South African
Health Products
Regulatory Authority

Regulatory Authority
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## Port Health Referrals

**27 October 2021**

**Review of detained product at a port of entry as a Category D medicine**

## To all stakeholders

Customs and Port Health Service (PHS) in SA, is the first line of defense to protect the citizens of the Republic of South Africa against the health risks associated with cross-border movement of people, conveyances, baggage, cargo and imported consignments. Among the imported consignments are medicines in terms of the Medicines and Related Substances Act, 1965 (Act 101 of1965).

Customs officers and Port Health officials, as applicable, are legally capacitated to detain the importation of any goods for their verification of compliance with applicable legislation. This may be for verification of the product as a foodstuff or as a medicine, each of which may hold a different tax implication for the importer.

Following the progression of the regulatory roadmap for Category D medicines, allowing for the continued sale of CMs while the importer may not yet hold a licence issued in terms of Section 22C of the Medicine Act or certificate of registration for an individual product, considerable referrals by to SAHPRA have continued to take place in an unstructured manner. This has resulted in delays in trying to address referrals with deficient information and the issuing of any opinions provided by SAHPRA.

To address the above-mentioned challenges, and following engagements with both Port Health and the National Department of Health, the SAHPRA had provided input to the development of a single form to be used by Port Health and importers to refer products that are detained for the review by SAHPRA or the National Department of Health, as may be required.

Further to this, SAHPRA has developed and implemented an electronic referral mechanism on the SAHPRA CM portal which will allow importers to request SAHPRA to review a detained product at the port of entry and issue an opinion concerning its status as a Category D medicine (Complementary Medicine) and to determine whether the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), have been complied with.

SAHPRA, therefore, advises all importers of *bona fide* Complementary Medicines to visit **www.sahpracm.org.za – Applications – Medicines – Request: Review of detained product at Port of Entry** and utilise the form issued for the referral of such detained product to SAHPRA.

The request sent from the SAHPRA CM portal will be processed within **five (5) working days** from the date of submission, provided that the information submitted is complete and meets the requirements. Incomplete requests cannot be reviewed and will be rejected at the point of receipt. All requests submitted must ensure that all relevant fields are completed and all supporting documentation has been supplied. This request form is not intended to facilitate the importation of medicines for personal use.

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