South African Health Products
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Type II FAQs **February 2020**

FREQUENTLY ASKED QUESTIONS:

BACKLOG TYPE II DEEP DIVE SURVEY

This document serves to clarify questions received regarding the completion of SAHPRA's Type II Deep Dive Survey for products considered part of the variations backlog (i.e., those products which contain at least one un-finalised variation application submitted to SAHPRA prior to 01 February 2018).

Holders of Certificates of Registration (HCRs) / applicants are requested to consult this document prior to submitting any new questions related to the survey to backlog@sahpra.org.za. SAHPRA will not be responding to queries via email where the answers are already contained herein. This document will be updated as and when new, relevant questions are raised by SAHPRA's industry partners.

Date of most recent publication: **2019/08/08**.

1.	Q: Is the survey only applicable to Type II variations, and can one consider all (re-classified) Type I variations associated with the product outside of the scope of this survey?
	A: Yes, this survey is concerned with outstanding / un-finalised Type II variations which still require evaluation by SAHPRA. Former Type As, Bs and Cs which have been reclassified as either Type IA, Type IA_{IN} or Type IB variations are considered approved and implementable[1] where the mandated waiting period has lapsed. Former Safety-related Package Insert Notifications (SR-PINs) are also outside of the scope of this survey and should not be included. For example, an application for an additional manufacturer which was historically considered as a Type C26 may now have been reclassified as a Type IB variation. This application is NOT to be included in the Type II survey, and will be deemed implementable where the 30-day waiting period has lapsed.
2.	Q: Does the "Submission date of the oldest pending / un-finalised variation application" in Question 1 refer only to Type II variations which will still require evaluation by SAHPRA?
	A: Yes. As per Q1 above, (re-classified) Type Is will be deemed implementable and should no longer be considered as "pending" or "un-finalised" for the purposes of this survey.
3.	Q: Are previously submitted Type II variations which have received Inspectorate approval but have NOT yet received P&A approval considered in the scope of this survey?
	A: Yes, these variations are considered un-finalised and must thus be included in the survey.

[1] Subject to the implementation of the Variations Addendum [2.08] and launch of the Digital Variations Portal (which will initially be used to capture information on Type I variations previously submitted to SAHPRA).

4.	Q: If new variations arise between the submission date of the survey and the product's resubmission window, can they still be included in the consolidated resubmitted application?
	A: Yes, all relevant variation applications for a given product should be consolidated and resubmitted, including those which were not yet known at the time the survey was completed. While this survey only captures current variation applications at a point in time, it still proves useful for work planning and for creating a list of products which will be evaluated by the backlog clearance team.
5.	Q: Old Medicines do not have a pharmacological classification contained in their registration numbers. How does one account for outdated pharmacological classifications (module 1.2.1) in this survey?
	A: Applicants should still use Question 3 to provide information on outdated pharmacological classifications associated with the product. In the case of Old Medicines, answer Q3 with "No" and provide the correct classification in 3.1 below, including the term "old medicine." For example (Q3.1), "16 – Ear, nose and throat preparations. Old medicine."
6.	Q: Is there an option to save the survey and finalise it over multiple sessions?
	A: No, unfortunately not. It is recommended that applicants first familiarise themselves with the content and questions of the survey, and then proceed to collect all of the required information for a given product. Once this information has been collected the survey can be completed relatively quickly in a single session.
7.	Q: For products associated with a Transfer of the Holder of Certificate of Registration (ToHCR) application, should the "Name of the HCR" in the survey reflect the proposed HCR or the current HCR?
	A: The survey should reflect the *current* HCR as recognised by SAHPRA prior to the finalisation of the ToHCR application. Applicants should use question 11 of the survey to provide further details on the proposed HCR and the status of the application.
8.	Q: For products associated with a ToHCR application, should the current HCR or the proposed HCR complete the survey?
	A: SAHPRA has a preference for the *current* HCR completing the survey. However, it is ultimately up to SAHPRA's industry partners to decide on what is practical and to align on which party will complete the survey for these products. As with Q6 above, SAHPRA requests that whoever completes the survey provides further details on the ToHCR application through question 11 at the end.
9.	Q: Is it necessary to include ToHCRs in this survey where P&A and Ops. & Admin have issued approval letters for the product, but an Inspectorate letter has yet to be issued?
	A: Yes, include these applications in the survey and clarify any outstanding approvals in question 11 at the end of the survey. This will help SAHPRA assess the status of near-final applications and avoid understating any work required.
10.	Q: For Type II Clinical Backlog re-submissions (to commence Feb/Mar 2020): will applicants be allowed to update to the SmPC format as well as update the PI/PIL to the latest safety information not previously submitted in order to ensure that the labelling has the most up to date safety information?
	A: Yes, applicants must reformat to SmPC format and consolidate and include all safety updates (those submitted previously, and those pending submission).

11.	Q: Type II backlog variations involving safety updates such as additional Contra-indications are being requested to be submitted as a Type II. When the portal opens, however applicants already have additional safety updates which have not yet been submitted (these include both Type IB and Type II). To prevent a backlog of Type II safety variations and to allow reliance approach in recognizing the EU approved SmPC, SAHPRA to review the variation guidelines to allow addition of contra-indication to be included as a Type IB as well.
	A: These can be submitted as Type 1B. The variations guideline will be amended.
12.	Q: Timeline for Type II variation approval needed please.
	A: Answered by Q2.1.2 of the Variations Communication v2 Nov 19
13.	Q: Can applicants reach out to their Project Coordinator to follow up on the variations?
	A: Refer to the variation FAQ