



ARSO African Organisation For Standardisation

Overview of the Harmonization of Standards for the Pharmaceuticals and Medical Devices Project

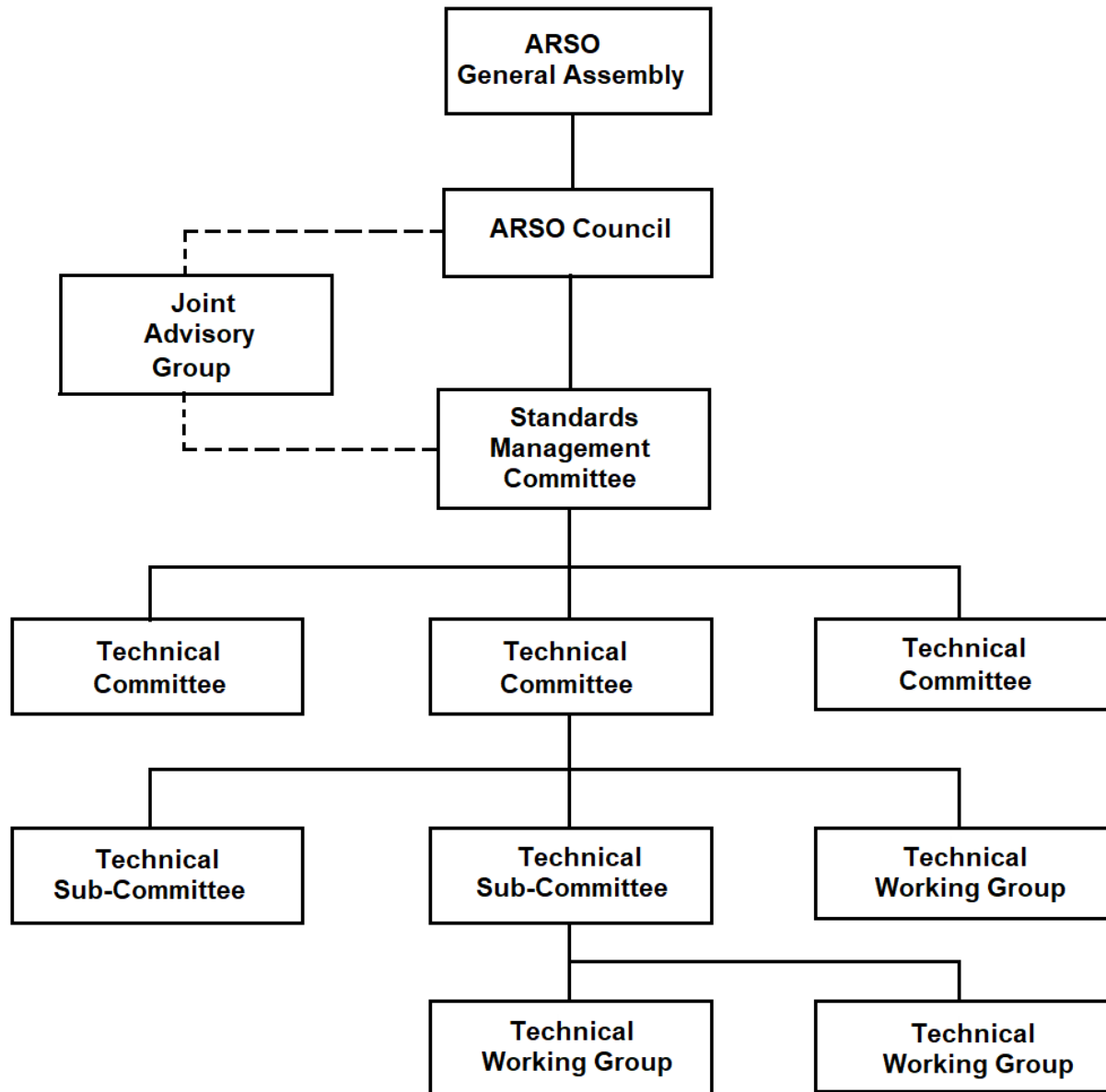
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Reuben Gisore, Technical Director, ARSO



