DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

208/NDA/DPS/04/2020

28th April 2020

CIRCULAR NO. 036

Attention: Sponsors, Researchers, Research Ethics Committees.

Joint reviews for Multi-national COVID-19 Clinical Trial Applications within Africa

In line with section 40 of the National Drug Policy and Authority Act Cap 206, the National Drug Authority (NDA) authorizes drug-related clinical trials by issuing a certificate. NDA works in collaboration with the Uganda National Council for Science and Technology (UNCST), Research Ethics Committees (RECs) and the Uganda National Research Health Organization (UNHRO).

In line with this mandate, the NDA in collaboration with the UNCST has agreed to combine expertise with other National Regulatory Agencies and National Ethics Committees across Africa to expedite clinical trial review and decision for new multi-national preventive, diagnostic and therapeutic interventions to the COVID-19 pandemic using the African Vaccines Regulatory Forum (AVAREF) joint review platform. This agreement was reached during a virtual meeting convened by the World Health Organization (WHO) on 1 April 2020.

AVAREF was established by WHO in 2006 as a capacity-building platform aimed at strengthening regulatory and ethics reviews in the oversight of interventional clinical trials conducted in Africa. It serves as one of the Continental Technical Committees of the African Medicines Regulatory Harmonization Initiative.

The AVAREF platform 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.

AVAREF has promoted harmonized standards and approaches and accelerated the review of vaccines of high public health value – most recently in relation to vaccines against Ebola. 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

In line with the guidelines for conduct of clinical trials in Uganda (2019), NDA will participate in the joint review of COVID-19 related clinical trial applications that fall within its mandate and as will be coordinated by the AVAREF secretariat. Ultimately NDA will remain solely responsible for authorization of clinical trials to be conducted within Uganda.

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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In view of the reduced opportunities for face-to-face meetings during the ongoing COVID-19 pandemic, the Member States of AVAREF have agreed to adopt the measures below to address this challenge:

1. Use of an online platform (SharePoint), made available for joint reviews of clinical trial applications for preventive, diagnostic and therapeutic interventions related to the COVID-19 pandemic. This platform will be used by the national regulatory authorities; national ethics committees and targeted ethics review boards of all participating countries.
2. 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.
3. 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.
4. Mutual sharing of information on planned or ongoing clinical trials within the country between NDA, UNCST, the RECs and UNHRO using a separate platform (MedNet).
5. A timeline of ten (10) working days has been suggested for processing of COVID-19 related clinical trial applications via the joint review pathway where the product is already registered for other indications, and fifteen (15) working days for novel products.

For more information or clarification, please contact the National Drug Authority on clinicaltrials@nda.or.ug or the AVAREF Secretariat representative Diadié Maiga at maigad@who.int.

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