Medicines Control Authority of Zimbabwe

Medicines Information Bulletin

July 2021

PROTECTING YOUR RIGHT TO QUALITY MEDICINES AND MEDICAL DEVICES

MISSION STATEMENT
To protect public and animal health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality.

VISION
To be an effective medicines regulator in Zimbabwe and a leading regulatory authority in the world

VALUES
- Customer focus
- Integrity
- Continuous improvement
- Accountability

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Content

Five (5) COVID-19 Vaccines have been granted Emergency Use Authorisation in Zimbabwe

Sinopharm
Sinovac
Covaxin
Sputnik V
Johnson & Johnson

COVID-19 Vaccines Update

Vaccines to protect against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) have risen up the agenda of most policy makers as nations continue to battle against the virus and there is increasing pressure on health-care systems (1).

Scientists around the world have worked faster than ever to develop and produce vaccines that can stop the spread of COVID-19. Since the emergence of this novel coronavirus in December 2019, several vaccines have now been rolled out across the world, including some that use new RNA technology that has never been approved for use on humans before(2).

There are several vaccines being developed around the world that are in the pre-clinical phase or beyond as shown in figure 1. In pre-clinical studies, a vaccine is tested to see whether it is toxic and how it reacts with the body – this is to identify a safe dose before testing the vaccine candidate in people (3). When candidate vaccines make it to human clinical trials, they first go through phase 1 trials primarily to test the vaccine's safety, determine dosages and identify any potential side effects in a small number of people. Phase 2 trials further explore safety and start to investigate efficacy on larger groups. Phase 3 trials, which few vaccines ever make it to, are much larger, involving thousands or tens of thousands of people, to confirm and assess the effectiveness of the vaccine and test whether there are any rare side effects that only show up in large groups. The final stage, phase 4 trials, is conducted after national regulatory approval and involves further monitoring in a wide population over a longer timeframe as a form of post-marketing surveillance (pharmacovigilance) (2).

The MCAZ is responsible for ensuring that any pharmaceutical product including vaccines used within the country is of good quality, effective and safe for the purpose or purposes for which it is proposed. MCAZ as the national pharmacovigilance center is also responsible for the safety monitoring of all the COVID-19 vaccines administered in the country, including ensuring timely submission of COVID-19 adverse events following Immunization (AEFIs) and adverse events of special interest (AESIs) data from Ministry of Health and Child Care (MOHCC) - Zimbabwe Expanded Programme on Immunization (ZEPI) and all vaccination sites across the country for data compilation, analysis, and signal detection.

Five vaccines have been given Emergency Use Authorisation by MCAZ, these are Sinopharm (China), Sinovac (China), Covaxin (India), Sputnik V (Russia). and Johnson & Johnson (Netherlands) The Sinopharm and Sinovac vaccines have been listed by WHO for Emergency Use Listing (EUL) (4, 5). The EUL assesses the quality, safety and efficacy of COVID-19 vaccines, as well as risk management plans and programmatic suitability, such as cold chain requirements. The assessment is performed by the product evaluation group, composed by regulatory experts from around the world and a Technical Advisory Group (TAG), in charge of performing the risk-benefit assessment for an independent recommendation on whether a vaccine can be listed for emergency use and, if so, under which conditions. The assessment also weighs the threat posed by the emergency as well as the benefit that would accrue from the use of the product against any potential risks (4).

Although all the COVID-19 vaccines have been produced at record speed, there have been many checks and balances to ensure their safety, including being subject to the same scientific and regulatory rigour as any other vaccine. Ultimately safety is paramount throughout the entire vaccine development and the regulatory approval process. Moreover, any possible risks that may exist are considerably lower than those associated with COVID-19 infection, and vastly outweighed by the benefits of protecting people and preventing the virus from spreading.

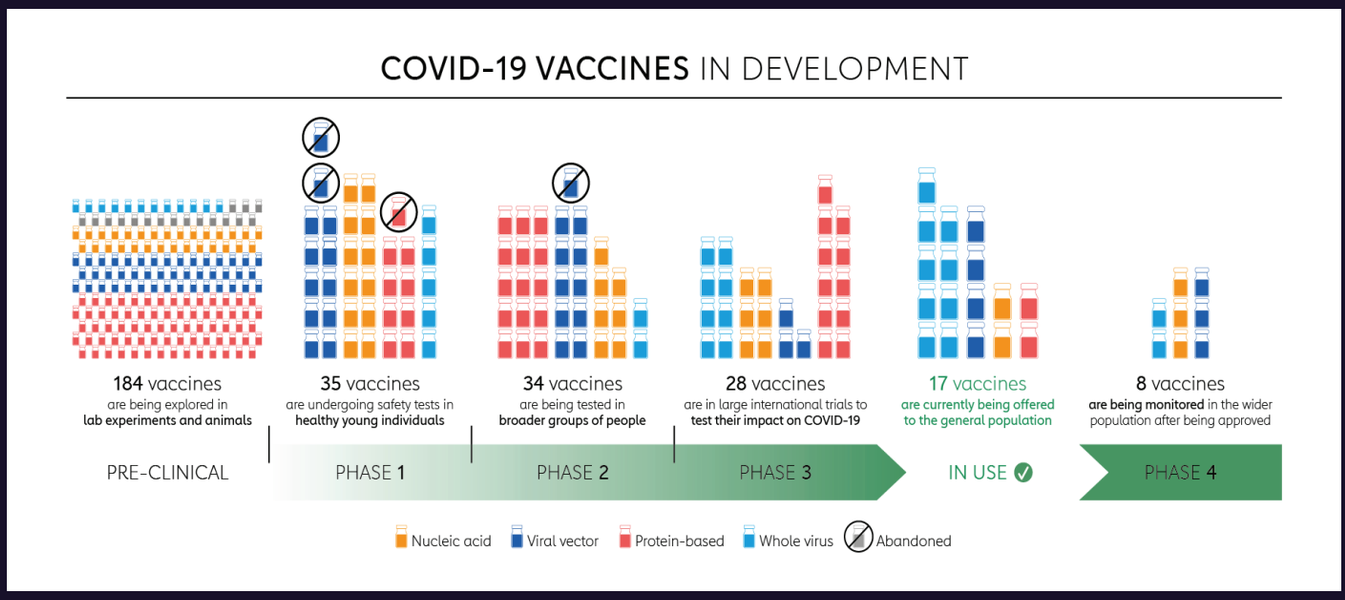

Figure 1. Schematic representation of COVID-19 vaccine development (2)

