

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.*

GHANA: Quinine Sulphate

In August 2013, the Food and Drugs Authority of Ghana discovered, in a hospital, the following medicine which later proved to be falsified:

- **Product name:** Quinine Sulphate 300mg B.P.
- **Manufacturer:** Biochemie GmnH
- **Dosage:** 300mg
- **Batch number:** 33587Q
- **Expiry date:** 05/15
- **Manufacturing date:** 05/12

Laboratory testing has revealed very small traces of the active pharmaceutical ingredient. Following analysis the 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.

Please see photograph in Annex.

LIBERIA: Quinine Sulphate

In March 2014, the Liberian Medicines and Health Products Regulatory Authority reported to WHO that they had discovered the following two batches of suspected falsified medicines bearing the same batch number:

- **Product name:** Quinine Sulphate 300mg USP
- **Manufacturer:** Weiders Farmasotiske
- **Dosage:** 300mg
- **Batch number:** 4400Q1
- **Expiry dates:** 04/15 and 09/16
- **Manufacturing dates:** 04/11 and 09/13

Laboratory results are awaited, but enquiries with Weiders' parent company confirm that they did not manufacture these products.

Please see photograph in Annex.

SUMMARY

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. In addition, vigilance is requested for any medicines bearing the previous WHO Essential Drugs Programme logo (no longer in use by WHO). If discovered, steps should be taken to ensure that they meet full specifications.

If you have any information or discover any of these products or medicines bearing the previous WHO Essential Drugs Programme logo please contact rapidalert@who.int.

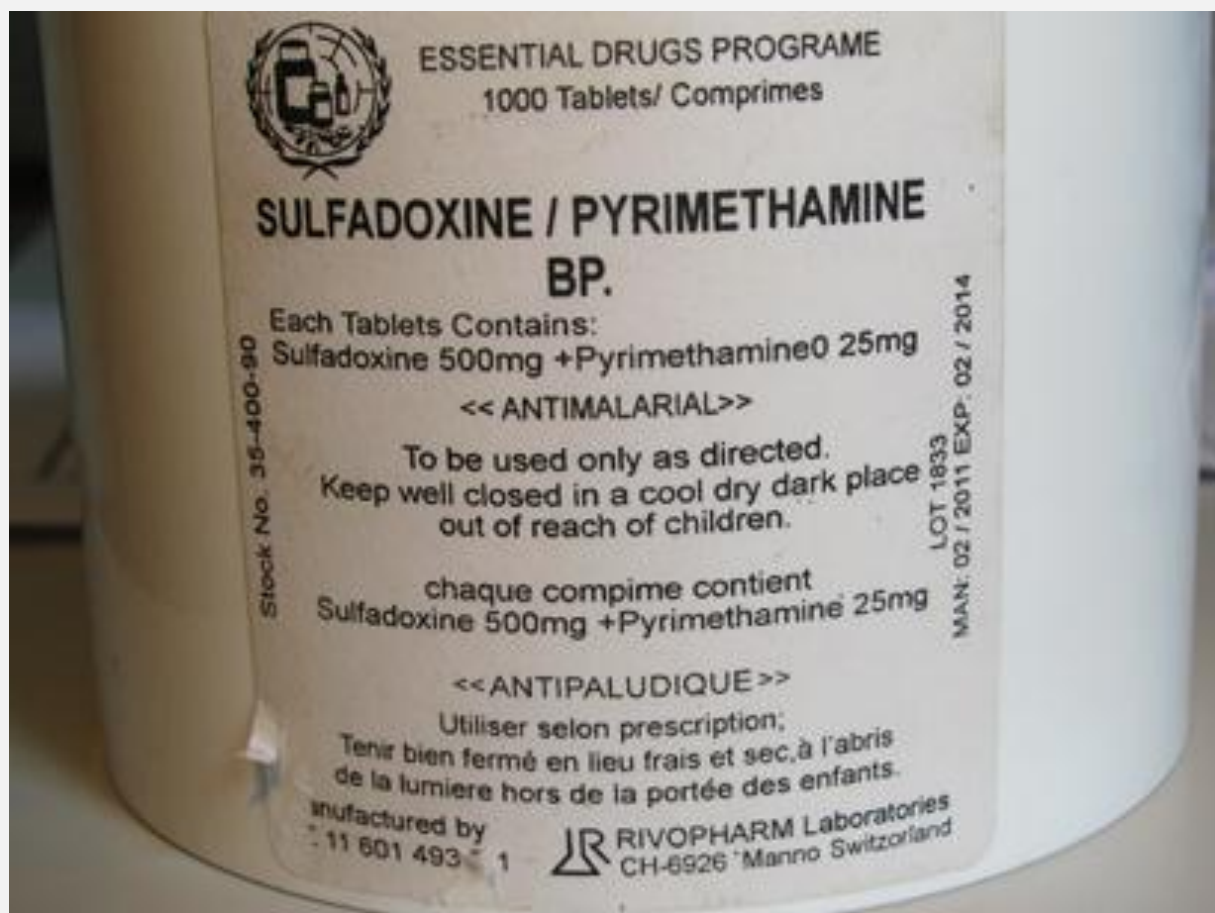
ANNEX TO DRUG ALERT NR. 131

FOUR PHOTOGRAPHS OF FALSIFIED ANTIMALARIAL PRODUCTS

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



CAMEROON: discovered in June 2013 by a local nongovernmental organization



GHANA: discovered in August 2013 by the Food and Drugs Authority of Ghana



LIBERIA: discovered in March 2014 by the Liberian Medicines and Health Products Regulatory Authority

