GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN,
TILAK MARG, JAIPUR

No. DC/D-1/2014/ Dated:-

All Asstt. Drugs Controller's, Rajasthan State.
All Drugs Control Officer's, Rajasthan State.

Sub:- 1. Falsified Antimalarial medicines in West and Central Africa.
2. Strict implementation of provision of Drugs and Cosmetics Rules in respect of manufacture and sale of Oxytocin, which is reported to be used clandestinely by dairy owners for mulching milk animals-reg.

Ref:- Drugs Controller General (India) letter No. 7-5/2014/IM/028 dt. 13.05.2014 & 18-4/2014-DC dt. 09.05.2014

Reference to subject cited above, Photocopies of letter with enclosures received from Drugs Controller General (I), New Delhi by referred letter is hereby enclosed.

You are directed to keep vigilance in your area.

Encl.:- As above.

Sd
(Ashok Bhandari)
Drugs Controller
Rajasthan, Jaipur

No. DC/D-1/2014/308 Dated:-09/06/2014

Copy to:- 1. Drugs Controller General (I) FDA Bhawan , Kotla Road, New Delhi in reference of letter No. 7-5/2014/IM/028 dt. 13.05.2014 & 18-4/2014-DC dt. 09.05.2014 for information.

2. Incharge Server room with request to upload this letter & enclosures on Deptt. Website.

Sd
(Ashok Bhandari)
Drugs Controller
Rajasthan, Jaipur

कार्यालय
औषधि नियंत्रक (राज.) जयपुर
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26 MAY 2014
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क्रमांक

F. No. 7-5/2014/IM/028
Directorate General of Health Services
Drugs Controller General (India)
(International Cell)

Date: 13 MAY 2014

To,
All State/UTs Drugs Controller

Subject: **Falsified Antimalarial medicines in west and central Africa – Regarding.**

Dear Sir

This is in reference to a letter from World Health Organization No. WR/D.7 received vide FTS No. 22791/DCGI/2014 dated 09.04.2014 (Copy Enclosed) wherein they have informed about various cases of falsified antimalarial medicines discovered in Cameroon, Ghana and Liberia.

None of the medicines were manufactured by the companies named on the labels. Two of the medicines contain less than 2% of the Active Pharmaceutical Ingredient and analysis is awaited concerning the third sample. All three products are contained in tubs of 1000 tablets designed for hospitals and clinics. They also show a previous WHO Essential drugs Programme Logo.

All of these products have been intentionally falsified and are circulating within the formal and informal supply chains. Details on the falsified medicinal products are as follows:

Case No.	Manufacturer Details	Product Details	Remarks
01	CAMEROON: Sulfadoxime/Pyrimethamine BP Manufacturer: Rivopharm Laboratories	Product Name: Sulfadoxime/Pyrimethamine BP Dosage: 500 mg + 25 mg Batch Number: 1833 Expiry Date: 02/2014 Manufacturing Date: 02/2011	Lab testing revealed less than 2% of the API. WHO issued warning to African Regulatory Authorities requesting them to increase vigilance. The firm confirmed that no batch of this product had been manufactured for 15 years.
02	Ghana: Quinine Sulphate Manufacturer: Biochemie GmnH	Product Name: Quinine Sulphate Dosage: 300 mg Batch Number: 33587 Q Expiry Date: 05/2015 Manufacturing Date: 05/2012	Lab testing revealed very small traces of the API. Following analysis Ghana Food and Drugs Authority issued an alert and recalled the product from the market. It has been established that Biochemie no longer exists under this name.
03	Liberia: Quinine Sulphate Manufacturer: Weiders Farmasotiske	Product Name: Quinine Sulphate 300 mg USP Dosage: 300 mg Batch Number: 4400Q1 Expiry Date: 04/15 and 09/16 Manufacturing Date: 04/11 and 09/13	Lab results are awaited but enquiry from Weiders Farmasotiske confirms that they did not manufacture these products.

Hence, you are requested to increase vigilance within the supply chains for these specific batches in public interest.

Yours Faithfully

(Dr. G.N. Singh)
Drugs Controller General (I)

World Health Organization
COUNTRY OFFICE FOR India

Reference: WR/D.7

Mr R. K. Jain
Additional Secretary & DG (CGHS)
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110011

28 March 2014

Dear Mr Jain,

Subject: Falsified antimalarial medicines in west and central Africa

This is to bring to your kind notice that three separate falsified antimalarial medicines were discovered in Cameroon, Ghana and Liberia.

