Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 JUN 2020

FDA ADVISORY
No. 20201053

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unregistered Medical Devices in Foreign Characters:**

1. **KX white box (Type C, Infusion Sticker)**
2. **10ml Syringe**

The Food and Drug Administration (FDA) warns the general public and all healthcare professionals against the purchase and use of the following unregistered medical devices:

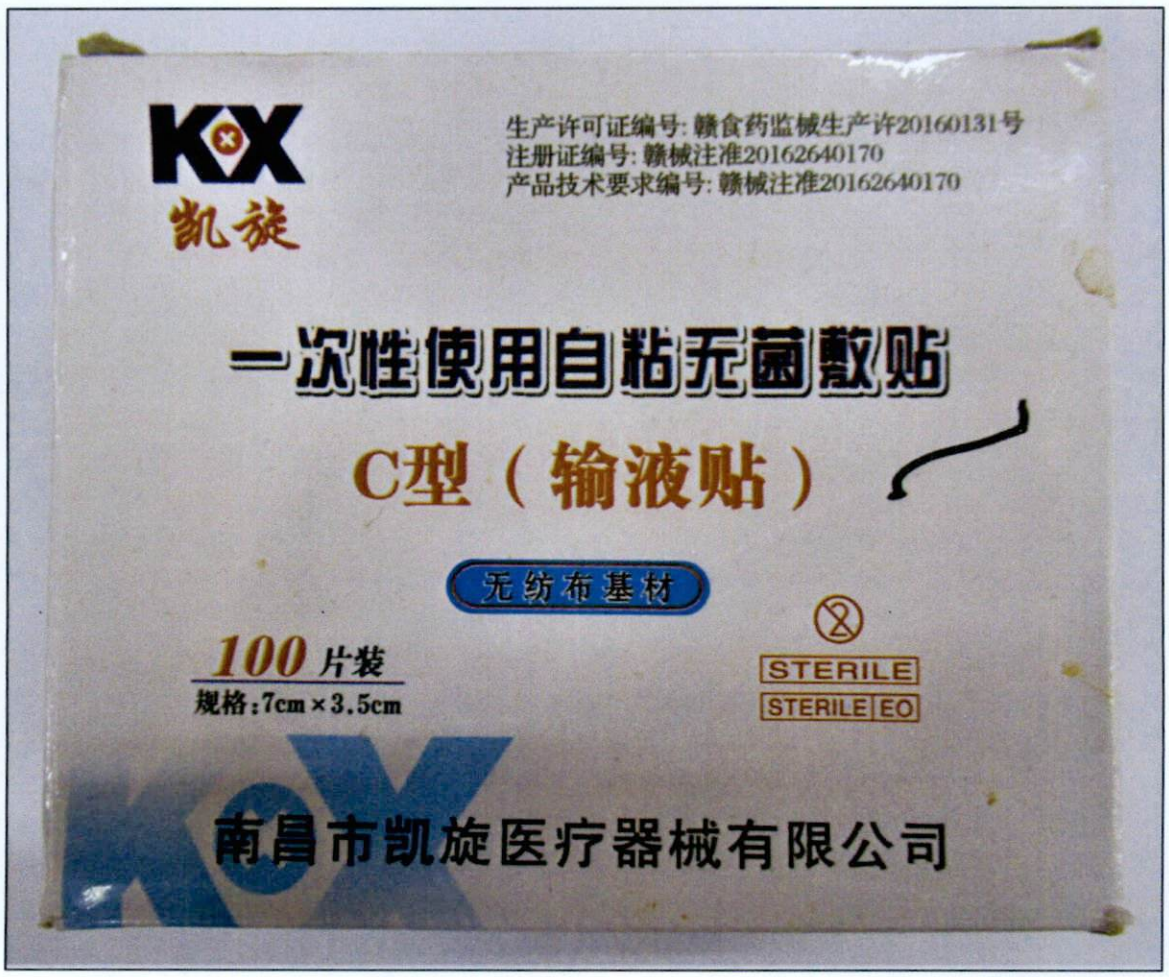

Figure 1. Unregistered KX white (Type C, Infusion Sticker) box in Chinese Character

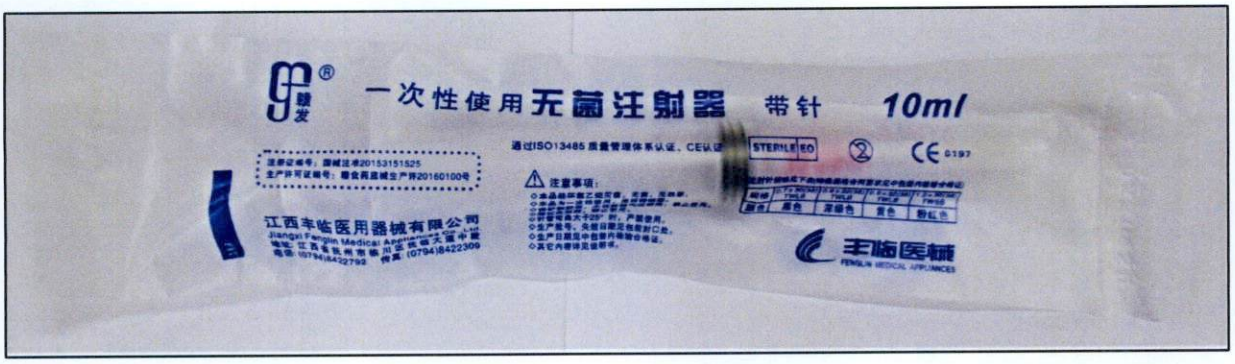

Figure 2. Unregistered 10ml Syringe in Chinese Character

The FDA verified through post-marketing surveillance conducted on 28 May 2020 that the above mentioned medical devices are not registered and no Certificate of Product Registration (CPR) have been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since these unregistered medical device products have not gone through the evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until CPR are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr-prsdd@fda.gov.ph**, or call **(02) 857-1900 loc. 8301**.

To report any sale or distribution of unregistered medical device product, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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