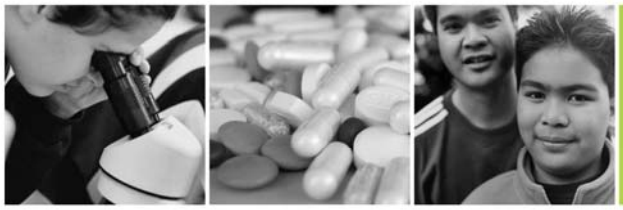

QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME MANAGED BY WHO

World Health Organization

PREQUALIFICATION UPDATE: 12 MARCH 2010

Clarification regarding prequalification status of a Ugandan manufacturer

As indicated by the posting[1] of the WHO Public Inspection Report relating to the manufacture of finished pharmaceutical products by Quality Chemical Industries Ltd (QCIL) of Luzira, Uganda, QCIL was inspected in January 2010 and found to comply with WHO good manufacturing practice (GMP). This does not constitute prequalification by WHO of the products manufactured by QCIL.

The inspection followed the receipt of a variation application from Cipla Ltd, to include QCIL's site at Luzira as an additional manufacturing site for one of its antiretroviral products. This particular product, currently manufactured in India, has already been prequalified by WHO.

Prequalification of a product has two major components: evaluation of a dossier containing product-related information and inspection of the manufacturer for compliance with GMP. The variation application to add QCIL's site at Luzira is currently under assessment by WHO.

A variation is a change to the prequalified product dossier. Any such changes (variations) may involve administrative and/or more substantial changes (that may impact on safety, quality and efficacy) that are subject to approval by WHO.

1 http://apps.who.int/prequal/WHOPIR/WHOPIR_QCIL25-28January2010.pdf