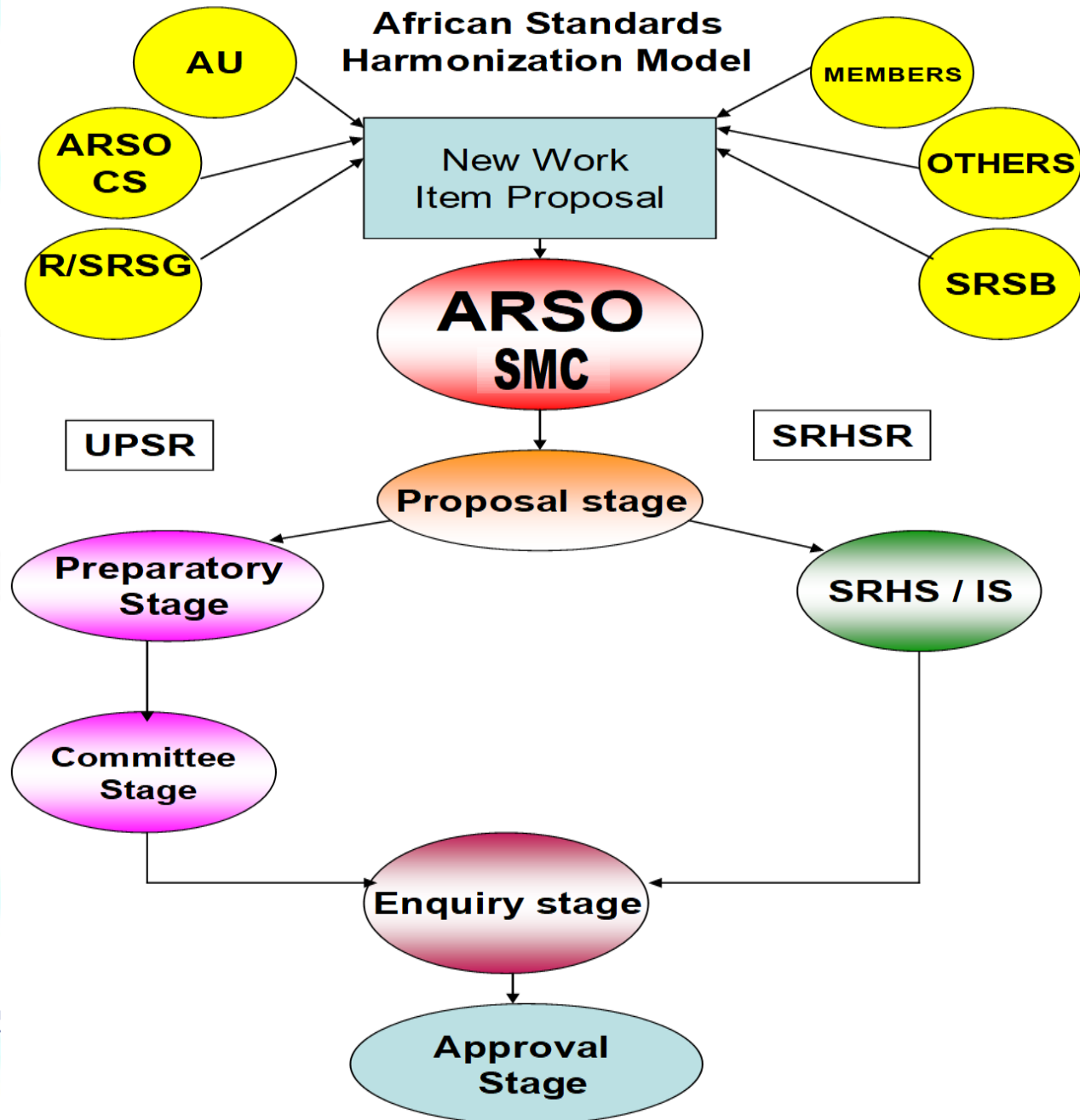


Organizational Structure for the development of African Standards





Paths for Harmonizing African Standards





ARSO Current 3-Year Project

Sponsored by: The African Export-Import Bank (Afreximbank) and the International Islamic Trade Finance Corporation (ITFC) through Arab-Africa Trade Bridges Program (AATB)

Project Title: ***Harmonisation of Standards for Pharmaceutical and Medical Devices in Africa***, aimed at promoting quality and safety of medicines and medical devices imported or produced on the continent.

ARSO Committees:

- (1) ARSO/TC 78, Medical devices and equipment
- (2) ARSO/TC 80, Pharmaceuticals and medicinal products
- (3) ARSO/TC 82, African traditional medicine
- (4) ARSO/CACO Technical Regulations Sub-Committee





ARSO Project Phases and Components

Components

- (a) **Component 1:** Harmonization of standards for pharmaceuticals and medical devices
- (b) **Component 2:** Harmonization of conformity assessment and regulatory compliance

Phases

- ▶ **Immediate and Short-Term Standards Harmonization and Response to Covid-19:** African standards needing fast-tracking will be processed within 6 months and stylized on existing standards of equivalent nature
- ▶ **Long-Term Standards, Conformity Assessment and Regulatory Harmonization:** Standards in this category deal with products which require substantial investments which have a long-term impact. This may include permanent facilities. While foreign standards can be utilized as an interim measure, there is need to engage with stakeholders to in the manufacturing sector to establish practical production practices which utilize local resources and expertise.





