SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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Subject: Request for comment on draft Variations Addendum for Orthodox Medicines, eCTD and eSubmission Guidelines, and eCTD and eSubmission New Registration Validation Templates
Date: 10 May 2019

Comment period: 10 May – 24 May 2019
Comment submissions: backlog@sahpra.org.za
Subject line for email: [Industry comments] Organisation name

One of the critical priorities of the South African Health Products Regulatory Authority (SAHPRA) is to clear its inherited backlog of new medicine registration and variation applications. SAHPRA's Board has committed to achieving this objective within 2 years. In addition, SAHPRA also needs to ensure that such a crisis does not arise again. It is thus imperative that SAHPRA designs and implements new evaluation policies and models for evaluation.

SAHPRA has a mandate to ensure the safety, quality, and efficacy of medicines available in South Africa. Part of this responsibility is revising its guidelines to reflect global regulatory best practices and to appropriately manage the regulatory burden on our industry partners to ensure access to quality, affordable medicines for all South Africans.

After consultation with our industry partners, the SAHPRA management team has decided to harmonise certain SAHPRA human medicine policies and procedures with those of the European Medicines Agency (EMA). Harmonisation will align South Africa with global best practices and enable increased collaboration with foreign regulators.

The following documents were published for comment mid-April; please note that the window for comment closes on 15th May 2019:

1. Professional Information (PI) and Patient Information Leaflet (PIL) guidelines
2. Clinical guideline
3. Clinical cover letter
4. Pharmaceutical and Analytical (P&A) guideline
5. Summary of Critical Regulatory Elements (SCoRE) document

SAHPRA is now releasing for industry comment:

6. Variations Addendum for Orthodox Medicines
7. eCTD and eSubmission Guidelines
8. eCTD and eSubmission New Registration Validation Templates

These documents are DRAFT documents. SAHPRA may refine components of these documents prior to the industry comment period ending.

6. Variations Addendum for Orthodox Medicines

SAHPRA is adopting the EU variations guideline for orthodox human and veterinary medicines.

To aid its application and interpretation in South Africa, SAHPRA has developed a Variations Addendum, which should be read in conjunction with the EU guideline. The Variations Addendum details specific classification and procedural deviations to the adoption of the EU guideline, as well as clarifications to facilitate a smooth transition. Any codes and/or procedures not mentioned in the Variations Addendum are implicitly adopted by SAHPRA in full.

Please note that the EU variations guideline will be adopted retrospectively for all variation applications submitted prior to the implementation date of these guidelines and addendum. More communication on this will follow.

7. eCTD and eSubmission Guidelines

To further SAHPRA's objective of improving efficiency, all applications which are yet to receive final approval (including certification) will need to be resubmitted electronically. This will apply to both backlog applications and applications submitted from 1 February 2018 onwards, i.e. "business as usual". The digital submission implementation roadmap, with timelines for backlog and "business as usual", will be communicated in the next month.

eCTD will be the preferred format for submission; however, SAHPRA will be accepting eSubmissions for a limited period of time to enable applicants to transition to eCTD where necessary. SAHPRA's updated eCTD guideline and new eSubmission guideline provide recommendations to applicants for submissions in each format.

8. eCTD and eSubmission New Registration Validation Templates

SAHPRA's New Registration Validation Template is an administrative and technical screening checklist to verify that all information required for evaluation has been submitted by an applicant. The validation template comprises:

1. Section A: Administrative validation (compliance checks, and technical and business validation)
2. Sections B – E: Technical verification (Inspectorate, Pharmaceutical and Analytical, Pre-clinical and Clinical, and Names and Scheduling)

For both eCTD and eSubmission, automatic validation will be performed when the submissions are loaded to ensure the structure of the submissions conforms to SAHPRA criteria. For the time being, eCTD validation criteria remain unchanged. eSubmission validation criteria will be published in the coming weeks. Please note that for eSubmission format no validation is required to be performed by industry.

The majority of the validation template will be standard across both electronic submission formats, with some minor differences in Section A due to additional checks required for eCTD. The validation template should be completed in full by the applicant for applications in both eCTD and eSubmission format. Applications will be thoroughly screened to ensure only high-quality dossiers proceed to evaluation. Any application that does not meet the requirements will not be evaluated.

Comment period

SAHPRA requests industry comment on the guidelines attached. Please supply written comments to backlog@sahpra.org.za by 24 May 2019.

We look forward to continued support from all stakeholders to achieve our shared goal of clearing the backlog in two years, and to ensure greater efficiency across SAHPRA going forward.

Yours faithfully,

Ms. P Nkambule

Acting Chief Executive Officer