

## Commentary

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# Lapdap<sup>®</sup> – A threat or an opportunity? <sup>1</sup>

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Lapdap<sup>®</sup> is a fixed dose combination (chlorproguanil-dapsone) antimalarial developed specifically for use in sub-Saharan Africa. It was registered for use initially by the Medicines and Healthcare Regulations Agency of the UK and has subsequently been launched in several African countries. Unlike medicines in use in the developed economies of the world where adequate monitoring systems exist, Lapdap<sup>®</sup> is being introduced into countries with poorly developed or non-existent monitoring systems. This may pose a threat to public health, particularly as the contraindication for Glucose-6-Phosphate Dehydrogenase (G6PD) enzyme deficiency, which is prevalent in Africa, is not indicated on the product label for these countries. While the Lapdap<sup>®</sup> situation is worrying, the discussions around Lapdap<sup>®</sup> may present an opportunity for resource-poor countries to develop unique systems for monitoring drugs in use in their settings.

Given that drug development is disease-driven and that some diseases are more prevalent in certain geographic regions than in others, it is imperative to make sure that these regions have the capacity to monitor the safety of drugs that will be specifically introduced for their use. A well-developed adverse drug reaction (ADR) monitoring system, designed to address adverse reactions specific to drug-use in resource poor settings, should be in place even as disease-specific drugs are being introduced into these countries. That alone can ensure the rapid detection of ADR-problems in these settings. Several sub-Saharan African countries have absolutely no drug safety monitoring systems. These countries also have the additional problem of unscrupulous drug promotion, direct to consumer advertising and the presence of sub-standard and counterfeit drugs. There is, therefore, an urgent need to establish pharmacovigilance programmes as well as improve public education in these countries. Each country should examine its own needs and priorities and adopt a system that takes into consideration the existing facilities, personnel and other resources.

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<sup>1</sup>First published in the WHO Pharmaceuticals Newsletter No. 1, 2004. (<http://www.who.int/medicines/library/pnewslet/1news2004.pdf>.)