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2. https://www.gavi.org/vaccineswork/covid-19-vaccine-race
3. https://www.gavi.org/vaccineswork/how-safe-are-covid-19-vaccines
4. https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations
5. https://www.who.int/news/item/07-05-2021-who-lists-additional-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations
6. https://www.who.int/news/item/12-03-2021-who-adds-janssen-vaccine-to-list-of-safe-and-effective-emergency-tools-against-covid-19

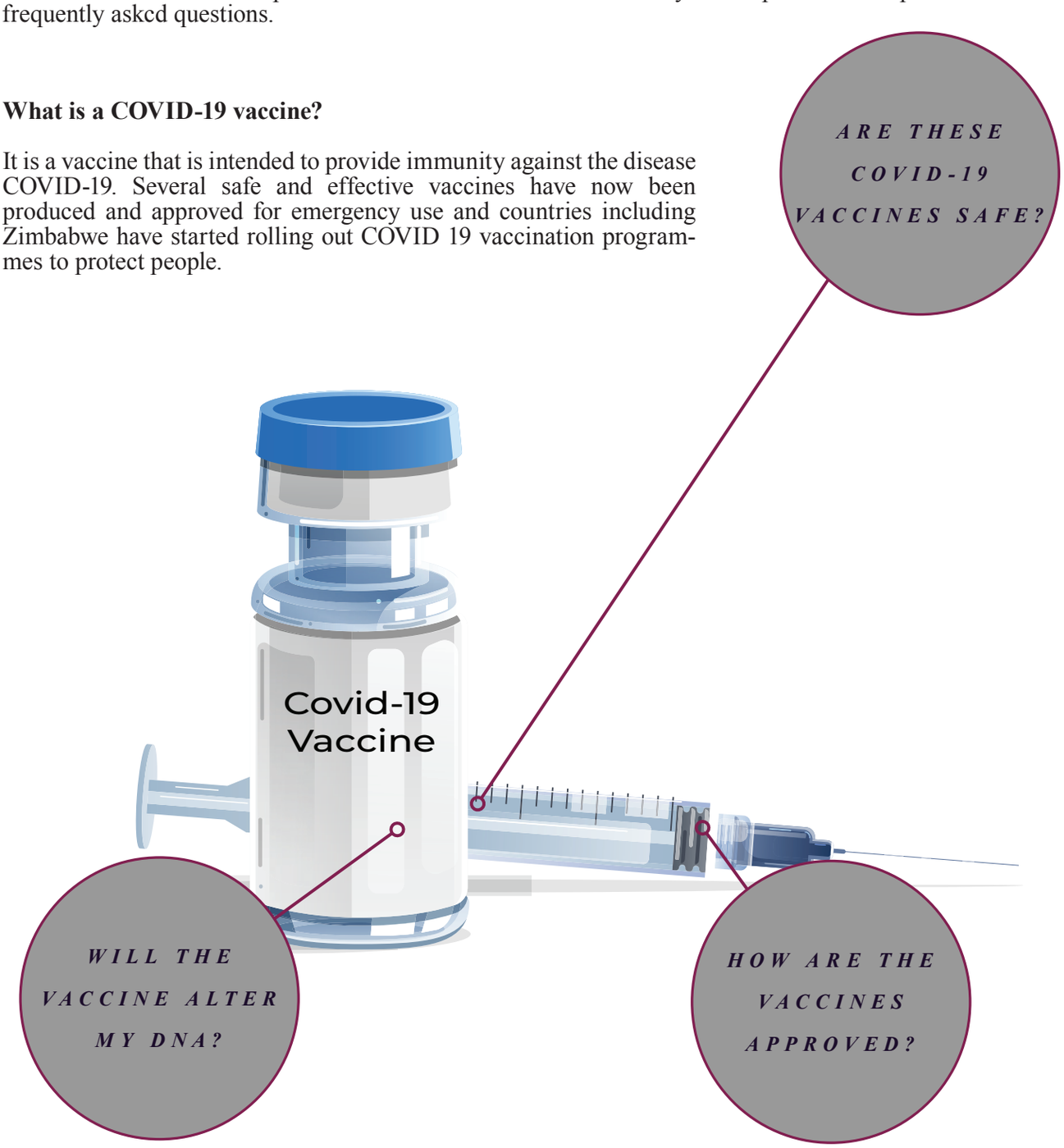

COVID-
Coronavirus
Vaccine
Injection

COVID-19 Vaccines FAQs

With the rapid development of COVID-19 vaccines, a number of questions arise. There has been a lot of disinformation with respect to vaccines therefore the Authority developed some responses to the frequently askcd questions.

What is a COVID-19 vaccine?

It is a vaccine that is intended to provide immunity against the disease COVID-19. Several safe and effective vaccines have now been produced and approved for emergency use and countries including Zimbabwe have started rolling out COVID 19 vaccination programmes to protect people.



COVID-19 Frequently Asked Questions

What steps are taken to ensure the COVID-19 vaccine is safe?

COVID-19 vaccines go through a rigorous, multi-stage testing process, including large trials that involve tens of thousands of people. These trials, which include people at high risk for COVID-19, are specifically designed to identify any common adverse events or other safety concerns.

