SAFETY ALERT

DRAP SAFTEY ALERT NO. 10

SAFETY ALERTS OF FALSIFIED ANTIMALARIALS IN WEST AND CENTRAL AFRICA DISPLAYING AN OUTDATED WHO ESSENTIAL DRUGS PROGRAMME LOGO.

Date: 13th March, 2020

Target Audience:

- Healthcare Professionals.
- Patients, consumers or caregivers.

Problem or Issue:

World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified Medical Products through a Medical Product Alert No.1 /2020 have informed about confirmed falsified quinine sulphate 300mg, presented in six different combinations of batch numbers, expiry and manufacturing dates, displaying out-dated WHO Essential Drugs Programme logo are circulating in West and Central Africa.WHO further informed that results of the samples analyzed showed that they do not contain any of the expected active ingredient and at present no adverse drug reaction to these falsified products have been reported to WHO. These entire falsified products claimed to be manufactured by REMEDICA Ltd-Cyprus and to contain 300mg of quinine sulphate; but, Remedica has confirmed that they did not manufacture the above falsified products and the variable data (batch number and dates) on the said product has never been used by Remedica.

Therapeutic Goods Affected:

Name: **Falsified Quinine Sulphate 300mg claim to be manufactured by REMEDICA LTD-Cyprus of the following specification:**

Identified In Country	Batch Number	Date of Manufacture	Expiry Date	Analysis Results
CHAD	44680	10/2018	10/2023	No quinine identified; Traces of chloroquine
CHAD	44680	04/2017	04/2021	No quinine identified; Traces of chloroquine
CHAD	44680	03/2015	03/2018	No samples available; No analysis conducted
CAMEROON	44680	09/2017	10/2020	No quinine identified
NIGERIA	44680	04/2017	04/2021	No quinine identified
NIGERIA	44680	09/2017	10/2020	No quinine identified

Advice for Patient, Healthcare Professionals and Other Stakeholders:-

Those patients, who are using any of above falsified product, should immediately stop it. If the patient has taken any of these falsified medical products, and has suffer an adverse event, should immediately seek the advice from a qualified healthcare professional, and ensure that they report the incident to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan. All drugs must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Healthcare professionals are requested to ensure that necessary information related to the above products are reported to them by the patient and is subsequently reported to the Pakistan National pharmacovigilance Centre, DRAP, Islamabad. Other concerned stakeholders are requested to take further necessary action on their part.

Both healthcare professionals and patients are requested to report any suspected adverse drug reactions to **Pakistan National Pharmacovigilance Centre,** Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance e-reporting system** http//: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK or at npc@dra.gov.pk.

For further details see the enclosures.

World Health Organization

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Ref. RPQ/REG/ISF/Alert N°1.2020 09 March 2020

Medical Product Alert N°1/2020
Falsified antimalarials in West and Central Africa displaying an outdated WHO Essential Drugs Programme logo

This Medical Product Alert relates to a series of confirmed falsified antimalarials circulating in West and Central Africa. Medicines subject of this alert display a similar logo to the outdated WHO Essential Drugs Programme logo.

Since 2013, different falsified medicines, all displaying the outdated WHO Essential Drugs Programme logo, have been reported to the WHO Global Surveillance and Monitoring System by various stakeholders. The continued and widespread availability of these falsified medicines highlights a strong need for additional vigilance. WHO previously published two alerts on this issue (No.132 in Oct 2014, and No.131 in March 2014).

This WHO medical product alert N°1/2020 refers to falsified Quinine Sulphate 300mg presented in six different combinations of batch numbers, expiry and manufacturing dates (see Table 1). The fraudulent use of the outdated WHO Essential Drugs Programme logo may create a false sense of product quality.

Table 1: List of identified falsified Quinine Sulphate 300mg, subject of WHO Alert N°1/2020

IDENTIFIED IN:	BATCH NUMBER	DATE OF MANUFACTURE	EXPIRY DATE	ANALYSIS RESULTS
CHAD	44680	10/2018	10/2023	No quinine identified; Traces of chloroquine
CHAD	44680	04/2017	04/2021	No quinine identified; Traces of chloroquine
CHAD	44680	03/2015	03/2018	No samples available; No analysis conducted
CAMEROON	44680	09/2017	10/2020	No quinine identified
NIGERIA	44680	04/2017	04/2021	No quinine identified
NIGERIA	44680	09/2017	10/2020	No quinine identified

Recently received results of analysed samples show **they do not contain any of the expected active ingredients.**

Quinine sulphate is referenced on the WHO Model List of Essential Medicines, to manage and treat severe malaria. At this stage, no adverse reactions attributed to these falsified products have been reported to WHO.

All the above falsified products claim to be manufactured by REMEDICA LTD - Cyprus and to contain 300mg of quinine sulphate. Remedica Ltd has confirmed that:

- they did not manufacture the above falsified products; and
- the variable data (batch number and dates) on the above products has never been used by Remedica.

These falsified medicines display the following common characteristics (please see photographs):

- grey or white plastic containers which contain 1000 loose circular tablets each;
- display the outdated WHO Essential Drugs Programme logo;
- English and French labelling with mistakes and inconsistencies; and
- discovered at patient level in both regulated and unregulated outlets.

Product details, photographs and advice to the public are available on the following pages.

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Outdated WHO Essential Drugs Programme logo

Photographs of confirmed falsified Quinine Sulphate 300mg tablets subject of Medical Product Alert N°1/2020

1. **Falsified Quinine Sulphate Tablets B.P 300mg identified in Chad (Batch 44680)**

2. **Falsified Quinine Sulphate Tablets B.P 300mg identified in Nigeria and Cameroon (Batch 44680)**

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

If you are in possession of the above products, please do not use. If you have used these falsified products, or if you suffer an adverse event having used these products, please seek immediate advice from a qualified healthcare professional, and ensure they report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

National health authorities are asked 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 further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/