DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

4th November 2020

735/NDA/DPS/11/2020

CIRCULAR NO: 040

To: All Pharmaceutical Importers

Re: Pharmacovigilance requirements for Remdesivir products under emergency importation

Reference is made to our communication ref no. 008/DIE/2020 dated 23rd September 2020 regarding the emergency importation of Remdesivir in the context of the COVID 19 Pandemic.

In line with the National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014, all entities that have been authorised to import Remdesivir should take note of the following safety monitoring requirements to ensure its continuous safe use;

a) Before importation, please submit a duly signed pharmacovigilance system for collecting and analysing safety and efficacy data during the use of the product to the National Drug Authority for review and approval.

b) Submit on a quarterly basis, updates of the safety and efficacy information collected.

c) Submit the names and contact details of the responsible person for Pharmacovigilance (QPPV)

Importers who have already been authorized to import the product are expected to submit documentation of their systems in accordance with requirement (a) above within one month from date of this communication.

Thank you for your continued cooperation.

Sincerely,

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, Email: 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,
Northen Region, Lira- Tel/Fax +256 414 671 032