

5th May 2023

601/ID/NDA/05/2023

All importers and distributors

CIRCULAR NO. 002/DIE/2023

IMPORTATION AND DISTRIBUTION OF HYPODERMIC SYRINGES AND NEEDLES

National Drug Authority through the National Drug Policy and Authority (NDPA) Act Cap 206 regulates surgical instruments and appliances to ensure that they meet the quality, safety and performance standards.

Among the surgical instruments and appliances are the hypodermic syringes and needles which we have identified through our post market surveillance systems as having a differing understanding of the applicable quality requirements.

In pursuit of attaining systematic application and reduction on the burden of meeting the requirements for import and distribution, the National Drug Authority clarifies as follows;

- 1) Hypodermic syringes and needles are regulated under the NDPA Act Cap 206 and are classified under Class B Drugs, Group II and also included in the Surgical Instruments and Appliances Regulation Statutory Instrument No. 77. of 2019.
- 2) The syringes and needles are required to meet safety and performance standards as laid down in the ISO 7886-4, ISO 7864 and US 2140.
- 3) The National Policy on Injection Safety and Healthcare Waste Management 2004 requires that all syringes and needles of 10 ml and below meet the requirements for the reuse prevention feature.

National Drug Authority encourages importers and distributors to take note of the country requirements and comply with them as hypodermic syringes and needles not meeting the standards will not be authorized for distribution.


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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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