Once a clinical trial shows that a COVID-19 vaccine is safe and effective, a series of independent reviews of the efficacy and safety evidence is required, including regulatory review and approval in the country where the vaccine is manufactured, before WHO considers a vaccine product for prequalification.

An external panel of experts convened by WHO analyses the results from clinical trials, along with evidence on the disease, age groups affected, risk factors for disease, and other information. The panel recommends whether and how the vaccines should be used.

Who approves COVID-19 vaccines?

In the countries where vaccines are manufactured, national or regional regulators oversee a vaccine's development. This includes approving clinical trials, evaluating their results, and taking decisions on licensing. In deciding, regulators refer to very strict international standards on acceptable ethical clinical practice. Once a vaccine has been developed, our local regulator- the Medicines Control Authority of Zimbabwe (MCAZ) decides whether to introduce the vaccine in Zimbabwe and with what conditions. This is done through a process called Emergency Use Authorisation (EUA), whereby a team of regulatory experts from MCAZ technical divisions conduct a Benefit-Risk assessment of these vaccines that would had undergone Phase I and II Clinical trials and had started Phase III studies but were already showing favourable safety and efficacy in preventing COVID-19. Approval is granted after a vaccine demonstrates a favourable benefit-risk balance.

Are there side effects from COVID-19 vaccines?

Minor reactions can occur after getting a vaccine such as a pain or swelling on injection site, mild fever, fatigue, headache and itchiness. These are usually indications that the vaccine has started to work.

More serious side effects such as anaphylaxis and persistent fever are possible, but extremely rare and vaccinators are trained to manage these.

What happens if you experience side effects from COVID-19 vaccines?

It is recommended to visit your health facility for advice if you are worried about your condition after vaccination.

If you experience side effects from COVID-19 vaccines, report to your healthcare provider or vaccination centre and they will assist you to complete an Adverse Event Following Immunisation (AEFI) reporting form.

Report online – https://e-pv.mcaz.co.zw

You can also use the MCAZ Pharmacovigilance Android and IOS mobile applications

What happens if a problem is suspected with a vaccine?

If a potential problem is reported following vaccination in Zimbabwe, a thorough investigation will take place. Investigations involve a thorough examination of the case in question, including medical assessment by experts. If necessary, detailed studies are conducted.

During these investigations, it is extremely rare that health problems are found to be caused by the vaccine itself.

Health events are most often found to be coincidental, i.e. entirely unrelated to vaccination or may be linked to some underlying medical conditions or comorbidities.

In the rare cases where a genuine adverse reaction is suspected, the vaccine may be suspended and or recalled if necessary to protect the people. Further investigations will take place to determine what exactly caused the event, and corrective measures put in place.

Myth	Fact
Vaccines are unsafe and normal safety protocols have been circumvented to fast track their authorisation for use.	The fast development and approval of vaccines is a great human achievement worthy of celebration. This has been possible because we have learnt over many decades how to make and test vaccines and we were able to take those lessons and challenge ourselves to produce a vaccine much quicker. No step in the development, testing or ratification of the COVID-19 vaccines has been skipped. The world was able to develop vaccines fast because scientists and governments around the world collaborated in a manner that has never been achieved before and pooled resources and information to ensure that everyone can contribute to the knowledge.
COVID-19 vaccines give you the virus.	COVID-19 vaccines do not give you the virus. The vaccine does not contain a live virus strain. It contains an inactivated virus, which doesn't cause disease, but still prompts an immune response.
The vaccine will change my DNA	Vaccines work by stimulating the body the same way the virus would if someone was infected. That means when you receive the vaccine the body then recognises that it looks like the coronavirus and then it releases certain chemicals that start a chain reaction to make immune cells that can fight the real virus. The vaccine does not work on the DNA of the body. Some people think that because some of the vaccines are made using RNA technology that means the RNA will interact with the DNA. That is not how it works. The technology is simply the way the vaccine is made - not what it will do to the body.
The COVID-19 vaccine will give you COVID-19	You cannot get the COVID-19 virus from the COVID-19 vaccines because they do not contain live coronavirus. The vaccines are designed using killed whole or part of the virus, which will help trigger your immune system to recognize and fight the virus, if infected.

Summary

Available COVID-19 vaccines are safe and they provide immunity and protect us, and our communities from severe forms of COVID 19. It is critical that all of us continue to adhere to recommended COVID-19 prevention behaviours such as frequent hand washing and sanitizing, physical distancing and proper use of face masks to ensure that we stay protected.

Safety monitoring for all COVID-19 vaccines in Zimbabwe will be conducted throughout the vaccination period

Ivermectin human oral formulations for prevention and/or treatment of COVID-19

Ivermectin is an antiparasitic drug approved for the treatment of parasitic infections, including strongyloidiasis and onchocerciasis in humans. There is a reported increase in the use of ivermectin for the prevention and treatment of COVID-19 by the public. However, there is limited scientific evidence on its effectiveness i.e. currently, there is:

1. No scientific evidence from pre-clinical studies on the therapeutic effect of ivermectin for the management of COVID-19;
2. No evidence of its clinical efficacy for the management of patients with asymptomatic, mild, moderate or severe COVID-19; and
3. No safety data regarding the use of ivermectin for COVID-19 in the majority of the published studies.

In response to the growing interest and unregulated use of ivermectin for the treatment and prophylaxis of COVID-19, the Authority, through the Secretary for Health and Child Care, approved off-label use of ivermectin human oral prescription preparations (PP) under prescription and supervision in line with MCAZ MASCA Chapter 15:03 section 75 authorized conditions only. The operational framework objectives are to:

1. Authorise procurement of quality assured human formulations of ivermectin for use in COVID-19 cases,
2. Ensure that qualified and suitably experienced healthcare providers have access to human formulations of ivermectin for management of COVID-19 cases,
3. Gather information on whether patients are obtaining clinical benefits from use of human formulations of ivermectin in management of COVID-19 cases,
4. Monitor and report any side effects and any unexpected adverse events associated with use of human ivermectin for management of COVID-19 cases.