Manufacturer details	Product details
CAMEROON: Sulfadoxine/Pyrimethamine BP Manufacturer: Rivopharm Laboratories	Product name: Sulfadoxine/Pyrimethamine BP Dosage: 500mg + 25mg Batch number: 1833 Expiry date: 02/2014 Manufacturing date: 02/2011
GHANA: Quinine Sulphate Manufacturer: Biochemie GmnH	Product name: Quinine Sulphate 300mg B.P. Dosage: 300mg Batch number: 33587Q Expiry date: 05/15 Manufacturing date: 05/12
LIBERIA: Quinine Sulphate Manufacturer: Weiders Farmasotiske	Product name: Quinine Sulphate 300mg USP Dosage: 300mg Batch number: 4400Q1 Expiry dates: 04/15 and 09/16 Manufacturing dates: 04/11 and 09/13

None of the medicines were manufactured by the companies named on the labels. Two of the medicines contain less than 2% of the active pharmaceutical ingredient and analysis is awaited concerning the third. All three products are contained in tubs of 1000 tablets designed for hospitals and clinics. They also show a previous WHO Essential Drugs Programme logo (no longer in use by WHO). *Please see photographs in annex document.*

All of these products have been intentionally falsified and are circulating within the formal and informal supply chains. National regulatory authorities are requested to increase vigilance within the supply chains for these specific batches.

The Drug Alert Notification with batch details and photographs are enclosed for your reference.

Thank you and best regards,

Yours sincerely,

Dr Nata Menabde
WHO Representative to India

Encl: As stated above

cc: Dr Arun Kumar Panda, Joint Secretary, MoH&FW, Nirman Bhawan, New Delhi-110011
Mr Shailendra Kumar, Director (Drugs), MoH&FW, Nirman Bhawan, New Delhi-110011
Mr Amal Pusp, Director (IH), MoH&FW, Nirman Bhawan, New Delhi-110011
Dr G.N. Singh, Drugs Controller General of India, FDA Bhawan, Kotla Road, New Delhi-110002

532, A - Wing, Nirman Bhawan, Maulana Azad Road, New Delhi 110 011 | Tel: 91-11- 66564800 | Fax: 91-11-23062450; 26162996
www.searo.who.int/India

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Ref. RHT/SAV/MD/IEA.131

25 March 2014

Information Exchange System

Drug Alert No. 131

Falsified antimalarial medicines in west and central Africa

BACKGROUND

This drug alert concerns three separate falsified antimalarial medicines discovered in Cameroon, Ghana and Liberia.

None of the medicines were manufactured by the companies named on the labels. Two of the medicines contain less than 2% of the active pharmaceutical ingredient and analysis is awaited concerning the third.

- All three products are contained in tubs of 1000 tablets designed for hospitals and clinics.
- The labelling on all three products is in English and French and contains spelling mistakes. They also show a previous WHO Essential Drugs Programme logo (no longer in use by WHO). *Please see photographs in annex.*

These products have been intentionally falsified.

Details on the falsified products and advice can be found on the following pages. Photographs of each product are compiled in the annex to this drug alert.

FALSIFIED MEDICAL PRODUCTS DETAILS

CAMEROON: Sulfadoxine/Pyrimethamine BP

In June 2013, a nongovernmental organization active in Cameroon discovered, at a wholesalers, the following medicine which later proved to be falsified:

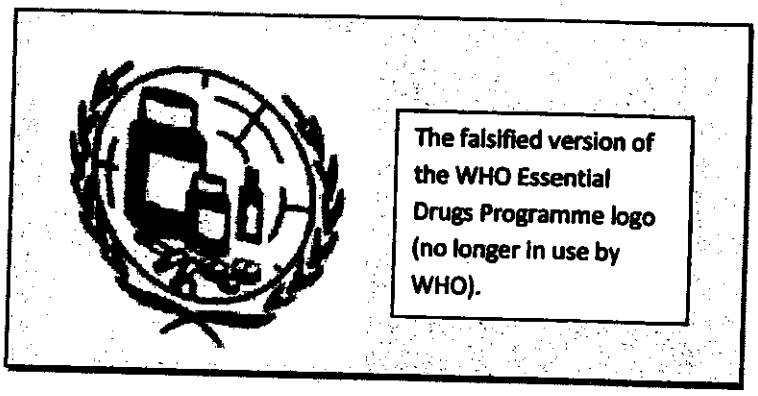
- ***Product name:*** Sulfadoxine/Pyrimethamine BP
- ***Manufacturer:*** Rivopharm Laboratories
- ***Dosage:*** 500mg + 25mg
- ***Batch number:*** 1833
- ***Expiry date:*** 02/2014
- ***Manufacturing date:*** 02/2011

