Media Release

African Medicines Regulatory Agencies, Ethics Committees to expedite COVID-19 Related Clinical Trial Reviews

Brazzaville, 20 April 2020 – National Medicines Regulatory Authorities and National Ethics Committees from across Africa have agreed to combine their expertise to expedite clinical trial review and approvals for new multinational preventive, diagnostic and therapeutic interventions to the COVID-19 pandemic. However, joint reviews are based on voluntary cooperation between the relevant national regulatory authorities and ethics committees. Each country is solely responsible for granting regulatory approval.

The agreement was reached during a virtual meeting convened by the World Health Organization (WHO) on 1 April 2020 under the platform of the African Vaccines Regulatory Forum (AVAREF), one of the Continental Technical Committees of the African Medicines Regulatory Harmonization Initiative.

AVAREF, established by WHO in 2006, is an informal capacity-building platform aimed at improving the regulatory oversight of interventional clinical trials conducted in Africa. Over the years the platform has demonstrated its value in strengthening regulatory and ethics reviews, promoting harmonized standards and approaches and accelerating the review of vaccines of high public health value – most recently in relation to vaccines against Ebola – among member countries. It has also shed light on the growing complexity of biomedical research, which calls for increased cooperation between partners including donors, researchers, product developers, regulators and the medical ethics community.

The conventional approach to clinical trial regulatory and ethics review is sequential, with each agency reviewing applications without oversight of each other's inputs. This results in inefficiencies and delays in providing a final response to the sponsor. The approach proposed by AVAREF has already been successfully applied to important vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia and Ebola and has been extended to other therapeutic interventions. Importantly this process retains country specific requirements so that participating agencies do not compromise protection of its citizens by a top-down approach. A comprehensive AVAREF Strategic Plan that promises longer term efficiency gains via alignment with the African Medicines Regulatory Harmonization objectives has been endorsed by Member States at the AVAREF Assembly in November 2017 in Accra.

COVID-19 pandemic has dramatically reduced the opportunities for face-to-face meetings. Therefore, the Member States of AVAREF agreed to adopt below measures to address this challenge:

- An online platform (SharePoint) will be made available for joint reviews of clinical trial applications for preventive, diagnostic and therapeutic interventions related to the COVID-19 pandemic. Participating countries (national regulatory authorities, national ethics committees and targeted ethics review boards) will post their queries online for real-time response from sponsors/applicants

- The secretariat of the AVAREF will convene and coordinate virtual meetings for participating countries to conduct joint reviews of clinical trial applications on COVID-19
- Virtual meetings will also be used to discuss pertinent issues on how regulators and ethics committees can better prepare and respond to the COVID-19 pandemic
- Regulatory authorities and ethics committees can use a separate platform (MedNet) to share information on planned or ongoing clinical trials in their countries
- A timeline of 10 working days is suggested for processing of clinical trial applications via the joint review pathway where the product is already registered for other indications, and 15 working days for novel products

For more information please contact your National Regulatory Authority, Ethics Committee or Diadié Maiga at maigad@who.int

Weblinks: https://www.afro.who.int/health-topics/immunization/avaref