SAHPRA
South African Health Products Regulatory Authority

SAHPRA Head Office
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Variations Addendum 28 September 2020

Interim measures pending update of Variations Addendum

Dear Industry colleagues,

Please be advised that the Variations addendum (*2.08_Variations Addendum for Human and Veterinary Medicines_June2020_v1.docx)* has been withdrawn on 1st September 2020 from the SAHPRA website for updates to some general aspects including administrative and quality variation coding.

An Interim guidance namely, *2.08a_Interim Variations Addendum for Human and Veterinary Medicines_September2020_v1.docx* will we uploaded as the interim measure until the revised guidance is accepted for implementation.

The Interim guideline reverts the below listed Quality variation coding to the EMA variation classification. The proposed Inspectorate timelines of 60 days will be revisited within 12 months from implementation. The interim guideline also includes the update on the interpretation of Quality Variation Type II fees.

Please note that the Clinical, amendments will not be affected and that these will remain essentially unchanged from the 2.08_Variations Addendum for Human and Veterinary Medicines_June2020_v1.

List of Quality Variation codes

SAHPRA/EMA code	Code description	EMA/SAHPRA Classification
B.I.a.1a	The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacture	Type IA_{IN}
B.I.a.2a	Minor change in the manufacturing process of the active substance	Type IA
B.I.a.3a	Up to 10-fold increase compared to the originally approved batch size	Type IA
B.I.a.3d	More than 10-fold increase compared to the originally approved batch size	Type IB
B.II.a.3b1	Any minor adjustment of the quantitative composition of the finished product with respect to excipients	Type IA
B.II.b.3a	Minor change in the manufacturing process	Type IA
B.II.b.4a	Up to 10-fold compared to the originally approved batch size	Type IA

B.II.b.4e	More than 10-fold increase Type IA_{IN} compared to the originally approved batch size for immediate release (oral) pharmaceutical forms	Type IB
B.III.1a3	New certificate of suitability (CEP) from a new manufacturer (replacement or addition)	Type IA_{IN}

List of Inspectorate quality codes

Code	Classification	Timeline required	Description of change
B.II.b.1.b	IAin	60 days	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site
B.II.b.1.e	IB	60 days	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products
B.II.b.1.f	IB	60 days	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/immunological medicinal products

Applicants are advised that the alteration for the above mentioned codes is a temporary alteration which SAHPRA commit to revisit within 12 months.

Applicants who have already prepared quality variations for submission based on the *2.08_Variations Addendum for Human and Veterinary Medicines_June2020_v1.docx* guidance may wish to reconsider submission based on the above.
Applicants are advised that variations submitted as Type 1A and Type IA_{in} (whilst implemented or implementable) should receive a response from SAHPRA within 30 days of the date of submission of these notifications in line with EMA guideline for submission of notifications. No communication from SAHPRA following the 30-day notification period implies that the implementation of the notification is accepted.

For any further enquiries on the above please contact silverani.padayachee@sahpra.org.za