PHARMACOVIGILANCE - FDIC NEWS

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This issue of the newsletter focuses on the reported adverse drug reactions (ADRs) attributable to ACT Antimalarials medicines as received by National Pharmacovigilance Centre (NPC), through spontaneous reporting system across the country as at October 2011. Other features in this edition include compilation of adverse drug reaction reports of interest as reported in "Reaction Weekly'',

Your comments and acknowledgement of receipt of this issue through our email would be most appreciated.

PHARMACOVIGILANCE OF ACT ANTIMALARIAS

Treatments containing an artemisinin derivative (artemisinin-combination therapies, ACTs) are now standard treatment worldwide for falciparum malaria. The starting compound artemisinin is isolated from the plant **Artemisinin** , also known as **Qinghaosu** , and its derivatives are a group of drugs that possess the most rapid action of all current drugs against falciparum malaria.[1] The World Health Organisation has recommended that artemisinin combination therapies (ACT) be first-line therapy for *P. falciparum* malaria worldwide. Combinations are effective because the artemisinin component kills

the majority of parasites at the start of the treatment while the more slowly eliminated partner drug clears the remaining parasites. WHO currently recommends the following combination therapies (in alphabetical order):

1. artemether/lumefantrine
2. artesunate plus amodiaquine (In areas where the cure rate of amodiaquine monotherapy is greater than 80%)
3. artesunate plus mefloquine (Insufficient safety data to recommend its use in Africa)
4. artesunate plus sulfadoxine/pyrimethamine (In areas where the cure rate of sulfadoxine/pyrimethamine is greater than 80%)

Many African countries have simultaneously adopted artemisinin derivative based combination therapy (ACT) as first-line treatment for uncomplicated malaria, offering an opportunity to assess the safety of these drugs when used widely. However While ACTs appear to be safe and well-tolerated, there is little experience with these medicines in Africa, outside clinical trials hence the essential need for pharmacovigilance of ACT antimalaria medicines. Obtaining information on adverse reaction profile of ACT will be necessary in countries (such asNigeria) where self-treatment with antimalarial drugs is pervasive. This is to ensure that the common and rare adverse drug events to ACT are documented and, also to ensure that patients are getting the desired therapeutic benefits rather than negative consequences on account of such adverse drug effects.

Malaria transmission intensity is high and antimalarial medicines are used frequently . Presumptive treatment of fever with antimalarials is common, often in the absence of a confirmed diagnosis, using drugs obtained without a prescription. Informal use of antimalarial drugs may increase the risk of incorrect dosing, inappropriate treatment, and drug interactions, which may impact negatively on drug safety. Furthermore, the administration of antimalarial treatments in patients with a concomitant illness, including HIV/AIDs, tuberculosis and malnutrition, is a concern.

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