News Flash

16 May 2023

Decree No. 19/2023, of May 2

Regulation for authorization to market health products, herbal and homeopathic medicines

Deyse Nuvunga

(*Junior Consultant*)

The Decree[1] that regulates the requirements for authorization to introduce health products, herbal and homeopathic medicines for human use on the market was recently published, with the aim of guiding those responsible for research, manufacture, import, distribution and export and sale to retailers and other interested parties on the conditions to be met in order to obtain a Marketing Authorization ("AIM") in line with the provisions of Law No. 12/2017, of September 8 and with the WHO and the guidelines of SADC countries, with a view to ensuring that products marketed in the country do not cause public health problems.

This Decree applies to all entities of cosmetic and body hygiene products, nutritional supplements, disinfectants, antiseptics, medical and in vitro diagnostic devices, herbal and homeopathic medicines.

The AIM, in case of approval, is granted by decision of the National Regulatory Authority for Medicines, IP ("ANARME, IP"), to the manufacturer, holder of the AIM, in the country of origin of the product, or its legal representative (based in Mozambique), for a period of 5 (five) years, renewable for equal and successive periods. However, it is clarified that the request for renewal must be made in the fourth year after granting, at least 90 (ninety) days in advance of the deadline for validity of the authorization granted, and, without the request, it is considered AIM is automatically cancelled, so reactivation of the authorization depends on a new AIM request.

By this Decree, the following are exempt from the AIM by means of registration: **(i)** health products, which are included in the classification list of exempt and non-controlled products approved and periodically updated by ANARME, IP; **(ii)** the registered medical device accessories; **(iii)** extemporaneous and artisanal preparations on a small scale; and **(iv)** special import and emergency health products.

It should be noted that the change in the terms of the AIM must always be submitted to ANARME, IP, failing which, it will imply the suspension of the registration. An identical penalty is applied in case of non-payment of the annual retention fee, in due time.

[1] The Decree is in full force.

If the authorization is suspended, and without correction of the deficiencies that gave rise to the suspension within a period of 30 (thirty) days, the offender, without prejudice to civil and criminal liability, may be punished with the application of the following measures:

- Revocation of authorization;
- Payment of a fine, under the terms established in the Medicines Law;
- Seizure of health products, herbal medicine, homeopathic and reversal in favor of the State or, incineration of the same, whose expenses will be borne by the MA holder; and
- Prohibition of carrying out research, manufacturing, distribution, import and commercialization throughout the national territory.