The procedures outlined in the framework are not intended to replace the procedure for clinical trials, and any researchers intending to do research should use the existing clinical trial application guidelines. The MCAZ is also in compliance with the current World Health Organization (WHO) COVID-19 Disease Treatment Living Guideline that recommends use of ivermectin for treatment of COVID-19 disease under clinical trials setting only. This is due to the limited evidence and goal to generate evidence-based practice at country level, and promote patient safety.

For more information regarding the framework and the forms that must be submitted, please visit the mcaz website www.mcaz.co.zw, alternatively email mcaz@mcaz.co.zw.

Medication Errors

Medication errors (MEs) are a common preventable cause of patient harm associated with increased morbidity, mortality and healthcare costs. Detection and root-cause analysis of MEs can identify individual and system weaknesses that should be addressed to improve patient safety. However, MEs are largely underreported, which undermines quality improvement and medication risk management in healthcare .(1)

In a systematic review of medication errors in African hospitals (Mekonnem A.B et al (2018), commonly reported errors included a prescription and/or administration of an incorrect dose, wrong drug combination and/or selection , wrong route of administration, omission errors and wrong frequency and/or duration. A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. The phrase "failure in the drug treatment process" does not refer to lack of efficacy of the drug, rather to human or process mediated failures (2).

These errors may happen when patients receive healthcare services for preventive, diagnostic, curative or rehabilitative purposes as unintended mistakes in the process of prescribing, storing, dispensing, preparing or administering medicinal products and may or may not have adverse consequences.

If a medication error occurs with the same pattern or at an unacceptable frequency, or if it results in serious harm for the patient, it is essential to understand the causes, contributing factors and clinical consequences of the error, as well as possible mitigating actions and solutions which could prevent the error from happening again.

Healthcare professionals (HCPs) are the cornerstone of the effective functioning of ME reporting systems, both as a key source of ME reports and as users of the information arising from the analysis of these ME reports. HCPs are encouraged to report medication errors using the Medication Incidence Reporting Form (PVF 45), available on request at mcaz@mcaz.co.zw and accessible from the MCAZ website (https://www.mcaz.co.zw/index.php/downloads/category/16-forms?download=326: medication-incidence-report-form&start=15).

Factors that can precipitate medication errors

Medication	Patient	Healthcare Professional	Latent
Low therapeutic index	Poor renal/hepatic function	Use of abbreviations in prescriptions	Staffing issues
Look alike drug names like dopamine and dobutamine	Impaired cognition	Poor prescription writing	Fatigue
Closely similar packaging	Polypharmacy	Cognitive errors	Distractions
	Comorbidities		

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1. Kiguba R, Waako P, Ndagije H.B, Karamagi C(2015), Medication Error Disclosure and Attitudes to Reporting by Healthcare Professionals in a Sub-Saharan African Setting: A Survey in Uganda, Drugs - Real World Outcomes, DOI 10.1007/s40801-015-0032-7

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3. Goverwa-Sibanda T.P, Saruchera S, Tshuma N, Chikwati E, Sinoia F, Tawodzera (2019), 20th ICASA Conference on AIDS and STI's in Africa (ICASA) Kigali, Rwanda, Abstract number: TUPEE360

4. Wittich CM, Burkle CM, Lanier WL. Medication errors: an overview for clinicians. Mayo Clin Proc. 2014 Aug; 89(8):1116-25. doi: 10.1016/j.mayocp.2014.05.007.

Substandard & Falsified Medicines

A substandard medical product is an authorized product which does not meet quality standards or specifications, produced by a known manufacturer with no intent to fool or defraud the patient. A falsified medical product is one that is deliberately and fraudulently labeled in a way that misrepresents its identity, source or composition and is often produced in unsanitary and unregulated conditions by an unknown manufacturer.

Summarized below are medicinal products alerts for communicated by World Health Organization (WHO) Global Surveillance and Monitoring system for Substandard and Falsified Medical Products to date for the year 2021.

Suspected substandard and falsified products can be reported using Product Defect Forms, available on request and accessible via the MCAZ website on the following link: https://www.mcaz.co.zw/index.php/downloads/category/16-forms?download=107:product-defect-form.

WHO MEDICAL PRODUCT ALERT NO. 1 OF 2021

Falsified VITAMIN A (retinol) identified in WHO region of Africa.

This WHO Medical Product Alert refers to two falsified VITAMIN A (retinol) capsules identified in Chad and reported to WHO in November 2020. Laboratory analysis of recovered samples identified that both products are severely degraded and underdosed – containing less than the stated active ingredient. Both falsified products also carry now-defunct logos – the outdated WHO Essential Drugs Programme logo and the outdated Micronutrient Initiative logo. Both falsified products were supplied at patient level and may still be in circulation in the region.

Source: https://www.who.int/news/item/10-03-2021-medical-product-alert-n-1-2021-falsified-vitamin-a

Falsified VITAMIN A (retinol)

Product name	Vitamin A (Retinol)	Vitamin A (Retinol)
Stated Active ingredient	Vitamin A (USP) 200 000 I.U and Vitamin E (USP) 40 I.U	Vitamin A (USP) 200 000 I.U and Vitamin E (USP) 40 I.U
Stated manufacturer	Accucaps Industries Limited	Banner Pharmaceuticals (Canada) Ltd
Batch Number	UI4004	39090439
Manufacturing date	01/2019	01/2019
Expiry date	09/2022	09/2022
Packaging Language	English & French	English & French
Identified In	Chad	Chad

Falsified COVID-19 Vaccine BNT162b2

WHO MEDICAL PRODUCT ALERT NO. 2 OF 2021

Falsified COVID-19 Vaccine BNT162b2 identified in the WHO region of the Americas

This WHO Medical Product Alert refers to falsified COVID-19 Vaccine identified as "BNT162b2" detected in Mexico in February 2021 and recently confirmed as falsified to the WHO. The falsified product was supplied and administered to patients outside authorized vaccination programs.

