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NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

PRESS RELEASE
FOR IMMEDIATE RELEASE

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RE: NATIONAL DRUG AUTHORITY HAS NOTIFIED COVIDEX AS A LOCAL HERBAL MEDICINE.

Kampala, – June 29, 2021. National Drug Authority (NDA) informs the public that after a record time of 14 days of engagements with the innovators and assessments of the product information, Covidex, has been notified to be sold in licenced drug outlets for supportive treatment in management of viral infections **BUT NOT** as a cure of COVID-19. The product should be used under the guidance of a professional health worker. Notification is an initial approval granted to herbal medicines based on evaluation of scientific data to confirm the quality, safety and efficacy of the drug and inspection of the factory for good manufacturing practices.

As you are all aware, on June 14th 2021, NDA released a statement notifying the public that it had not authorized the production, sell and use of Covidex (manufactured by Jena Herbals Uganda Ltd) that had claims of preventing and treating COVID-19. NDA engaged with innovators and an application for notification was submitted on June 15th, initial assessments were scientifically done and a response with further guidance was sent to the innovators within three days! NDA received the answers on June 27th and a comprehensive assessment was undertaken including an inspection of the factory to assess compliance with good manufacturing practices to ensure that the product is of good quality, safe and efficacious. After engagements, the innovators have removed unsubstantiated claims that the product treats and prevents COVID-19 and revised it to ***supportive treatment in management of viral infections.***

NDA has granted Covidex an approval based on initial assessment, published literature and safety studies conducted by the innovator. The product has been formulated from herbal plants that have been traditionally used to alleviate symptoms of several diseases. To further support the efficacy of the drug for other uses, NDA has advised the manufacturer to conduct random controlled clinical trials which are the highest level of evidence to ascertain any claims of treatment.

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As our standard procedure, NDA will continue to monitor the safety of Covidex through our post-market surveillance activities. We call upon the public to immediately report any side effects from use of this product on our toll free line **0800 101 999.**

NDA remains committed to ensuring that all drugs imported, produced and sold in Uganda are of good quality, safe and efficacious as a way of safeguarding public health as empowered by the National Drug Policy and Authority Act cap 206. NDA also prioritises research and development of traditional medicine, that's why we have in place a comprehensive Herbal Medicine Guidelines for local drug research, a herbal unit that engages, trains and provides technical support to herbal medicine manufacturers to improve the quality of their products and with these efforts, in the last 3 years, NDA has authorized over 190 local herbal products and provided technical support through over 70 inspection of local herbal medicine manufacturers.

NDA advises all innovators and manufacturers whose products have not been notified to engage with our team for assistance to have their products assessed. We advise the general public to only buy drugs from licenced drug outlets and avoid self-medication especially of prescription drugs. We encourage everyone to follow Ministry of Health (MOH) guidelines and SOPs and always seek treatment from licenced heath facilities.

ENDS