



SAFETY ALERT

DRAP SAFETY ALERT NO. 12

SAFETY ALERT OF FALSIFIED MEDICAL PRODUCTS, INCLUDING IN VITRO DIAGNOSTICS, THAT CLAIM TO PREVENT, DETECT, TREAT OR CURE COVID-19.

Date: 14th April, 2020

Target Audience:

- Healthcare Professionals.
- Patients, consumers or caregivers.
- Hospitals.
- Laboratories.

Problem or Issue:

World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified Medical Products through a Medical Product Alert No.3 /2020 have warned against a growing number of falsified medical products that claim to prevent, detect, treat or cure COVID-19. WHO informed that Coronavirus disease (COVID-19) pandemic (caused by the virus SARS-CoV-2) has increased demand for medicines, vaccines, diagnostics and reagents, all related to COVID-19, creating an opportunity for ill-intended persons to distribute falsified medical products.

Medical Product Affected:

1. Falsified In-Vitro Diagnostics and Laboratory Reagents:-

WHO informed that they have received multiple reports regarding falsified in vitro diagnostics (IVDs) and laboratory reagents for the detection of SARS-CoV-2. In this regard, they referred to WHO's Emergency Use Listing (https://www.who.int/diagnostics_laboratory/EUL/en/) for a list of diagnostics approved for clinical use by WHO, where eight countries (Australia, Brazil, Canada, PR China, Russian Federation, Singapore, Republic of Korea, United States of America) have listed IVDs for COVID-19 diagnosis based on expedited regulatory assessments; whereas, in the European Union, regulatory compliance for SARS-CoV-2 diagnostics are self-declared by the manufacturers. Further, it was informed that WHO has published the links to these emergency lists (https://www.who.int/diagnostics_laboratory/EUL/en/), together with contact details. These links (https://www.who.int/diagnostics_laboratory/EUL/en/) provide information on IVDs authorized for use in the jurisdictions of the International Medical Device Regulators Forum. The WHO encouraged end-users to check the labelling against the information posted by regulatory authorities upon listing to ensure they are in possession of the genuine product, which might include product name, product code, expiry date, instructions for use and manufacturer details.





2. Falsified Medicines and Vaccines:-

Furthermore, WHO also informed about Falsified Medicines and Vaccines that might be claimed for the treatment of COVID-19. It was informed that, at this stage, the WHO does not recommend any medicines to treat or cure COVID-19. However, the SOLIDARITY trial, led by WHO, is reviewing potential treatments for COVID-19. Further, it was also informed that there is no vaccine to prevent COVID-19. Products claiming to be vaccines to prevent COVID-19 may be considered falsified and may pose significant risks to public health. WHO informed that they are aware of unregulated websites supplying/selling medicines and/or vaccines for the treatment or prevention of COVID-19, particularly those concealing their physical address or landline telephone number, are frequently the source of unlicensed, substandard and falsified medical products. Such products are likely to be falsified medicines. In addition, some websites may appear to provide easy access to legitimate medicines that are otherwise not readily available. WHO informed that end-buyers and consumers should be especially wary of such online frauds and exert due-diligence when purchasing any medical product, whether online or not.

[FOR FURTHER DETAILS SEE THE ENCLOSURES.](#)



Ref. RPQ/REG/ISF/Alert N°3.2020

31 March 2020

Medical Product Alert N°3/2020

Falsified medical products, including in vitro diagnostics, that claim to prevent, detect, treat or cure COVID-19

This Medical Product Alert warns consumers, healthcare professionals, and health authorities against a growing number of falsified medical products that claim to prevent, detect, treat or cure COVID-19.

The Coronavirus disease (COVID-19) pandemic (caused by the virus SARS-CoV-2) has increased demand for medicines, vaccines, diagnostics and reagents, all related to COVID-19, creating an opportunity for ill-intended persons to distribute falsified medical products

Due diligence is required from all actors in the procurement, use and administration of medical products, in particular those affected by the current crisis of, or related to, COVID-19.

1. FALSIFIED IN VITRO DIAGNOSTICS AND LABORATORY REAGENTS

WHO has received multiple reports regarding falsified in vitro diagnostics (IVDs) and laboratory reagents for the detection of SARS-CoV-2. Please refer to [WHO's Emergency Use Listing](#) for a list of diagnostics approved for clinical use by WHO. To date, eight countries (Australia, Brazil, Canada, PR China, Russian Federation, Singapore, Republic of Korea, United States of America) have listed IVDs for COVID-19 diagnosis based on expedited regulatory assessments. Please note that, in the European Union, regulatory compliance for SARS-CoV-2 diagnostics are self-declared by the manufacturer.

To assist Member States and stakeholders, WHO has published the [links to these emergency lists](#), together with contact details. These [links](#) provide information on IVDs authorized for use in the jurisdictions of the International Medical Device Regulators Forum, as well as policies and guidance. WHO will provide updated versions as new information becomes available.

End-users are encouraged to check the labelling against the information posted by regulatory authorities upon listing to ensure they are in possession of the genuine product. This information might include product name, product code, expiry date, instructions for use and manufacturer details.

2. FALSIFIED MEDICINES AND VACCINES

At this stage, WHO does not recommend any medicines to treat or cure COVID-19. However, the [SOLIDARITY trial](#), led by WHO, is reviewing potential treatments for COVID-19.

At this stage, there is no vaccine to prevent COVID-19. Products claiming to be vaccines to prevent COVID-19 may be considered falsified and may pose significant risks to public health.

Unregulated websites supplying medicines and/or vaccines, particularly those concealing their physical address or landline telephone number, are frequently the source of unlicensed, substandard and falsified medical products. WHO has been made aware of various unregistered websites claiming that products on sale can treat or prevent COVID-19. Such products are likely to be falsified medicines. In addition, some websites may appear to provide easy access to legitimate medicines that are otherwise not readily

available. End-buyers and consumers should be especially wary of such online frauds and exert due-diligence when purchasing any medical product, whether online or not.

WHO requests increased vigilance from national health authorities, healthcare professionals, members of the public and supply chain stakeholders worldwide to prevent the distribution of these falsified medical products. Increased vigilance should focus on hospitals, clinics, health centres, clinical laboratories, wholesalers, distributors, pharmacies and any other suppliers of medical products. All medical products must be obtained from authentic and reliable sources. Their authenticity and condition of the product should be carefully checked. Consumers are advised to seek advice from a healthcare professional in case of doubt.

National health authorities are requested to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int.

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit: www.who.int/medicines/regulation/ssffc/en/