A Newsletter from KENAS

ACCREDITATION

The independent evaluation of Conformity Assessment Bodies (CABs) against recognized conformity assessment standards to ascertain their integrity, impartiality, objectivity and competence to carry out specific conformity assessment activities.

PHARMACEUTICAL LABORATORY ACCREDITATION

Each year many new pharmaceutical products are introduced to the market. These may be products containing new chemical entities, improved formulations for better or more controlled drug delivery or generic formulations.

All have common requirements of adequate documentation and must meet internationally accepted standards of quality. Accreditation provides formal recognition that a facility meets certain standards. These are standards of quality, performance, technical expertise and competence. The need for Kenya and EAC pharmaceutical laboratories to achieve global recognition, as well as conformity against international standard led to the establishment of an accreditation programme for pharmaceutical laboratories under the auspices of the Kenya accreditation service (KENAS). Pharmaceutical laboratories accredited by KENAS are allowed to display the KENAS symbol on their communication, certificates and reports.

ISO 17025 ACCREDITATION VERSUS WHO (WORLD HEALTH ORGANISATION) PRE-QUALIFICATION

•The ISO accreditation process allows for a narrow scope as a measure to assure adherence to quality management systems while WHO Pre- Qualification focusses on all activities within a laboratory.
•In an ISO accredited facility, test reports are only authorized by assessed and competent technical signatories while in the WHO PQ laboratory, it can be authorized by competent personnel not necessarily a technical signatory.
•ISO accreditation process allows for a step by step approach where the scope of accreditation will be widened with time while pre-qualification focuses on all activities within the laboratory.

REQUIREMENTS FOR ACCREDITATION

Pharmaceutical laboratories seeking accreditation need to comply with the following requirements:
• The quality management, scientific and technical aspects of pharmaceutical laboratories as determined by ISO/IEC 17025;
• Technical requirements documents which may have been developed by the KENAS Specialist Technical Committee (STC);
• Participation in proficiency testing or inter-laboratory comparisons.

Report Compiled by Assistant Director, Health & Safety, Doris Mueni