

# NATIONAL



# AUTHORITY

797/NDA/DPS/12/2020

23<sup>rd</sup> December 2020

**CIRCULAR NO: 041**

**To: All Pharmaceutical Importers and Healthcare Professionals**

## **Emergency use of Remdesivir in the context of the Covid-19 Pandemic**

The National Drug Authority (NDA) authorized Remdesivir importation into Uganda due to the growing scientific and clinical evidence of potential clinical outcomes in the management of Covid-19.

Remdesivir was approved by NDA under the Emergency Use framework to be used in treatment of Covid-19, in adults and children (12 years of age and older or weighing over 40kg) hospitalised with severe disease.

Under the emergency framework, several conditions are to be followed by importers while importing the drug and clinicians while using the drug.

These included but not limited to;

- 1) Importation is strictly for use within health care facilities designated for management of Covid-19.
- 2) The importer has to avail evidence of compliance with regulation 3(3) and (4) of the National Drug Policy and Authority (pharmacovigilance) regulation 2014. The importer is required to submit safety update reports every three months, individual case reports on all serious adverse drug reactions and foreign regulatory actions related to the safety of Remdesivir to NDA.
- 3) The importer has to submit accountability and reconciliations for the distributed products.
- 4) The pharmacist in charge at health facilities shall submit periodic accountability on the use and the distribution as and when required by NDA. There should be responsibility for the safety of patients during the usage of the product.
- 5) It's important that all clinicians ensure that hepatic laboratory testing and renal assessment is done for all patients that are to receive Ramdesivir as provided in the product labeling information.
- 6) It's important that prothrombin time is determined for all patients that are to receive Remdesivir.

NDA wishes to remind importers and clinicians of their responsibility towards their patients as regards the above.

For further information or clarification please contact the undersigned

David Nahamya

**SECRETARY TO THE AUTHORITY**

### HEAD OFFICE

Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda  
Tel: (+256) 417 788 100/1 (+256) 417 788 124/417 788 129  
Toll Free: 0800 101 999, ☎ 0791 415 555  
Website: [www.nda.or.ug](http://www.nda.or.ug), Email: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug)  
Facebook: Uganda National Drug Authority  
Twitter: @UNDAuthority  
**NATIONAL DRUG QUALITY CONTROL LABORATORY**  
Tel: (+256) 414 540 067 / (+256) 414 583 095

### OUR MISSION

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

### REGIONAL OFFICES

Central Region, Nakawa - Tel: +256 393 261 548,  
Western Nile Region, Arua - Tel: +256 414 671 033,  
South Western Region, Mbarara - Tel: +256 414 671 034,  
South Eastern Region, Jinja - Tel/Fax: +256 434 122 176,  
Eastern Region, Tororo - Tel: +256 454 445 195,  
Western Region, Hoima - Tel./Fax +256 465 440 688,  
Northern Region, Lira - Tel/Fax +256 414 671 032