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

INFORMATION AND GUIDANCE ON THE IDENTIFICATION AND REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH THE NEW COVID-19 VACCINES

COMMUNICATION TO THE PUBLIC

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WHAT IS A COVID-19 VACCINE?

A **COVID-19 vaccine** is any of several different vaccine technologies intended to provide immunity against coronavirus disease 2019 (COVID-19).[1] In general, vaccines contain weakened or inactive parts of a particular organism (antigen) that triggers an immune response within the body. Messenger RNA (mRNA) vaccines contain the blueprint for producing antigens rather than the antigen itself. Regardless of whether the vaccine is made up of the antigen itself or the blueprint so that the body will produce the antigen, this weakened version will not cause the disease in the person receiving the vaccine, but it will prompt their immune system to respond as it would have on its first reaction upon exposure to the actual pathogen. Some vaccines require multiple doses, given weeks or months apart. This is sometimes needed to allow for the production of long-lived antibodies and development of memory cells. In this way, the body is trained to fight the specific disease-causing organism, building up memory against pathogen so as to rapidly fight it when exposed in the future.[2]

As of 02 December 2020, 58 Covid-19 vaccine candidates were in clinical research:[3] namely 43 in Phase I–II trials and 15 in Phase II–III trials. No vaccine candidate has yet fully completed a Phase III trial. In November 2020, Pfizer Inc. and BioNTech, Moderna and the University of Oxford (in collaboration with AstraZeneca), announced positive results from interim analyses of their Phase III vaccine trials. On 2 December, temporary regulatory approval was granted by the UK medicines regulator MHRA for the Pfizer-BioNTech vaccine, which is also under evaluation for emergency use authorization (EUA) status by the US FDA, and in several other countries.[1]

ARE COVID-19 VACCINES SAFE?

As with any other medicine that can have side-effects or adverse effects in some individuals while still being effective to cure or control disease, vaccines can prevent disease and also have adverse effects in some individuals. SAHPRA has a mandate to monitor such adverse effects and ensure that they are recorded and managed properly so that, should a vaccine become more dangerous than useful for the purpose it was intended for, regulatory action can be taken to either warn the public about newly discovered adverse effects or remove the vaccine from the market in order to protect the public. SAHPRA achieves this through its Pharmacovigilance Unit.

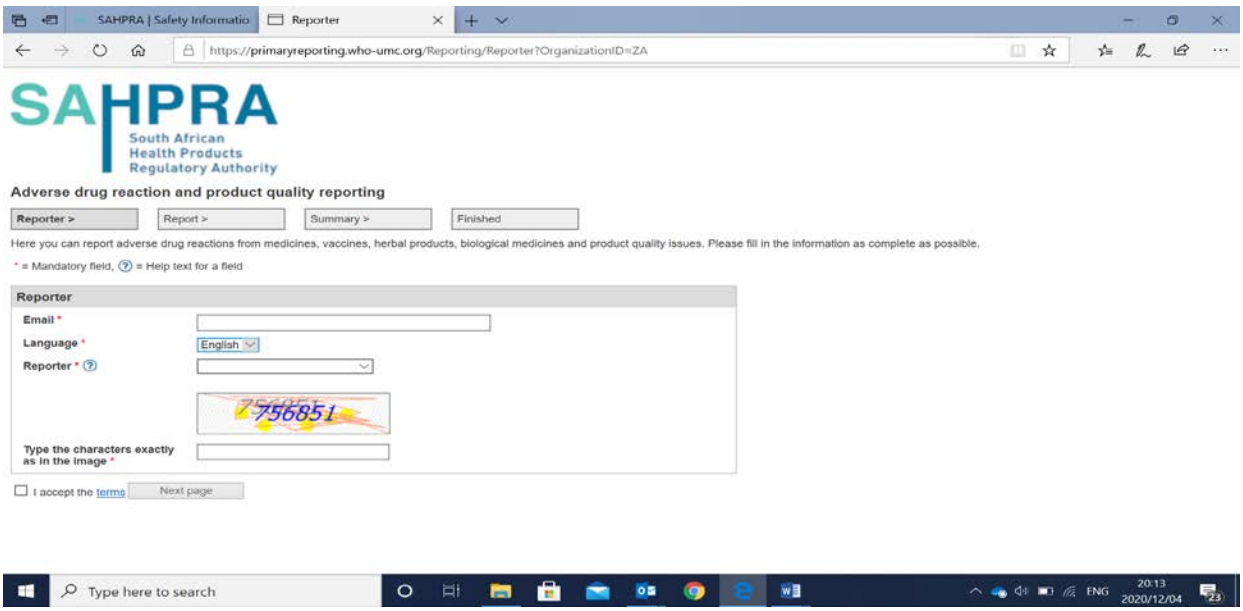
WHAT DOES THE PHARMACOVIGILANCE UNIT DO?

The Pharmacovigilance Unit of SAHPRA is responsible for the monitoring, detection, assessment,

understanding and prevention of adverse effects or any other medicine-related problems. This is to ensure that only safe and effective medicines of high quality are used in South Africa. To monitor and detect medicine adverse effects, the Unit receives reports of medicine adverse effects from the public and healthcare providers and assesses them in order to make the necessary regulatory decisions to prevent any further potential harms to the public.

HOW TO REPORT VACCINE OR MEDICINE-RELATED ADVERSE EFFECTS TO SAHPRA?

Reports of suspected adverse events following immunization can be submitted on the SAHPRA website using the link: [https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA].



Alternatively, an adverse event reaction form can be downloaded from the SAHPRA website using the link: [https://www.sahpra.org.za/wp-content/uploads/2020/01/6.04 ARF1_v5.1 27Jan2020.pdf].

Although anyone affected by an adverse event following immunization can report an event to SAHPRA, individuals are encouraged to report their suspected vaccine-related complaints through their healthcare provider at the healthcare facility from which the vaccination was administered to ensure that all important and relevant facts are captured on the reporting form to enable proper investigation and handling of the vaccine-related complaint. SAHPRA is exploring the use of a web application (“the app”) for the simplified

and convenient reporting of Adverse Drug Reactions (ADRs), including Adverse Events Following Immunization (AEFIs). Implementation of this reporting app will be communicated in due course.

WHAT HAPPENS AFTER A REPORT IS SUBMITTED?

SAHPRA will assess the reported adverse event and take action depending on the outcome of the assessment and the seriousness of the vaccine-related complaint. These actions include, updating the professional information and the patient information leaflet to warn health professionals and the public about the new adverse event; restricting the use of the vaccine to certain groups of individuals; or deregistration of the vaccine and removing it from the market to prevent further harm to the public.

References:

1. https://en.wikipedia.org/wiki/COVID-19_vaccine
2. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/how-do-vaccines-work
3. https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/