SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

Issue No.: CT02-2024/25

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Clinical Trial Applications – Investigational Product Import Licence

TO ALL APPLICANTS

This communication is intended to provide guidance to Applicants about investigational product import licences (clinical trial approval letters) that have been approved by the Department of Health (Medicines Control Council - MCC).

It is noted that some of the Clinical Trials approval letters issued do not specify the quantities of study medication authorised for importation. SAHPRA Regulatory Compliance is not able to ascertain if the Applicants have exceeded the quantity of investigational product to be imported. Consequently, this has resulted in the delay in the release of products by SAHPRA Border Control. To overcome this challenge, a protocol amendment application (CTF2) is required to request the approval of the remaining study medication to be imported for these specific trials. Kindly refer to the process and forms available on the SAHPRA website:

- https://www.sahpra.org.za/document/guideline-for-electronic-submission-of-clinical-trial-documents/
- https://www.sahpra.org.za/document/clinical-trial-application-for-protocol-amendment-ctf2/

Applicants will be allowed six months as from the date of this communication to obtain the necessary approvals.

Boitumelo Semete-Makokotlela
Boitumelo Semete-Makokotlela
SIGNIFLOW

19 September 2024

DR BOITUMELO SEMETE-MAKOKOTLELA
SAHPRA CHIEF EXECUTIVE OFFICER (CEO)