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NDA sued over fake Hepatitis B Vaccines

Three companies that procured Hepatitis B vaccines said to be fake have sued the National Drug Authority (NDA), saying the drugs were approved by the authority and are genuine.

Safe Script Pharmaceuticals, Eloipharm Uganda Limited and Agnes Gudoi Nabulwala are jointly accusing NDA of acting high-handedly and wantonly when they declared their imported Hepatitis B vaccines fake, thereby causing them losses.

The applicants are, therefore, seeking damages accruing from the losses they have incurred since many clients have shunned their vaccines, while others who have been immunised have asked for a refund of their money. The vaccine, which is administered in three doses apart, costs between sh20,000 and sh30,000 per dose.

Court documents indicate that the first and second applicants are licensed pharmaceuticals duly authorised by NDA to carry out sale and distribution of pharmaceutical products. The second applicant (Safe Script) is further a certified and approved importer of drugs.

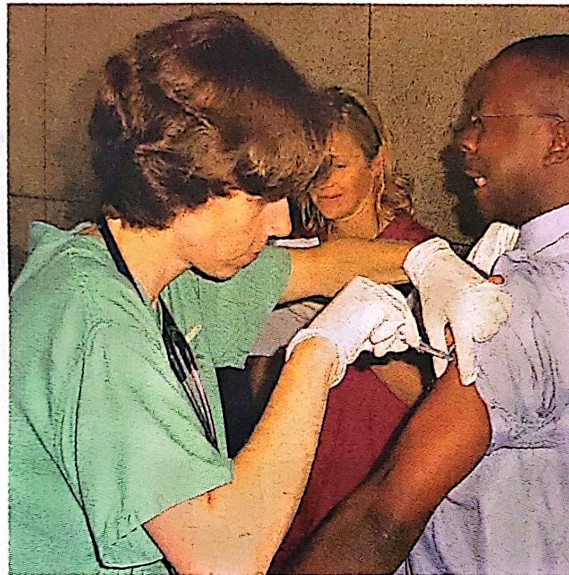
The third applicant, Nabulwala, who is trading as Alpha Clinical Laboratory, is registered and certified to carry out clinical services, including immunisation.

The petitioners are seeking to have NDA's decision to stop Safe Script and Eloipharm from supplying the vaccine for immunisation of Ugandans quashed.

They contend that NDA's directive to pharmacies that are in possession of the 10ml multi-dose Hepatitis B vaccine vials manufactured by Serum Institute of India to halt their use also be quashed, as they were certified and approved by the drug authority.

The court documents indicate that Eloipharm was contracted by Safe Script to import the vaccines and that Safe Script imported the vaccines, which Eloipharm later sold to Nabulwala. According to the documents, it is Nabulwala who has been using the product to carry out massive immunisation of Hepatitis B in accordance with the government programme and campaign.

According to court documents, the petitioners state that while immunisation was going on, NDA issued a statement indicating that the type of vaccine used by the



A medical worker injects a patient. NDA recently issued a statement indicating that the type of vaccine used by the applicants was fake and must be halted forthwith

applicants was fake and must be halted forthwith.

They aver that at the time of halting the immunisation exercise, they had already administered several doses

of the vaccine to many people. Some people had got the first and second doses, while others had got all the prescribed three doses.

According to Nabulwala,

the managing director of Safe Script, they vaccinated staff of Naalya Hillside Primary School Wakiso district and pupils above 10 years with consent from their parents. Also, members of staff of Naalya Secondary School in Namugongo were immunised as well as students and staff of Mbale School of Nursing and Midwifery. Nabulwala said they had just started vaccinating residents of Entebbe Municipality when NDA stopped them.

According to Helen Byomire Ndagije, the NDA director for product safety, their team visited the registered importer of the Serum brand and established that they did not have any stock of multi-dose (10ml) hepatitis B vaccine for the private sector.

The importer only had stock for the public sector, which was clearly marked Government of Uganda, not for sale.

The importer stated that they had not imported or distributed any 10ml multi-dose for the private sector in the last three years. That

meant that all 10ml multi-dose Hepatitis B vaccines in the private sector were either counterfeit or illegally imported.

"Vaccines from Serum Institute are available in two registered pack sizes, 1ml ampoules and 10ml multi-dose vials. The 1ml ampoule pack is supplied to the private market and is identified by a white label with two green bands at the top and bottom part of the label, respectively. The 10ml multi-dose vial is supplied to the public sector (government) and is identified by a white label with two purple bands at the top and bottom part of the label, respectively. The one supplied to the government also bears the words, 'Government of Uganda, Not for sale'.

The registered importer of this product is Norvik Enterprises Limited, located on Bombo Road," Muhammed Lukwago, the NDA head of eastern region, said.

But the applicants insist they legally imported the drugs and want court to declare that the 10ml multi-dose Hepatitis B vaccines in their possession are genuine, as they were certified and approved by NDA.

The petitioners also attached a copy of the verification certificate number VC-2017-5619 dated October 4, 2017, which NDA issued Eloipharm upon importation of the drugs via Entebbe airport.

By press time, NDA was yet to respond to the application.