Following laboratory testing which revealed less than 2% of the active pharmaceutical ingredients, WHO issued a warning to African regulatory authorities requesting increased vigilance for this batch. Rivopharm Laboratories have confirmed they have not manufactured this product for 15 years. *Please see photograph in Annex.*

ANNEX TO DRUG ALERT NR. 131

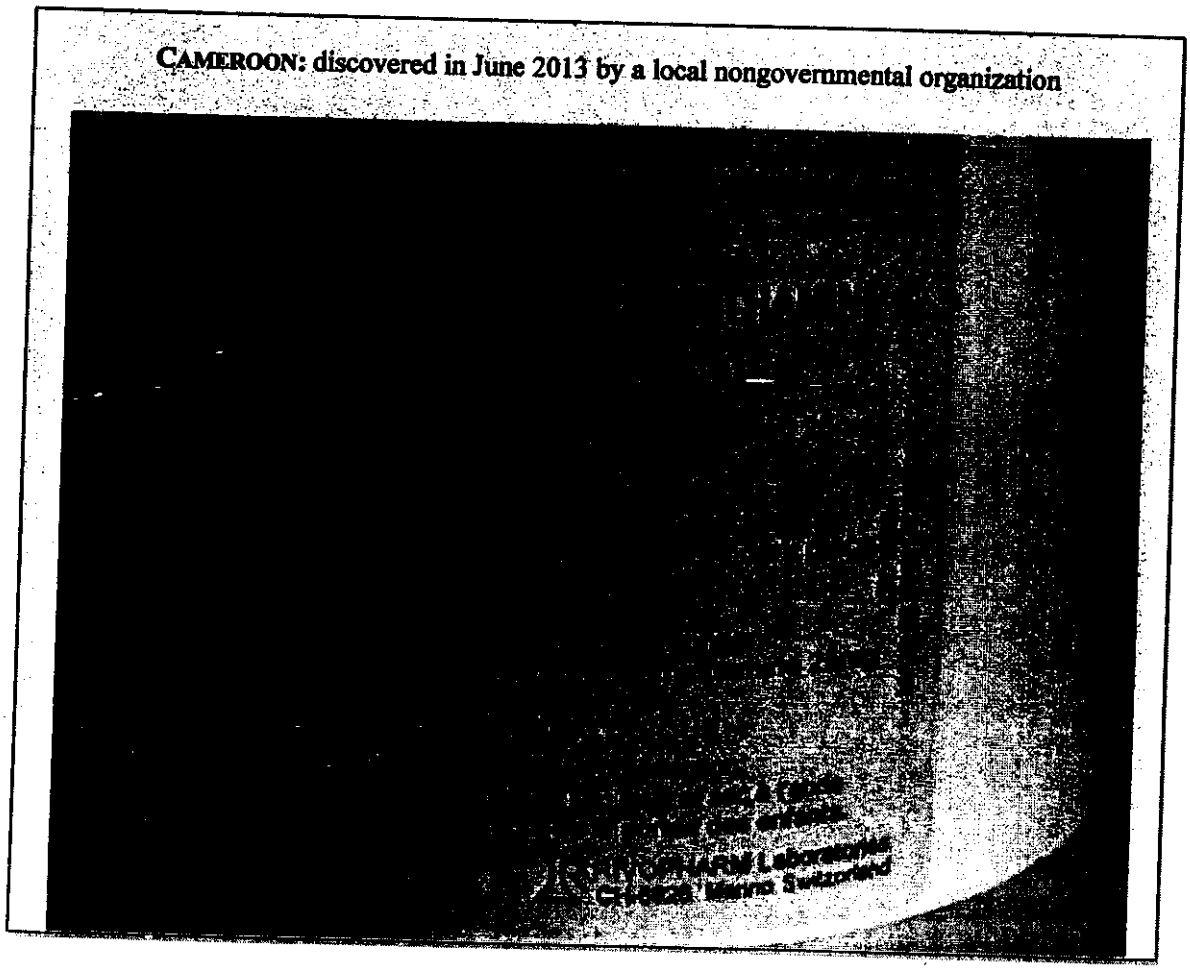
FOUR PHOTOGRAPHS OF FALSIFIED ANTIMALARIAL PRODUCTS

Discovered in west and central Africa between June 2013 and March 2014



The falsified version of the WHO Essential Drugs Programme logo (no longer in use by WHO).

