

DRUG



NATIONAL AUTHORITY

Safe Drugs Save Lives

25th July 2022

1235/ID/NDA/07/2022

Attention: All Domestic Pharmaceutical Manufacturers

CIRCULAR NO. 003/DIE/2022

RE: BAN ON THE USE OF CHLOROFORM (TRICHLOROMETHANE) IN PHARMACEUTICAL PREPARATIONS

The above subject matters.

Chloroform is a Class II organic solvent that has had a long history of use in the manufacture of pharmaceutical products. It has been used in the manufacture of drug products as an antitussive, counter-irritant, preservative, flavoring agent and solvent.

Several reputable studies have suggested that chloroform may be carcinogenic in rats and mice when administered over prolonged periods, although there is no direct evidence that chloroform as used in drugs has caused injury to the health of humans.

This however raises concerns about the long term safety of this solvent in finished pharmaceutical products and its potential as a human carcinogen.


The use of this solvent in pharmaceutical preparations has been banned in jurisdictions such as the USA, Canada, UK and most of Europe.

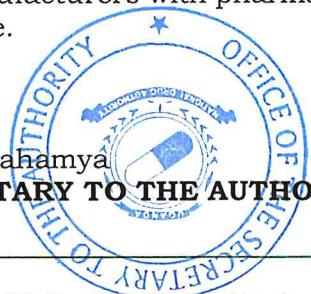
In light of this information and in a bid to ensure that only safe, quality and efficacious pharmaceutical products are available to the citizens of Uganda, National Drug Authority hereby **bans** the use of chloroform in all pharmaceutical preparations.

Marketing Authorization holders for all Finished pharmaceutical products registered with manufacturing processes that involve chloroform are hereby notified to reformulate their products to exclude chloroform and file relevant variations with National Drug Authority.

This ban takes effect on the **1st October 2022**. No recall will be required for pharmaceutical products manufactured and marketed in accordance with existing marketing authorizations before this date.

All manufacturers with pharmaceutical products in this category are expected to comply with this directive.


David Nahamya
SECRETARY TO THE AUTHORITY



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OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

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