This falsified COVID-19 Vaccine may still be in circulation in the region and may continue to be offered to patients outside authorized vaccination programs.

Source: https://www.who.int/news/item/26-03-2021-medical-product-alert-n-2-2021-falsified-covid-19-vaccine-bnt162b2

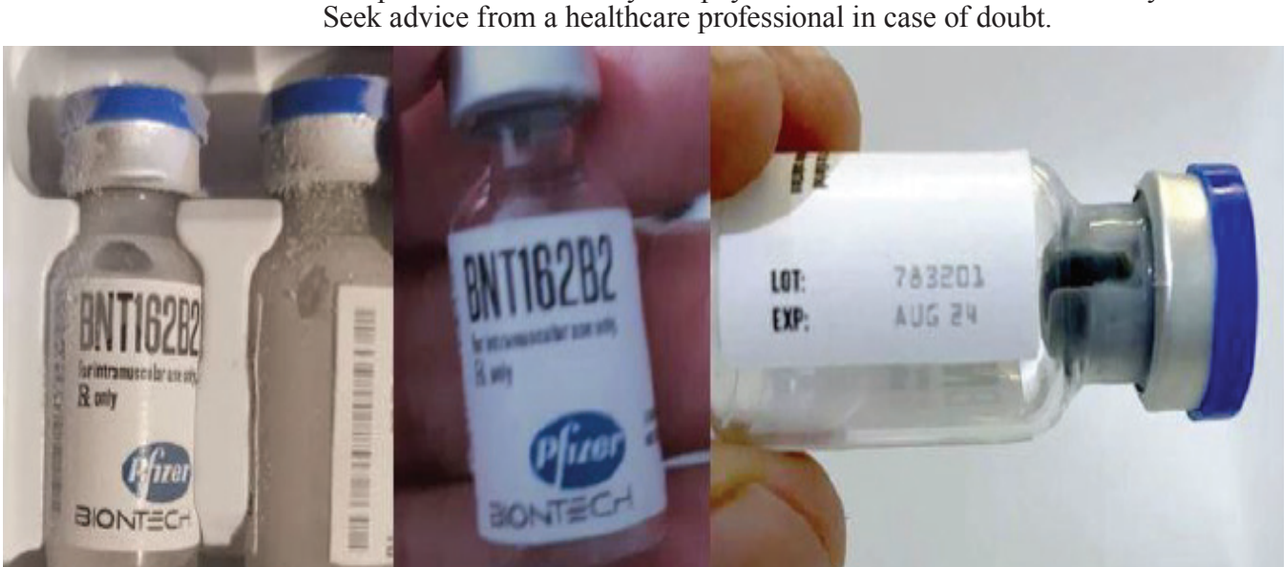
A falsified COVID-19 Vaccine identified as "BNT162b2" was detected in Mexico in February 2021 and confirmed as falsified. The falsified product was supplied and administered to patients outside authorized vaccination programs. The product identified in this alert was confirmed falsified on the basis that the genuine manufacturer of BNT162b2 confirmed they did not manufacture the product, the batch number and expiry dates were falsified and the glass vials are different from genuine COVID-19 Vaccine BNT162b2 vial. The products which are the subject of the WHO Medicinal product Alert No2/2021 are as follows:

Product Name	COVID-19 Vaccine BNT162b2
Stated Manufacturer	Pfizer BIONTECH
Lot Number	783201
Expiry Date	08/2024
Packaging Language	English
Identified in	Mexico

Advice from WHO to regulatory authorities and the public

WHO requests increased vigilance within the supply chains of countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies, and any other suppliers of medical products.

All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.



Pharmacovigilance Regulatory Safety Updates

Patient safety has been labelled as a constantly moving target of almost infinite variation and complexity. This underscores the importance of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported potential adverse reactions. The following updates have been made to the package inserts of listed products.

Name of product:	**Package Insert Safety Update**
Metoclopramide	Addition of "oculogyric crisis and visual disturbances" under Nervous system disorders
Docetaxel	Second primary malignancies, including Non-Hodgkins lymphoma have been reported in association with Docetaxel when used in combination with anticancer treatments known to be associated with second primary malignancies. Second primary malignancies may occur several months or years after docetaxel- containing therapy. Patients should be monitored for second primary malignancies
Levonorgestrel 75mg subcutaneous (Jadelle)	Jadelle is not indicated for use before menarche. Under the special warnings and precautions sections, the applicant added depressed mood and depression are known undesirable effects of hormonal contraceptives and for women to contact their physician in case of mood changes.
Betagan (Levobunolol) 0.5% liquifilm	Foreign body sensation in the eye and hair loss were added under the "side effects with unknown frequency" subsection
Montelukast Sodium (Singulair®) 4 mg	Enuresis in children-added as an adverse effect with uncommon frequency
Casodex 50mg (Bicalutamide)	A new precaution that close monitoring of Prothrombin Time (PT) and International Normalised Ratio (INR) is advised and anticoagulant dose adjustment should be considered. It has been reported that warfarin and other coumarin anticoagulants has an increased effect when taken with Casodex and this was added under "interaction with other medicinal products and other forms of interaction
Rosuvastatin	Drug-drug interactions of Regorafenib and Darolutamide with Rosuvastatin have been added

