DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

24th April 2018

344/NDA/DPS/04/2018

To: All Market Authorization Holders
Local Technical Representatives

CIRCULAR NO. 12

Subject: Pharmacovigilance requirements for Market Authorization Holders in Uganda

Reference is made to the National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014. Market Authorization Holders (MAH) are required to have an appropriate system for pharmacovigilance and risk management in place in order to assure responsibility and liability with regards to the safety, efficacy and quality of their products on the Ugandan market.

NDA developed, and following stakeholder consultation approved the fore-mentioned guideline as part of the implementation road map for this regulatory requirement.

Effective 26th April, 2018, all market authorization holders will be required to implement pharmacovigilance requirements as prescribed in the "***Guidelines on submitting periodic safety update report and any other reports that may be relevant to determine the safety, efficacy and quality of a drug***". The approved copies of these guidelines can be accessed on the NDA website, and through all our offices

The Authority remains committed to ensuring that safe, efficacious and good quality drugs are available to the population of Uganda at all time.

Sincerely,

Helen Byomire Ndagije
DIRECTOR PRODUCT SAFETY

HEAD OFFICE
Plot 19 Lumumba Avenue
P.O. Box 23096, Kampala, Uganda
Tel: (+256) 414 255665/347391/347392
Fax +256 414 255758
Hotline:(+256) 414 344052, 776 110 008, 712 001 199
Website: www.nda.or.ug, Email: ndaug@nda.or.ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority

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

REGIONAL OFFICES
Central Region, Nakawa - Tel: +256 312 261 548,
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 434122 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