South African Health Products
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Guideline 7.02 - Updated **17 December 2021**

GUIDELINE 7.02: ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF COMPLEMENTARY MEDICINES

To all stakeholders

The amended Guideline 7.02 (Roadmap and Transitional Process for the regulation of Complementary medicines) with transitional arrangements was developed and published on the SAHPRA website by early August 2019. The guideline established the roadmap and general overview for the regulatory pathway of complementary medicines including licensing in terms of section 22C(1)(*b*) and submission of applications for their registration following the implementation of the General Regulations in 2017 and applies to products for human use (discipline-specific medicines and health supplements).

The original priority licensing period which allowed for an administrative period which would achieve compliance with the provision of the Medicines Act, was started on 17 Feb 2020, and extended from June 2021 to 31 January 2022.

Following routine consideration of Guideline 7.02 scheduled for December 2021, amendments of the same guideline have been made as follows:

(a) General **process updates** to provide for actions which have been completed, such as the availability of systems or applications.

(b) Inclusion of **minor guidance updates** where required.

(c) Extension of **12 months** for **compliance of labelling with Annex B of Guideline 7.05** (28 February 2023).

(d) Adjustment of the licensing priority period to reflect the **first time of availability of the online licensing platform** (17 Feb 2020).

(e) Adjustment of the **licensing priority period** to end one year prior to the labelling compliance deadline in with respect to Annex B of Guideline 7.02 (28 Feb 2022). This provides for a **net extension of one month** and a **total licensing priority period of just over 24 months**.

(f) Associated with the extension in (e), the deadline by which licences should be held permitting the manufacture, import, export, wholesale or distribution of Category D medicines, as well as **recognitions of any applications for Category D licences in terms of section 22C(1)(*b*) submitted by that date** (28 Feb 2022).

(g) Extension for applicants to **continue to be able to submit SAHPRA licensing applications with proof of applications to the DOH/SAPC without GPP desktop outcomes** until 28 February 2023. This will cater for

the continued practice of simultaneous review of applications for a further one year after the licensing priority period.

(h) **Inclusion of the narrative explanation** to *Annexure C: Licensing of manufacturers, wholesalers, distributors, importers and Importers of Category D (Complementary) Medicines in terms of the Pharmacy Act and the Medicines Act* which explains the licensing process associated with NDOH/SAPC and SAHPRA.

Timeframes for applications are to be determined by the individual organisations concerned. Any timeframe prescribed is subject to any application being consistent with the requisite quality and format of information required.

The amendment of Guideline 7.02 seeks to facilitate stakeholders seeking compliance with the applicable legislation, general roadmap and any guidance issued by SAHPRA.

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