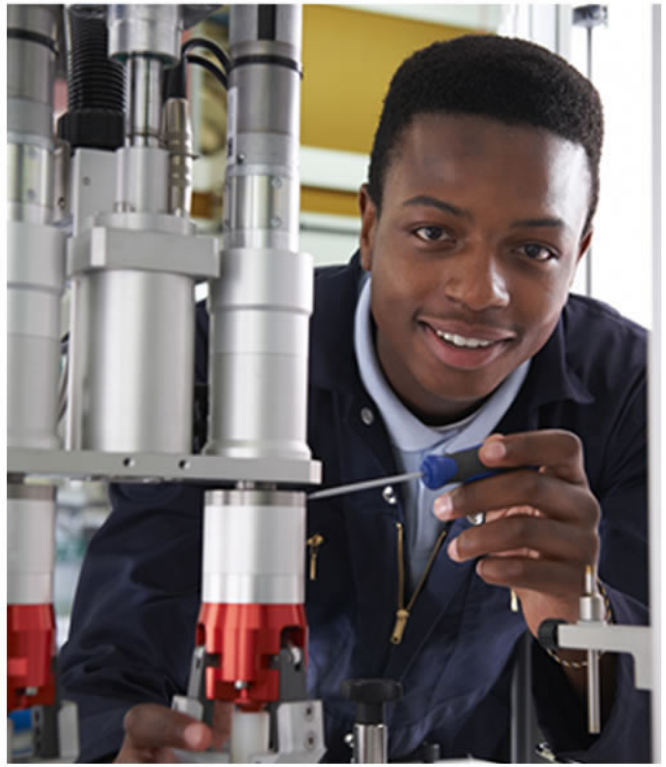
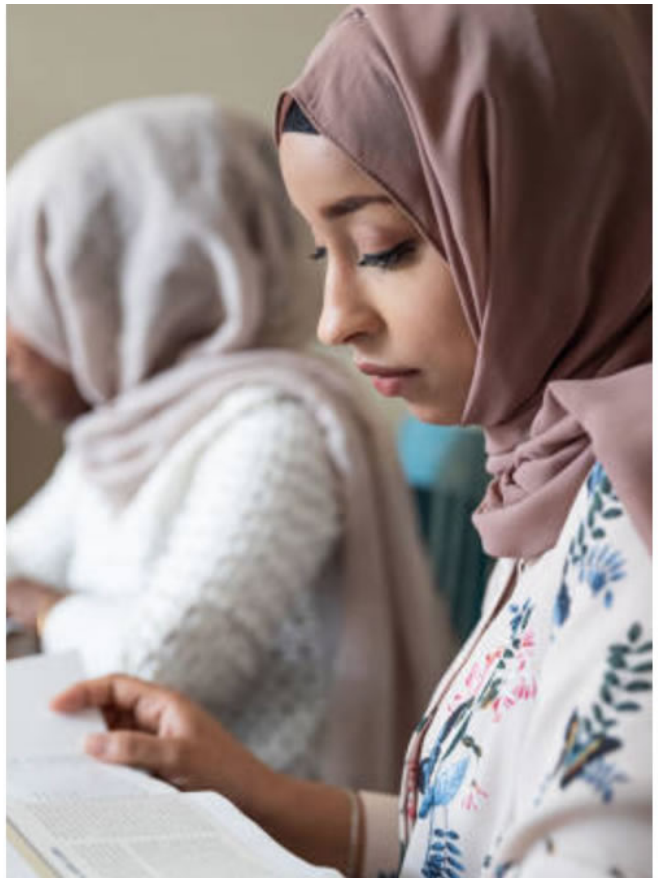
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

ABRF (TWG) UPDATE





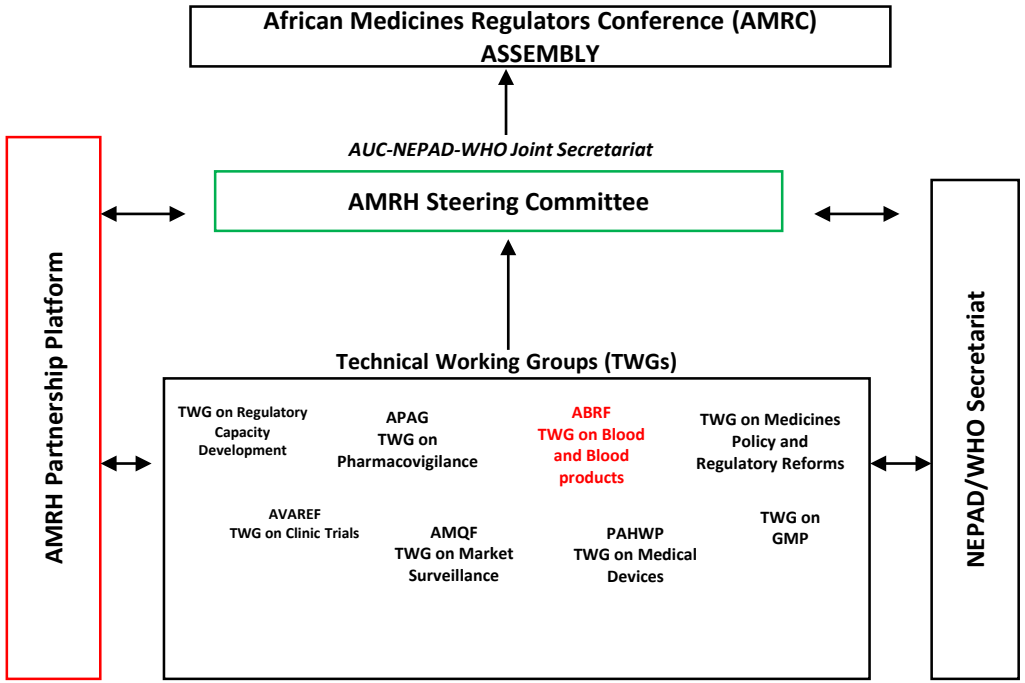
ABRF - ICDRA 20-24 September 2021
, 13H00 – 15H00


