Abbreviations and terms used during PAHWP meetings.

Abbreviations

ALADDIV	**The Latin American IVD Association**
AMRH	**African Medicines Regulatory Harmonization**
AHWP	**Asian Harmonization Working Party**
AMLDS	**African Medical Lab Diagnostic Supplies**
ASLM	**African Society for laboratory Medicine**
CSDT	**Common Submission Dossier Template**
DoC	**Declaration of Conformity**
EAC	**East African Community**
ESCA-HC	**East, Central and Southern African Health Community**
EPSP	**Essential Principles of Safety and Performance**
GHTF	**Global Harmonization Task Force**
GIZ	**Deutsche Gesellschaft fur Internationale Zusammenarbeit**
GMDN	**Global Medical Devices Nomenclature**
GLP	**Good Laboratory Practice**
GMP	**Good Manufacturing Practices**
GCC	**Grand Challenges Canada**
IVDD	**In Vitro Diagnostics Device**
IMDRF	**International Medical Device Regulators Forum**
ISO	**International Organization for Standardization**
LRP	**Local Responsible Person-**
LSHTM	**London School of Hygiene & Tropical Medicine**
MSF	**Médecins Sans Frontières**
NRA	**National Regulatory Authority**
PAHWP	**Pan-African Harmonization Working Party**
NEPAD	**The New Partnership for Africa's Development**
NAAT	**Nucleic Acid Amplification Test**
POC	**Point of care**
PQ	**Pre-qualification**
QMS	**Quality Management System**
REC	**Regional Economic Community**
SADC	**Southern African Development Community**
SALDA	**Southern African Laboratory Diagnostics Association**
STAG-TB	**Strategic and Technical Advisory Group for Tuberculosis (WHO)**
SRA	**Stringent Regulatory Authority**
STED	**Summary Technical Documentation**
WHO AFRO	**World Health Organization Regional Office for Africa**

Organisations promoting regulatory harmonization of IVD or medical devices

The Global Harmonization Task Force (GHTF) was a partnership between regulatory authorities and manufacturers. Its mission was to achieve greater uniformity between national medical device regulatory systems with the dual aims of enhancing patient safety and increasing access to safe, effective and clinically-beneficial medical technologies around the world. It was comprised of five Founding Members: Australia, Canada, European Union, Japan and United States. Founded in 1992, it transitioned to the International Medical Device Regulators Forum, discussed below, in 2012.

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the work of the GHTF and accelerate international medical device regulatory harmonization and convergence.

The Asian Harmonization Working Party (AHWP) is a forum for medical device regulatory authorities and the medical device industry to study and recommend ways to harmonize medical device regulations following the guiding principles defined by the Global Harmonization Task Force. It works with the Asia Pacific Economic Community (APEC) and other related international and regional organizations to establish harmonized standards and procedures for regulatory approval of medical devices. The AHWP has 23 member economies some of which are outside the region. It has a subgroup that focuses on IVDs.

The Latin America IVD Association (ALADDIV) is a regional forum for regulators, researchers, laboratory experts and representatives from ministries of health to promote the convergence of regulatory standards and procedures.

The Pan-African Harmonization Working Party (**PAHWP)** was conceived in 2012 with a technical working group and interim secretariat within the East African Community (EAC) to guide the priority activities towards the harmonization of regulation of IVDs in the Africa region. Once operational, PAHWP will be managed under the African Union-New Partnership for Africa's Development (AU-NEPAD)

DEFINITION OF TERMS

Calibrator Any substance, material or article intended by to be used in the calibration of a measuring instrument or measuring system.

Conformity Assessment The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that an In Vitro Diagnostic device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

Distributor Person or business that receives finished devices from another establishment for the purpose of offering them for commercial sale.

Effectiveness" or "efficacy: valid scientific evidence to show that a test can produce an intended clinical effect in a target population.

Facility: factory, warehouse, store, pharmacy, hospital, carrier, vessel or any other place where products are manufactured, processed, imported, packed, refurbished, held, distributed, dispensed or sold.

In Vitro Diagnostic (IVD) Medical Device A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Label Written, printed or graphic representation that appears on or is attached to the medical device or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the In Vitro Diagnostics or active ingredient when it is being supplied;

Labeling/information supplied by the manufacturer Written, printed or graphic matter affixed to an In Vitro Diagnostic device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the device, but excluding shipping documents.

Lay Person Individual who does not have formal training in a relevant field or discipline.

Manufacture to make, fabricate, produce or process an In Vitro Diagnostics and includes:

Manufacturer: Person or business that produces an article that meets the legal definition of medical device.

Medical device: An instrument, apparatus, machine, implant or in-vitro reagent whose use is intended for the diagnosis of disease, or for the cure, mitigation, treatment or prevention of disease, or for affecting the structure of function of the body for some medical purpose.

Near Patient Testing Testing performed by qualified personnel, near to, or at the side of, the patient.

Objective Evidence Information that may be proved true, based on facts obtained through observation, measurement, testing or other means.

Point of care tests IVD Medical Devices designed to be used at the point at which care is delivered that do not require referral of the patient or sample to a laboratory. Ideally such tests are fully portable and do not require mains electricity or water.

Process Validation Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

Quality System System which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System Management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

Reagent Chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as IVD devices.

Recall Action taken by the manufacturer, importer or distributor in respect of an In Vitro device that has been sold to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after being aware that the device may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or may not meet the requirements of the Act or regulations.

Recognised Standards National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Registration or notification Identification of the establishment seeking to sell or otherwise conduct business within a national jurisdiction, in addition to the identification (or "listing") of the products to be marketed in that jurisdiction.

Relabeller Person or business that changes the content of product labelling offered by the original manufacturer for distribution under its own name.

Repackager Person or business that packages finished devices from bulk or repackages devices made for shipment in multiple containers

Risk Combination of the probability of occurrence of harm and the severity of that harm.

Self test An IVD for self testing is a device or test designed to be used at home by a lay person

Specimen receptacles Devices, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination

Technical Documentation Documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices.

Verification Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.