DRUG

NATIONAL AUTHORITY

Safe Drugs Save Lives

23rd September 2020

To All Pharmaceutical Importers

CIRCULAR NO. 008/DIE/2020

PROVISIONS FOR EMERGENCY IMPORTATION OF REMDESIVIR IN THE CONTEXT OF THE COVID-19 PANDEMIC

National Drug Authority was established by the National Drug Policy and Authority Act (Cap 206) to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

There is growing clinical and scientific evidence indicating that Remdesivir injection shows potential for positive clinical outcomes in the management of COVID-19. As a result of this growing evidence, the drug has received emergency use authorisation for the management of COVID-19 from a number of drug regulatory authorities worldwide.

In an effort to make the drug available to Ugandan patients, NDA hereby informs you that all requests for importation of Remdesivir shall be handled in accordance with section 8(4) of the National Drug Policy and Authority Act, to meet emergency or extraordinary circumstances. In line with this provision, the following conditions shall apply to the importation of Remdesivir into Uganda:

1) Considering that the drug is an injectable formulation requiring close monitoring after administration, it shall strictly be imported for use within healthcare facilities designated for management of COVID-19, where patients can be closely monitored by a medical practitioner.

2) The importer shall avail evidence of compliance with regulation 3(3) and (4) of the National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014. The importer shall be required to submit post-market safety monitoring reports, as well as reports on all serious adverse drug reactions, annual pregnancy safety reports and any foreign regulatory actions related to the safety of Remdesivir; to the Directorate of Product Safety at NDA.

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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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3) The importer shall avail evidence that there will be accountability by the Pharmacist of Record. The Pharmacist in-charge shall submit periodic accountability on the use and distribution of the drug, and when required by the Authority. The Pharmacist shall be professionally responsible for ensuring safety of patients during the usage of products.

4) The importer shall liaise with the manufacturer to avail quality data confirming that the manufacturing processes and controls will consistently produce product of suitable quality for the intended use. This data shall include (but not limited to) certificates of Good Manufacturing Practices issued by NDA or a Stringent Regulatory Authority, certificates of analysis and manufacturing/validation/stability records.

5) National Drug Authority shall continue to closely monitor the safety of Remdesivir in Uganda and shall take prompt action should any safety concerns arise.

6) The Post Marketing Surveillance Team when on routine or special assignment will follow up on the products on the market.

For further information or clarification, please contact the undersigned.

OFFICE OF THE SECRETARY TO THE AUTHORITY

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David Nahamya

SECRETARY TO THE AUTHORITY

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