THE ASSEMBLY OF THE AFRICAN VACCINE REGULATORY FORUM (AVAREF) ASSEMBLY

AVAREF 1/R1

29 November 2017, Accra, Ghana

RESOLUTION

THE AVAREF STRATEGIC PLAN FOR NATIONAL REGULATORY AUTHORITIES (NRAs) AND NATIONAL ETHICS COMMITTEES (ECs), 2018 - 2020

(Document AVAREF/1/1)

The AVAREF Assembly,

Recalling that the regulatory and product development landscape in Africa has evolved substantially since the launch of AVAREF in 2006;

Recognizing that the past decade has also witnessed an increase in the sophistication of trials and the number and complexity of products undergoing clinical trials for diseases endemic to Africa for which no prior knowledge and evidence base exist in high income countries;

Having identified the urgent need for a regulatory platform for promoting human resource capacity, best practices, common technical requirements and the efficiency and transparency of the regulatory process, especially in acute times or crisis;

Recalling also the launch of the East Africa Community Medicines Regulatory Harmonization (EAC MRH) Project in March 2012 as an important initiative predicated on the principles of regional harmonization, work-sharing and reliance;

Acknowledging the endorsement by all Member States of the WHO Region of the document on status of reviews and authorization of clinical trial applications in the African region at the 67th Regional Committee meeting;

Having reviewed the progress they have made and identified their needs;

Concerned that the timelines for reviews and approvals of clinical trials and registration of medical products still remain too long;

1. APPROVES the AVAREF Strategic Plan 2018 -2020;

2. URGES NRAs and ECs to:

(a) increase the efficiency and quality of reviews and inspections and the timeliness and transparency of regulatory decisions for all interventional trials conducted in Africa;

(b) promote the safety of patients, through pharmacovigilance systems and regular reporting, investigations and communication;

(c) enhance emergency preparedness on the continent, in RECs and in individual countries

(d) stimulate innovation in ethics and regulatory work in Africa to improve access

3. REQUESTS the WHO AVAREF Secretariat, the AVAREF members and partners to:

(a) strengthen AVAREF's capacity building role;

(b) advocate for and promote awareness, sustainability and monitoring of AVAREF;

(c) foster continued collaboration between international and multilateral agencies, donor organizations and national Ethics Committees and NRAs;

(d) enhance the capacity of Member States to ensure the safety and timely conduct of clinical trials, report on timelines;

(e) continue monitoring the implementation of the strategic plan;

(f) report to the Assembly on the progress made.