Medicines Safety Alerts

The Medicines Control Authority of Zimbabwe (MCAZ) regularly reviews medicines safety issues for products that are registered and marketed in Zimbabwe. This information helps in ensuring ongoing safety monitoring by checking for any safety concerns raised by other regulatory agencies or World Health Organization (WHO), particularly for safety issues or adverse drug reactions (ADRs) that would not have been published before, or included in the pacakage inserts for medicines. The WHO publishes regular WHO Pharmaceuticals Newsletters, whose aim is to disseminate regulatory information on the safety of pharmaceutical products, based on communications received from our network of national pharmacovigilance centres and other sources such as specialized bulletins and journals, as well as partners in WHO. Healthcare professionals are sensitized to carefully monitor the below mentioned alerts, ensuring any event related to these drugs is reported to the MCAZ

Name of drug:	**Risk Warning**
Carbamazepine	Severe cutaneous adverse reactions
Chloroquine, Hydroxychloroquine	Psychiatric disorders
Erythromycin	Infantile hypertrophic pyloric stenosis
Fluoroquinolones	Heart valve regurgitation

SOURCE

https://www.who.int/publications/i/item/who-pharmaceuticals-newsletter---n-1-2021

Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS)

Under recommended conditions, all vaccines used in national immunization programmes are regarded as safe and effective if used correctly. In practice, however, no vaccine is completely risk-free and adverse events can occasionally occur after an immunization. It is of utmost importance that all adverse events following immunisation (AEFIs) are reported when they occur, especially if they are serious, even if they are unlikely to have been caused by the vaccine itself. Passive surveillance is recommended globally for the detection of adverse events following immunisation (AEFI) but this has significant challenges.

In a bid to strengthen pharmacovigilance (PV) in Zimbabwe using novel methods of e-health, MCAZ conducted a study titled, The use of e-health to improve post-marketing surveillance of vaccines in Zimbabwe. A case study of Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) (II) randomized trial assessing Adverse Events Following Immunization (AEFIs). The main purpose of the study was to explore a new way to collect information about adverse events that sometimes occur after vaccination. This new way makes use of SMS and cellphone calls to communicate with the participants' guardians and/or adult Covid-19 vaccine recipients. The primary aim of the study was to determine if STARSS is more effective in detecting an AEFI than the usual standard of practice of passive reporting of AEFIs. The study had two arms, the passive arm and the CATI arm.

The passive arm acted as the control arm and this group had individuals who reported AEFIs without being followed up. The CATI (Computer assisted telephone interview) arm, has individuals who are followed up with text messages on whether AEFIs occurred. A survey is also carried out at the end of 4 weeks using a phone call to the participants who are in the CATI arm.

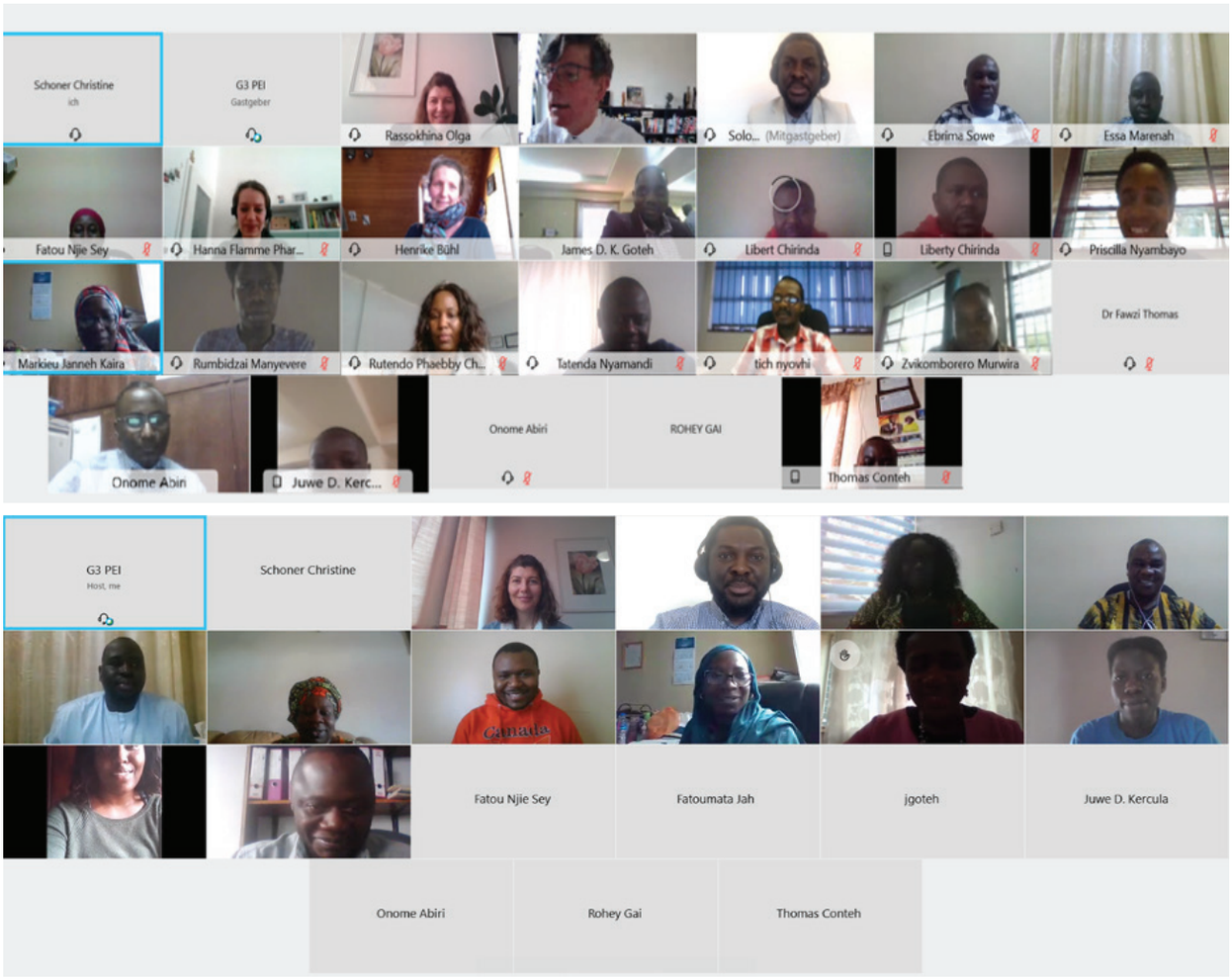
The study sites were Chitungwiza Central Hospital and Citimed Private Hospital. Site activation was done on the 6th of November 2020 for Chitungwiza Central Hospital with three wards participating in the enrolment of participants i.e. Post Natal Ward, Caesar Ward and OPD Vaccination clinic. Activation for Citimed Private Hospital was done on the 7th of November 2020 with the Post Natal Ward and Vaccination Clinic taking part in the enrolment of participants. A total of 4,500 participants including children and/or adult/healthcare worker vaccine recipients were recruited. Children 0 ≤5 years vaccinated at the 2 sites and adult/healthcare workers who got the COVID-19 vaccines at the 2 sites were recruited.

