DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

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TO:
HEADS OF PROVINCIAL HEALTH DEPARTMENTS
HEADS OF PHARMACEUTICAL SERVICES
DISTRICT MANAGERS
HOSPITAL CEOs and CLINICAL MANAGERS
EPI MANAGERS
AEFI COORDINATORS
HEALTHCARE MANAGERS AND PROFESSIONALS

NATIONAL VACCINATION PROGRAMME CIRCULAR 1 OF 2022

ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) REPORTING AND INVESTIGATION

1. Immunisation is among the most successful and cost-effective public health interventions. It is common that the benefits of immunisation are often not visible, particularly if the target disease incidence is low. In contrast, adverse effects that follow immunisation are promptly noticeable, especially when the vaccinee was apparently healthy at the time of immunisation.

2. Regulation 40 (3) of the General regulation made in terms of the Medicine and Related Substances Act 101 of 1965 indicates that "A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any-(a) suspected adverse drug reactions; or (b) new or existing safety, quality or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance."

3. Surveillance of adverse events following immunisation (AEFI) is essential to safeguard public confidence in vaccines used in the South African vaccination programme. The National Immunisation Expert Committee (NISEC) advises and monitors vaccine safety related events though causality assessment. Causality assessment requires AEFI to be investigated fully at a district/provincial level. This include completion of all relevant case reporting forms (CRF), case investigation forms (CIF), and collation of the clinical records, laboratory results and medical history of the vaccinee.

4. All health care providers or any other person who identify, treat or report an AEFI, are requested to share all requested information to facilitate AEFI reporting and

investigation as required by the relevant regulations with the district/provincial AEFI coordinators in a timely manner.

5. To address concerns regarding sharing of the vaccinee's personal information, the CRF (attached) and the MedSafety application terms has been updated to include a section whereby the vaccinee (or family member) provides informed consent for the necessary information to be provided to the relevant authority. Where an AEFI has been reported on a CRF that does not include the informed consent section, the additional consent form can be completed by the vaccinee/caregiver or family member.

DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 10.01.2022

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received.

The vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of case investigation, when required; ii) in the generation of statistics; and iii) to make policy decisions relating to vaccine safety and efficacy.

This consent may be withdrawn at any time, and the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) may, at any time, object to the collection and processing of their personal information, by contacting the Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of case investigation, in a manner that adheres to the Protection of Personal Information Act. The information will not be stored (in a manner that identifies the vaccine recipient) for any longer than is necessary to achieve the purpose for which the information was collected, unless the Department has a lawful basis to do so. If the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) wishes to access and/or rectify their personal information, they may do so by contacting the Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)
Signed by the vaccine recipient / relative / caregiver*

_____	_____	_____
Name and Surname	**Signature**	**Date**

**Delete what is not applicable*