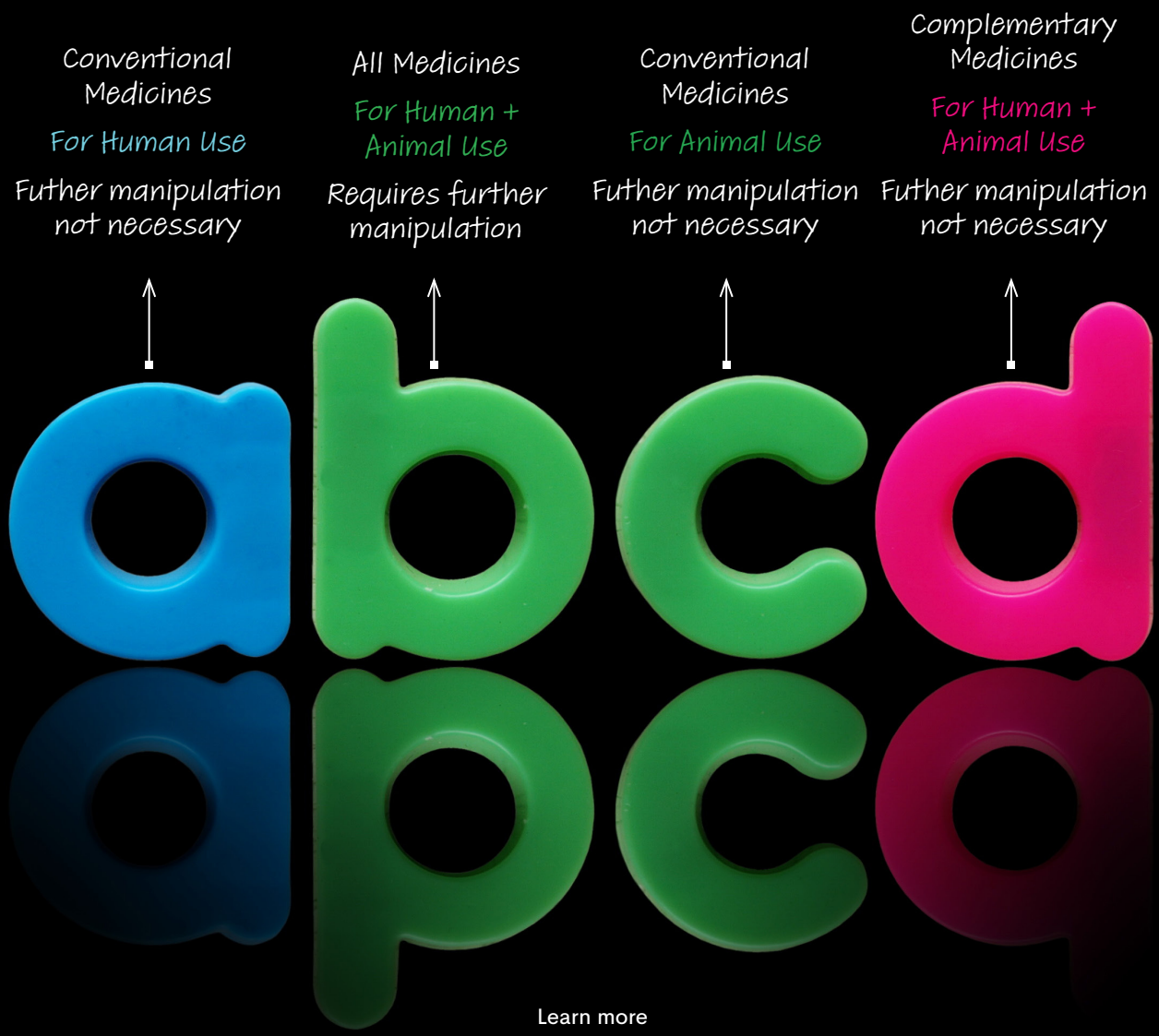
COMPLEMENTARY MEDICINES

CATEGORIES, SUB-CATEGORIES & LEGAL IMPLICATIONS

Medicines are categorized in accordance with the General Regulations made in terms of the Medicines Act. **Categories of medicines are designated as A, B, C and D.** Category A medicines are conventional medicines intended for human use and category C medicines are conventional medicines for animal use, both without further manipulation. Category D medicines are complementary medicines intended for use in both humans and animals, without further manipulation. Category B medicines are also intended for both humans and animals but cannot be administered without further manipulation.



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All categories of medicines fall within the ambit of the broad definition of medicines provided in the Medicines Act. However, **the General Regulations provide a separate definition for category D medicines or complementary medicines.** Where the original attempt to define complementary medicine in 2013 resulted in a definition with a too narrow ambit, the current second attempt of 2017 resulted in an ambit too wide. The outcomes of the **Alliance of Natural Health Products in South Africa v The Minister of Health and Another (2020)** case was therefore not surprising.

The definition of complementary medicines requires that these medicines fall within the ambit of the definition of a medicine provided in the Medicines Act and then also fall within the ambit of the definition of a complementary medicine provided in the General Regulations. **If it falls within the ambit of both definitions, it is indeed a category D complementary medicine.** If it only falls within the ambit of the definition of a medicine but not the definition of a complementary medicine, it will be a conventional medicine and may be a category A, B or C medicine.

Two sub-categories of complementary medicines have been provided for in the General Regulations which are discipline-specific complementary medicines and health supplements.

Here the identity of a health supplement has to deduced by a comparison of the two definitions provided.

Health supplements are defined as substances or mixtures of substances and extracts, excluding any substances listed in the schedules and injectables. Furthermore, these substances and extracts have been identified by SAHPRA in guidelines which also provide minimum and maximum daily dosages and allowable claims. The implication of this is that SAHPRA agrees to its general efficacy and safety within the limits set. However, the quality of these medicines will not be influenced by the limits set. The existence of a licensed manufacturing facility will remedy such a short-coming and SAHPRA has started a process to ensure such licencing.

In contrast to health supplements, the origins, claims and daily dosages of **discipline-specific complementary medicines** are less limited but requires a higher level of substantiation of quality, safety and efficacy. Also, discipline-specific complementary medicines may fall within any schedule of medicines with accompanying restriction of its current unregistered sale.

A classification system exists within the categories of medicines, which further divides such categories into classes. For discipline-specific complementary medicines these classes include aromatherapy, homeopathy, phytotherapy and traditional chinese medicine. For health supplements these classes include carotenoids, enzymes and minerals.

The Medicines Act prohibits the sale of medicines which are subject to registration and are not registered. It provides that SAHPRA may determine that a medicine, or class or category of medicine, or part of any class or category of medicine, is subject to registration. Despite an attempt by SAHPRA to subject the classes of discipline-specific complementary medicines to registration in 2013, the definition provided by SAHPRA was narrow and the impact was therefore limited. Currently, most complementary medicines are not subject to registration as yet.

Labelling, Professional Information (PI) and Patient Information Leaflet (PIL) requirements differ between categories and sub-categories of medicines.

Despite the category within which a medicine falls, limitations to its **advertising and control will ultimately depend on its scheduling status**. Thus, scheduling status will have an important impact on category A, C and the discipline-specific sub-category of category D medicines. Health supplements are unlisted and may be advertised to the public, within limits, and sold in an open shop.

All medicines of all categories, sub-categories and classes should however comply with all the provisions of the Medicines Act and its Regulations.