The study reached the target enrolment on the 24th of May 2021 and enrolment was stopped. Data analysis is now being done for the data collected and the results of the study will be published in due course. If you are interested in learning more about the study please visit the STARSS II Web page http://starss.mcaz.co.zw/ or contact us at pvct@mcaz.co.zw

Safety Review Of The Ingredients/Substances Gazetted As Undesirable In Pharmaceutical Preparations

Over the recent years the Authority conducted a safety review of the list of ingredients gazetted as undesirable substance to update the list in line with current safety information. The safety review was conducted for each ingredient and information from other regulatory agencies such as EMA, USFDA, TFDA, TGA and decisions made by several countries were taken into consideration. The WHO list of products banned/withdrawn and restricted products was also used as reference material for the safety reviews. The Authority was concluded that the all the gazetted undesirable substances remain on the list with the exception of ponceau 4R and tartrazine.

Ingredient/Substances	Description
Ponceau 4R	It is used as colorant in pharmaceutical products. It was believed to cause allergic and hyperactivity reactions. Studies have shown that Ponceau 4R have undesirable effects in children less than 12 years old only. Full safety review was done and it **was agreed that the ingredient is safe for use in pharmaceutical preparations for people older than 12 years.** It was recommended that Ponceau 4R be removed from the list of undesirable substances since current information indicates that it's safe for use in adult preparations and is approved for use in medicines by several countries
Tartrazine	It was believed to cause hypersensitivity reactions. Full safety review was done and it was agreed that in line with the current safety information the **ingredient is safe for use in medicines with the Average Daily Intake (ADI) of up to 7.5 mg/kg and the labelling should declare the presence of Tartrazine** in the formulation in line with the recommendations from other regulatory agencies. It is approved for use in medicines by several countries.



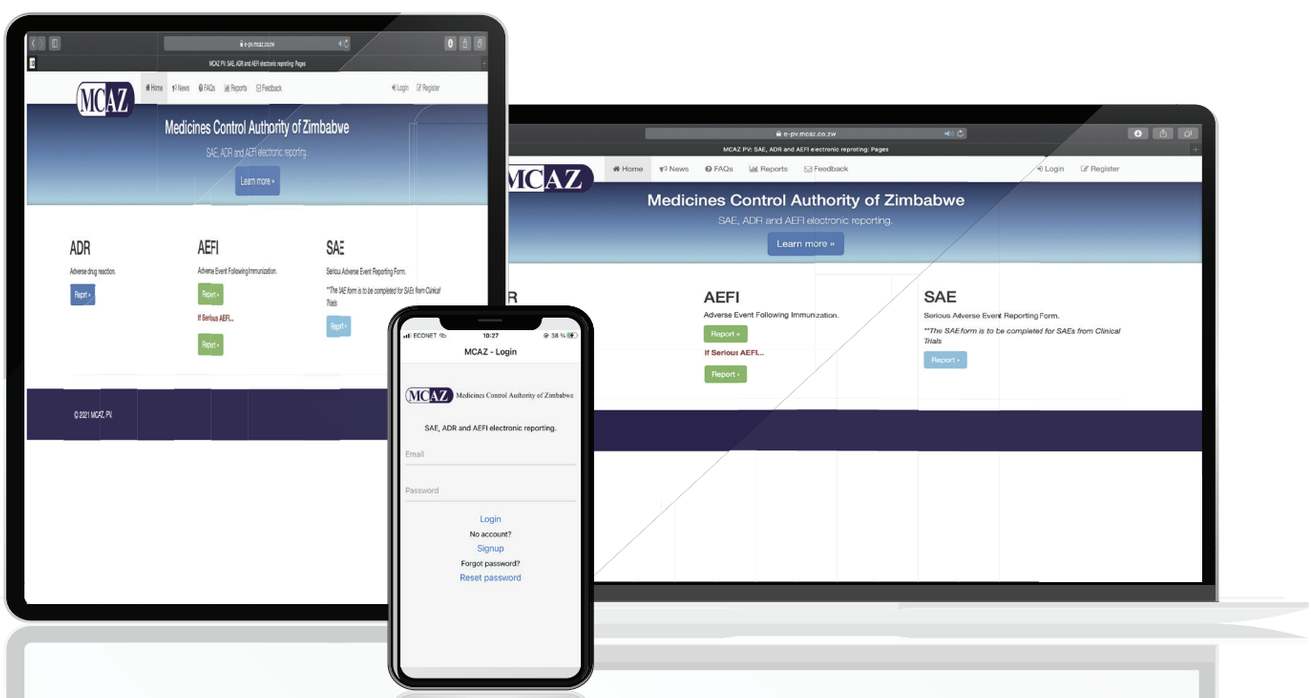
Pharmacovigilance ReCORE Update

MCAZ was designated a Regional Centre of Regulatory Excellence (ReCORE) for product registration, clinical trial oversight and quality control. Through its role as the National Pharmacovigilance Centre, the Pharmacovigilance and Clinical Trials Division in conjunction with the Paul Ehrlich Institute Global Health Protection Programme (GHPP) VaccTrain Project conducted virtual ReCORE trainings on Pharmacovigilance and Clinical Trials oversight on the 1st – 5th of March and 3rd – 6th of May 2021 respectively. The trained participants were from Gambia, Liberia and Sierra Leone.

