

The quality of sulphadoxine-pyrimethamine and amodiaquine products in the Kenyan retail sector

Amin, AA; Snow, RW; Kokwaro, G

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Abstract

Background and objectives: Malaria is a disease of major public health importance in Kenya killing 26,000 children under 5 years of age annually. This paper seeks to assess the quality of sulphadoxine-pyrimethamine (SP) and amodiaquine (AQ) products available over-the-counter to communities in Kenya as most malaria fevers are self-medicated using drugs from the informal retail sector. Methods: A retail audit of 880 retail outlets was carried in 2002 in four districts in Kenya, in which antimalarial drug stocks and their primary wholesale sources were noted. In addition, the expiry dates on audited products and the basic storage conditions were recorded on a proforma. The most commonly stocked SP and AQ products were then sampled from the top 10 wholesalers in each district and samples subjected to standard United States Pharmacopoeia (USP) tests of content and dissolution. Result and discussion: SP and AQ were the most frequently stocked antimalarial drugs, accounting for approximately 75% of all the antimalarial drugs stocked in the four districts. Of 116 SP and AQ samples analysed, 47 (40.5%) did not meet the USP specifications for content and/or dissolution. Overall, approximately 45.3% of SP and 33.0% of AQ samples were found to be sub-standard. Of the sub-standard SP products, 55.2% were suspensions while 61.1% of the substandard AQ products were tablets. Most SP failures were because of the pyrimethamine component. Conclusion: There is a need to strengthen post-marketing surveillance systems to protect patients from being treated with sub-standard and counterfeit antimalarial drugs in Kenya