Botswana
Limpopo
Namibia
Mpumalanga
North West
Gauteng
Swazi-land
Mozambique
South Africa
KwaZulu-Natal
Free State
Northern Cape
Lesotho
Eastern Cape
Africa
Western Cape
South Africa

Presentation Outline

- ABRF
  - Background
  - Organizational of the ABRF: members, secretariat, chair, report to, etc
  - Workplan (including funding support)
  - Progress and Activities
  - Future plan

AMRH Governance Framework



Existence of ABRF /Background

Background

- **Consistent with the World Health Assembly (WHA) Resolution 63.12 (2010) and 67.20 (2014), regulatory authorities are encouraged to ensure that the quality, safety and efficacy of blood products across the entire transfusion chain meet internationally recognized standards. However, many countries in Africa face challenges in maintaining a sufficient supply of quality, safe and effective blood products and ensuring their appropriate use. Correspondingly, a need has been recognized to strengthen the capacity of National Regulatory Authorities (NRAs) to regulate blood products and to assure standards to permit fractionation of "surplus" plasma not needed for transfusion.**

- Discussions of this issue at a series of WHO-hosted meetings since 2013 led to the concept that a Forum of blood regulators in Africa would be a significant force to advance access to quality, safe and effective blood products across the continent through effective blood regulation. This concept aligns with the listing of whole blood, red blood cells, platelets and fresh frozen plasma on the WHO Model List of Essential Medicines in 2013, whereby regulation of blood components is recognized by WHO as part of regulation of medicinal products.

Existence of ABRF /Background

Background

- In regional workshops convened by WHO in 2013 in Johannesburg, South Africa, and in 2015 and 2016 in Cotonu, Benin, leaders of NRAs of African countries met together with Directors of National Blood Transfusion Services (NBTS) to discuss needs for and strategies to improve access to safe blood for transfusion, including blood regulation.

- In this context, the concept of a Forum for blood regulators in Africa was raised several times as a possible continental approach toward promoting national advancements as well as international harmonization in this area.

Existence of ABRF /Background

Background

- Additionally, at a meeting in September 2017 in Johannesburg, South Africa, the Steering Committee (SC) of the African Medicines Regulatory Harmonization (AMRH) program of the African Union recommended the establishment of such a Forum. Furthermore, at a WHO hosted Regional Workshop on the Regulatory System for Blood and Blood Products, held in Douala, Cameroon in March 2018, representatives of NRAs and blood operators in 20 African countries spanning all the eight Regional Economic Communities (RECs) of Africa reached a consensus to cooperate in establishing a Forum for blood regulators in Africa.
- A subgroup of the regulators who attended the March 2018 workshop in Douala was tasked with developing Terms of Reference (ToR) for this Forum, which were drafted in November 2018..

ABRF Purpose /Existence

- The ABRF is a network of regulators and allied stakeholders operating as a Continental Technical Working Group (CTWG) under the AMRH Initiative, dedicated to cooperation and coordination in blood products regulation across Africa. The ABRF works closely with Regional Economic Communities (RECs) to increase access to quality assured, safe and effective blood products through harmonizing of regulations, strengthening of national regulatory systems and enhancement of international cooperation in this area.
- The purpose of the ABRF (or “Forum”) is to facilitate access to quality, safe, and affordable blood products for all people of Africa through continental enhancement of the work of the RECs to advance technical and regulatory harmonization and cooperation among the Member States.