For more information, visit:

- https://ghpp.de/en/projects/regtrain-vacctrain/south-south-knowledge-transfer-regulators-from-zimbabwe-ghana-and-vacctrain-train-west-african-colleagues-in-pharmacovigilance/
- https://www.nepad.org/countries/zimbabwe - See under - African Medicines Regulatory Harmonisation (AMRH)

Electronic ADR Reporting



The Medicines Control Authority of Zimbabwe (MCAZ) with support from the Global Fund and in partnership with United Nations Development Programme (UNDP) developed* an electronic platform for reporting adverse drug reactions (ADR) or side effects, with both online and offline reporting capabilities. This gives healthcare providers and patients a number of reporting options that would allow the Authority to continuously monitor medicines safety. The available options are listed below:

Web-based platform

- For healthcare professional reporting

https://e-pv.mcaz.co.zw

For patient/consumer reporting

- The link for use by patients/consumers who intend to report any adverse reactions

https://www.mcaz.co.zw/index.php/online-services/pv-reporting/e-reporting

NOTE

Developed by IntelliSoft Consulting Ltd Kenya

Electronic ADR Reporting

Mobile apps for e-pv system

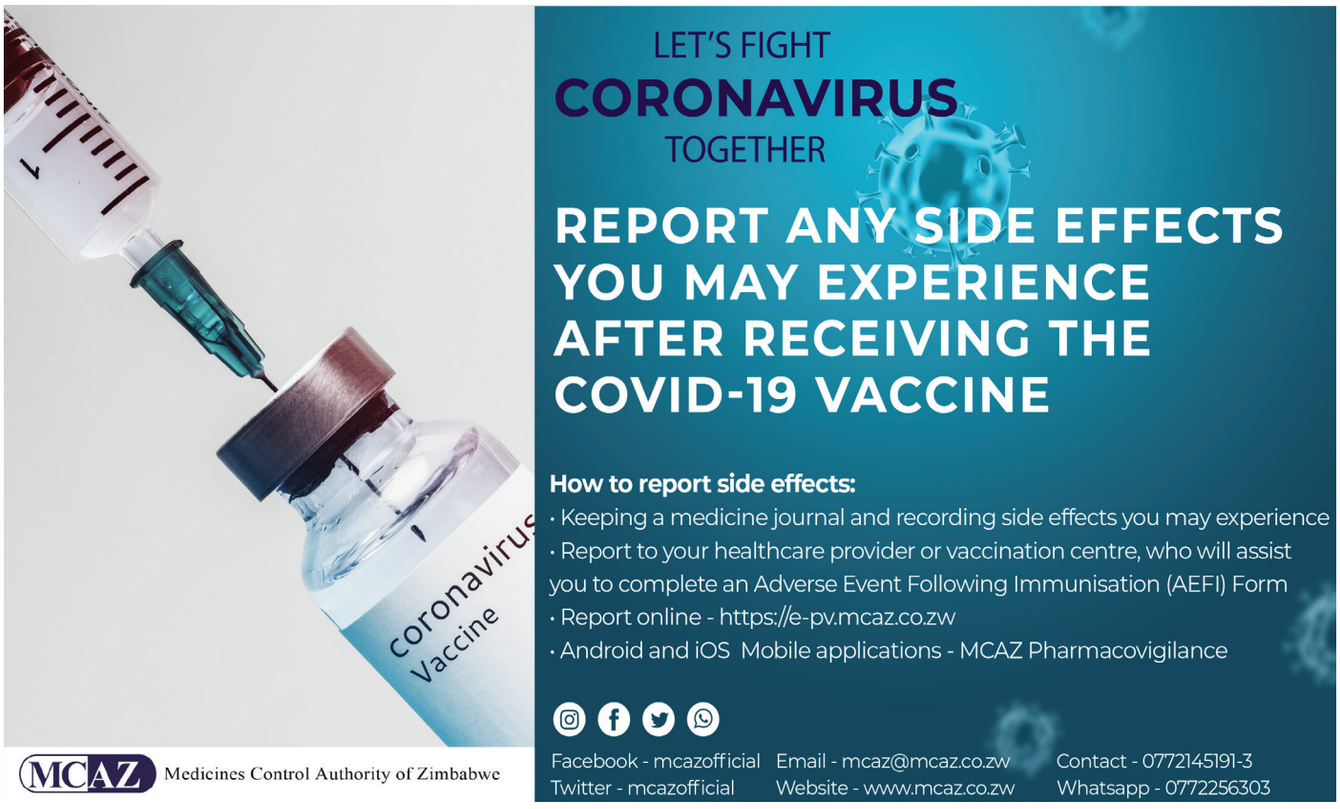
Mobile phone applications are available for two major operating systems listed below.

- Android – search "**MCAZ Pharmacovigilance**" on the Google Play Store
- iOs (iPhone and iPad) – search "**MCAZ Pharmacovigilance**" on the Apple App Store

Desktop apps

Desktop applications for three major operating systems listed below can be downloaded from the MCAZ website.

- Windows desktop application
- MacOs desktop application (MacBook)
- Linux based operating systems



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