CAMEROON: discovered in June 2013 by a local nongovernmental organization



(Dr. G. N. Singh)
DRUGS CONTROLLER GENERAL (INDIA)

Central Drugs Standard Control Organization
Directorate General of Health Services
Tele – 011-23236965
Fax - 011 -23236973
Email :- dci@nic.in
Web : WWW.cdsco.nic.in
FDA Bhawan, Kotla Road, New Delhi –110002.

F.No. 18-4/2014-DC
Dated the, 09th May, 2014

To,

All State Drug Controllers

Subject: Strict Implementation of provision of Drugs and Cosmetics Rules in respect of manufacture and sale of Oxytocin, which is reported to be used clandestinely by dairy owners for mulching milk animals – reg.

Sir,

The continued misuse of oxytocin injections by the dairy owners for extracting milk from milch animals and its harmful effects on the health of cows and buffaloes as well as on the consumers has been raised from time to time by Smt. Maneka Sanjay Gandhi, Hon'ble Member of Parliament, Lok Sabha. She has expressed concern that misuse of oxytocin is leading to a substantial loss of livestock in the country. Not only does this drug made cows barren sooner, but also lowers the life span of the animal, thus causing economic loss to the owner in the long run. It is being widely used in the dairy industry despite there being a ban on its sale, except by a prescription from a registered medical practitioner.

The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity. The alleged abundant availability and use of the drug in a clandestine way for mulching animals is however, a matter of great concern for public health. It has been reported that dairy owners use this drug on milch animals twice or more every day for extracting milk regardless to the facts that the drug may cause harm to the animal.

Under the Drugs and Cosmetics Rules, 1945 the drug oxytocin is covered under Schedule H and is required to be dispensed on the prescription of a Registered Medical Practitioner only. Further, oxytocin injection is required to be packed in single unit blister pack only.

The manufacture and sale of the drug with or without a licence for such clandestine activity is an offence under the Drugs and Cosmetics Act, 1940. There are strict provisions now available for taking action against such illegal activity. However, to curb this clandestine

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manufacture and sale of the drug to the farmers or dairy owner require constant surveillance and interstate coordination.

On the basis of recommendations of the Drugs Technical Advisory Board in its 65th meeting of the held on 25th November, 2013, the Ministry of Health and Family Welfare issued a notification G.S.R 29(E) dated 17.01.2014 under Section 26A of the Drugs and Cosmetics Act, 1940 further restricting the manufacture and sale of oxytocin as under:

1. The manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.
2. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

The matter was again considered by the DTAB in its 67th meeting held on 1st April, 2014 and the Board opined that misuse of the drug for milking purposes is a matter of serious concern and is required to be stopped for the health of life stock. One of the recommendation made by DTAB was that the misuse can be contained only by enhanced surveillance by the regulatory authorities followed by strict action against the violators. The public at large is also required to be sensitized. Campaigns could be launched by the public spirited organizations in the areas prone to such misuse through print and audio visual media to educate the public about the harmful effects of misuse of Oxytocin. The help of the local police could also be enlisted to book cases under Prevention of Cruelty to Animals Act, 1960, the Drugs and Cosmetics Act, 1940 which does not permit the sale of the drug except under proper prescription.

It is however, observed that inspite of the various provisions made under the law to check the misuse of oxytocin, the drug is stated to be available clandestinely at cheap rate to the dairy owners.

You are therefore requested to ensure strict implementation of the provisions of the Drugs and Cosmetics Rules in respect of manufacture and sale of oxytocin so as to ensure that the drug is not diverted through illegal channels to the dairy owners. The Drugs Inspectors under your jurisdiction may be asked to increase focused surveillance especially in the areas where such illegal manufacture or sale or misuse is suspected and take strict action against the culprits apprehended in this regard.

Action taken in the matter may kindly be intimated to the office of DCG(I).

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy forwarded for information to the zonal and sub-zonal offices.