Structural Organization of ABRF

No	NAME	COUNTRY	RECS
1	Dr. Anto Perpetua EBELE	Nigeria	CEN-SAD, ECOWAS
2	Dr. Elirehema H MFINANGA	UR of Tanzania	EAC, SADC, ICGLR
3	Ms. Linda MUDYIWENYAMA	Zimbabwe	COMESA, SADC
4	Mr. Alex MUTAI	Kenya	COMESA, CEN-SAD, EAC, IGAD, ICGLR
5	Mr. Khamusi Philip MUTOTI	South Africa	SADC
6	Dr. Mohamed CHAIB	Algeria	UMA
7	Dr. Bintou DIA	Senegal	CEN-SAD, ECOWAS
8	Dr. Jean-Bosco NDUWARUGIRA	Burundi	COMESA, EAC, ECCAS, ICGLR
9	Dr. Appolonie Tecla Cristelle OWONAMANGA	Cameroon	ECCAS
10	Dr. Janaki SONOO	Mauritius	COMESA, SADC
11	Mr. Solim ALEKA	Togo	CEN-SAD, ECOWAS
12	Dr. Amadou DIARRA	Mali	CEN-SAD, ECOWAS

ABRF workplan 2021 (2/2)

Objectives	Output/Activities	Resource gaps
Finalization of 2020 ABRF guidance documents	- ABRF Guidance on Collection and Use of COVID-19 Convalescent Plasma (CCP) - ABRF Guideline on GMP and GMP inspecting for blood establishments - ABRF Guidance on Development of a stepwise approach and framework for blood regulation in Africa	- Funding for editing costs - Funding for translation from English to other official languages
Development of Shorter version of the Guidance documents	- Paper for Publication in identified Journals/Platforms	• Funding for Editing • Funding for publication • Writing experts and cost related • Translation to other official languages

ABRF workplan 2021 (2/2)

Objectives	Output/Activities	Resource gaps
Replication of the workshops for blood regulation and haemovigilance	- Training workshop(s) on blood regulation - Training workshop(s) on haemovigilance	- Moderators, speakers and panelists - Funds to support participation of countries
In-country projects to further advance blood regulation and haemovigilance	Specific countries offered support to develop blood regulation frameworks	- Training material - Financial and technical support
Plenary Meetings (every Second Month)	Updates , Strategy alignment Feedback from SWG Endorsements of SWG outcomes	- Translation cost - Data Requirements for Members from individual Countries - Laptop /Devices Support for Individual members
Development and Establishment of a Budget based on Costing activities	Activity Costing	- Recruitment of Expert in Financials to assist the ABRF to cost the activities in line with currency requirements

Revised June 2020

1. **Operationalization of the Forum**

   - A working sub-group is established for each strategic goal
   - Steps are taken to build capacity amongst members of each working sub-group

2. **Resource Mobilization**

   - Cost estimates are developed for candidate projects to be undertaken by the Forum

3. **Advocacy**

   - A model blood law applicable to all Member States of the African Union is developed.

4. **Capacity Building**

- A guideline on GMP and GMP inspecting for blood establishments is developed
- A rapid situation analysis is conducted to assess the status of blood regulation in each country of the African Union
- A multi-country government-led initiative to expand experimental access to COVID-19 Convalescent Plasma is established
- Steps are taken to strengthen the expert capacity of NRAs in blood transfusion
- Guidance is developed on stepwise advancement of blood regulation.

ABRF 1st Annual Workplan (2019-2022) – Revised June 2020

- The Working Sub-Groups were restructured to address urgent priorities on COVID-19, guidance on GMP and GMP inspecting, and guidance on stepwise advancement of blood regulation;
- **COVID-19**
  - Position of the African Blood Regulators Forum (ABRF) on Use of Convalescent Plasma in Africa as a Potential Therapy in COVID-19”
  - BRF Guideline on Collection and Use of COVID-19 Convalescent Plasma (CCP)
- **GMP and GMP Inspection**
  - Guideline on GMP and GMP inspecting for blood establishments
- **Blood Law**
  - Development of a stepwise approach and framework for blood regulation in Africa.

Progress Activities/Achievements

- COVID-19 Sub- Group
  - **ABRF Guidance on Collection and Use of COVID-19 Convalescent Plasma (CCP)**
- Guideline on GMP and GMP inspecting for blood establishments – Sub Working Group
  - **ABRF Guideline on GMP and GMP inspecting for blood establishment**
- Development of a stepwise approach and framework for blood regulation in Africa – Sub Working Group
  - **ABRF Guidance on Development of a stepwise approach and framework for blood regulation in Africa**

Activities Planned before end of 2021

- **Adoption of Operational Procedures**
- **Review of the Strategic Plan and Current Workplan**
  - **Affirmation or revision of current priorities**
  - **Planning for any new activities**
  - **Strategy for development of a budget based on costing of activities and identification of needs for technical and funding support from Partner Organizations**
- **Planning process for a plenary meeting before AMRH week, December 2021**

Identified opportunities

- Opportunities for cooperation with the partners
  - Development of an African network for convalescent plasma
  - Project proposal on SARS-CoV-2 antibody testing in blood donor.

Thank you!

Ngiyabonga

Asante sana