ARSO/TC 78, Medical devices and equipment

Scope: Standardization in the following fields:

Assistive products for persons with disability; Electrical equipment in medical practice; Transfusion, infusion and injection equipment for medical and pharmaceutical use; Devices for administration of medicinal products and intravascular catheters; Dentistry and oral hygiene products; Anaesthetic and respiratory equipment; Implants for surgery; Prosthetic and orthotics; Surgical instruments; Mechanical contraceptives; Quality management and corresponding general aspects for medical devices

Participating Member States (15) (30 Experts) : (1) Algeria, (2) Botswana, (3) Cameroon, (4) DR Congo, (5) Egypt, (6) Kenya, (7) Malawi, (8) Mauritius, (9) Niger, (10) Nigeria, (11) Rwanda, (12) South Africa; (13) Togo, (14) Uganda, (15) Zimbabwe

Expected Standards Short-term: 65

Number of Meetings: 9 Frequency: Every Two Weeks: Type: Virtual

Standards Delivered: 76

WG1: Masks, surgical suits and gowns, with **15 experts**

WG2: Gloves and shields, with **13 experts**

WG3: Filters, respirators and lung ventilators, with **13 experts**

Chairperson: Professor Chomora Mikeka, Malawi

Secretary: Gunseyo Dzinjalama, Malawi





ARSO/TC 80, Pharmaceuticals and medicinal products

Scope: Elaboration of standards, specifications, codes of practice, methods of test and sampling for pharmaceuticals and medicinal products. Key aspects: (1) **Sterilization and disinfection;** (2) **Laboratory medicine;** (3) **Pharmaceutics;** (4) **Medicinal/medicated products;** (5) **Biotechnology**

Participating Member States (14); (28 Experts): (1) Algeria, (2) Cameroon, (3) DR Congo, (4) Egypt, (5) Kenya, (6) Malawi, (7) Mauritius, (8) Niger, (9) Nigeria, (10) Rwanda, (11) South Africa; (12) Togo, (13) Tunisia, (14) Uganda

Expected Standards Short-term: 31

Number of Meetings: 8 Frequency: Every Two Weeks: Type: Virtual

Standards Delivered: 38

WG1: sterilization and disinfection, with **12 experts**

WG2: laboratory and medicine, with **10 experts**

WG3: pharmaceuticals, with **14 experts**

Chairperson: Dr Baxter Kachingwe, Malawi

Secretary: Samson Magombo, Malawi





ARSO/TC 82, African traditional medicine

Scope: Standardization in the field of African traditional medical systems. Both traditional and modern aspects of these systems are covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicine, but not into the clinical practice or application of those products.

Participating Member States (20) (33 Experts): (1) Botswana, (2) Burkina Faso, (3) Cameroon, (4) DR Congo, (5) Egypt, (6) Ethiopia, (7) Gabon, (8) Ghana, (9) Kenya, (10) Malawi, (11) Mauritius, (12) Nigeria, (13) Rwanda, (14) Sénégal, (15) South Africa, (16) Sudan, (17) Tanzania, (18) Togo, (19) Zambia and (20) Zimbabwe

WG1: terminology and documentation, with **9 experts**

WG2: cultivation quality and safety of raw materials, with **9 experts**

WG3: quality, safety and efficacy of manufactured ATM products, with **10 experts**

WG4: medical devices and equipment, with **5 experts**

WG5: monographs, **9 experts**

WG6: treatment procedures and codes of practice, **11 experts**

Chairperson: Majorie Lorraine Amanda Gcabashe, South Africa

Secretary: Rahba Saeid Abdalla Mohamed, Sudan

Co-Secretary: Udoso Uduak Eyakeno





ARSO/CACO/TSC 2 Technical Regulations

WG 5 Pharmaceuticals and medical devices

Scope: Elaboration of technical regulations for pharmaceuticals, medicinal products, medical devices and equipment

Participating Member States (18); (36 Experts): Botswana, Burkina Faso, Cameroon, Cote d'Ivoire, Egypt, Kenya, Malawi, Nigeria, Mauritius, Rwanda, South Africa, Tanzania, Togo, Tunisia, Uganda, Mauritius, Zambia, Zimbabwe

Expected Guidelines Short-term: 4

Number of Meetings: 5 Frequency: Every Two Weeks: **Type:** Virtual

Guidelines Delivered: 5

TF1: African Traditional Medicine, with **6 experts**

TF2: Pharmaceuticals, with **7 experts**

TF3: Medical devices/IVDs, with **9 experts**

TF4: Hospital equipment **4 experts**

Guidelines for establishing emergency temporary / field hospitals

Convenor: Moomena Ormajee, South Africa

Secretary: Benson Abam, Nigeria





Long-Term Standards, Conformity Assessment and Regulatory Harmonization

Standards in this category deal with products which require substantial investments which have a long-term impact. This may include permanent facilities. While foreign standards can be utilized as an interim measure, there is need to engage with stakeholders to in the manufacturing sector to establish practical production practices which utilize local resources and expertise.

- (1) Good manufacturing practices for pharmaceuticals and biomaterials
- (2) Good manufacturing practices for medical devices
- (3) Guidelines for pharmacovigilance for medicinal products for human and veterinary use
- (4) Scientific guidelines for medicinal products for human use
- (5) Guidelines for clinical trials
- (6) Good pharmacy practice
- (7) Prequalification of quality control laboratories
- (8) Minimum standards for intensive care units
- (9) Standards for ICU beds
- (10) Standards for HDU and ICU Units
- (11) General requirements for field hospitals
- (12) Code of practice for medical teams in sudden onset disasters



Thank you!

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