South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

DEC 2020

Lot Release Guideline for COVID – 19 Vaccines

COMMUNICATION TO INDUSTRY

This document is intended to provide guidance to applicants for lot release requirements specific to Covid-19 vaccines. This will be a "living document" and will be updated on regular basis. It is important that applicants adhere to the prescribed requirements in order to avoid delays in the processing. This document should be read in conjunction with SAHPRA's related information and guidance on application for registration of candidate Covid-19 vaccine as well as with the latest South African National Control Laboratory circular on general information regarding vaccines and lot release available at NclFHS@ufs.ac.za

First publication released for implementation	v1 Dec 2020

1. Introduction

The lot release of human vaccines by the South African National Control Laboratory for Biological Products is performed within the framework of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended and Act 14 of 2015, regulations 15(1) and 15(2).
This guideline should be read together with the latest National Control Laboratory (NCL) circular on General Information Regarding Vaccines and Lot Release, which is available on request at (NclFHS@ufs.ac.za).

2. Samples

The following samples should be supplied to the South African National Control Laboratory for each lot to be released:

- Twenty samples of single or multiple dose final containers.

3. Independent lot release tests to be performed by the South African National Control Laboratory

3.1 Testing scope

The South African National Control Laboratory will, at a minimum, perform the following tests:

On the final lot:

- Appearance
- Identity (potency may serve as an identity test)
- Potency
- Integrity (if relevant)

32. Reliance

The requirement for independent lot release testing will be based on the SAHPRA/NCL risk assessment and whether reliance can be applied. Exemption from independent testing may be considered subject to the availability of a lot release certificate issued by a releasing NCL that is a full member of the WHO National Control Laboratory Network for Biologicals or a National Regulatory Authority (NRA) with which SAHPRA is aligned.

4. Protocol submission

The lot summary protocol submitted by the Holder of the Certificate of Registration (HCR) should reflect all appropriate production steps and controls as outlined in the Marketing Authorisation for the product. The manufacturer's data submission must comply with the European Directorate for the Quality of Medicines Official Control Authority Batch Release (EDQM OCABR) model protocol format or a WHO-recommended format.

5. Proof of cold chain integrity

A vaccine arrival report must be submitted to the South African National Control Laboratory for each lot to be released. In those instances where a lot is imported in multiple shipments, the documentation for each shipment must be clearly distinguished.

6. Payment of the lot release fee

SAHPRA requires payment of a lot release fee (https://www.sahpra.org.za/fees-2/) for the first release of each vaccine final lot. The release fee must be paid directly to the SAHPRA account, and proof of payment must be sent to the South African National Control Laboratory.

7. Lead times

The lead time countdown will commence once samples and a complete summary protocol has been submitted to the South African National Control Laboratory. The Lead time is determined by the nature and scope of the independent testing required and if reliance can be applied. The lead time will be communicated to the HCR at the time of product licensing.

8. Further lot release process and requirements

If consignments of the same final lot are imported after the release of the first consignment/s, it is regarded as a further lot release. In this case, only a vaccine arrival report and twenty retention samples are required.

SAHPRA does not require payment for further releases of the same lot. A lot release performed through the further release pathway will be processed within five working days.