

Ref. RHT/SAV/MD/IEA.132

10 October 2014

Information Exchange System – Drug Alert No. 132 Falsified Medicines West and Central Africa

BACKGROUND

This Drug alert is in follow up to Drug Alert 131 regarding falsified antimalarial products in circulation in West and Central Africa. Six (6) new falsified medical products (antimalarials and antibiotic) have been discovered in Niger in September 2014.

- All products are found in containers of 1000 tablets designed for hospitals and clinics.
- The labelling on the products is in English and French.
- They also show a previous WHO Essential Drugs Programme logo (no longer in use by WHO). *Please see available photographs in annex.*

These products have been intentionally falsified.

None of the manufacturers indicated on the labels have manufactured these products and they have all been informed of this incident.

Details on the falsified products and advice can be found on the following pages. Available photographs for four (4) products are compiled in the annex to this drug alert.

DETAILS OF THE FALSIFIED MEDICAL PRODUCTS

At this stage the following lots (in addition to those indicated in Alert 131) have been identified and confirmed as falsified.

| Product name | Label Claim Manufacturer | Batch number | Manufacturing Date | Expiry date |
|-------------------------------|-----------------------------|-----------------|-----------------------|----------------|
| Amoxycillin B.P 250 mg | Weiders Farmasøytiske | 53611 | Mar-12 | Mar-15 |
| Quinine sulphate 300 mg B.P | Remedica Ltd | 38763 | Oct-12 | Oct-15 |
| Quinine sulphate 300 mg B.P | Remedica Ltd | 44675 | Sep-13 | Sep-16 |
| Quinine sulphate 300 mg B.P | Weiders Farmasøytiske | 9765 | Mar-14 | Mar-17 |
| Quinine sulphate 300 mg U.S.P | Weiders Farmasøytiske | 4400Q12 | Apr-12 | Apr-15 |
| Sulfadoxine + pyrimethamine | Rivopharm | 2869 SP | Feb-14 | Feb-16 |

Samples of the above products are awaited for full laboratory testing but it should be noted that for Quinine Sulphate., batch number 4400Q12 was already highlighted in International Drug Alert N°131. This product contained almost no Active Ingredient. Further details are available at: http://www.who.int/medicines/publications/drugalerts/Alert_131_antimalarials_essential_drugs_programme_pre_final.pdf?ua=1 . In addition, it may happen that falsified products with different batch numbers than those listed here are in circulation.

SUMMARY AND ADVICE FOR ACTION

All of the above products have been intentionally falsified and have been found in pharmacies of public health facilities but were all purchased from private wholesalers. **National regulatory authorities are requested to increase vigilance within the supply chains for products with similar labelling and especially regarding the specific batches listed. In addition, more general 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 share rapidly information about these finding with other regulators in the region. In addition, quality control testing of these medicines should be carried out.

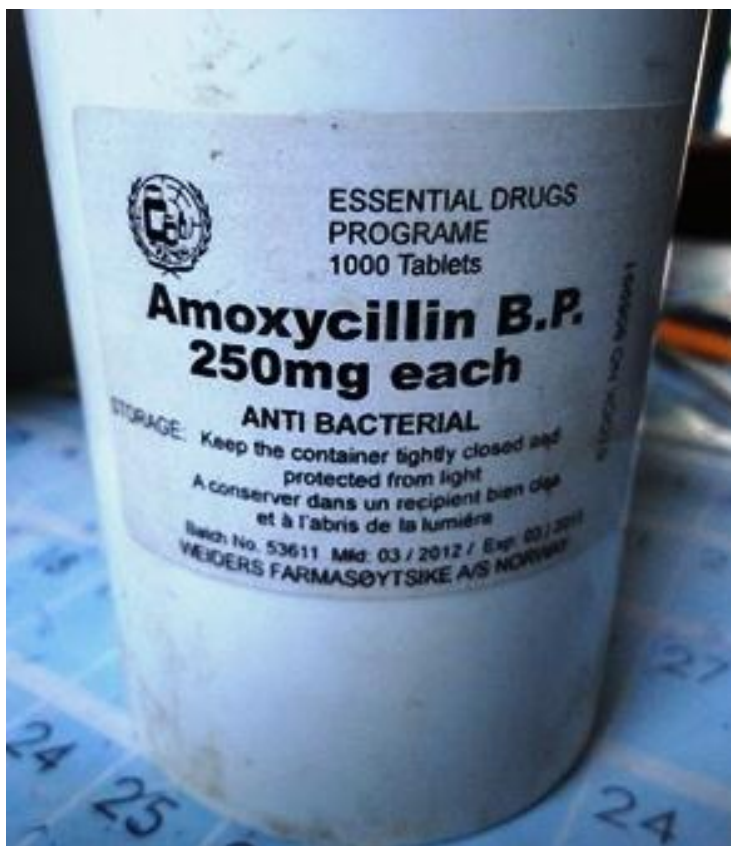
If you have any information or discover any of these products or medicines bearing the previous WHO Essential Drugs Programme logo please contact rapidalert@who.int.

Annex with photographs on next pages

ANNEX TO DRUG ALERT N° 132

Photographs of falsified products discovered in Niger in September 2014

❖ **Amoxicillin B.P 250 mg (Weiders ; BN 53611)**



❖ **Quinine sulphate 300 mg B.P (Remedica ; BN 44675)**



❖ Quinine sulphate 300 mg B.P (Weiders ; BN 9765)



❖ Sulfadoxine + pyrimethamine (Rivopharm ; BN 2869 SP)

