FDA ADVISORY
No. 2024-0501

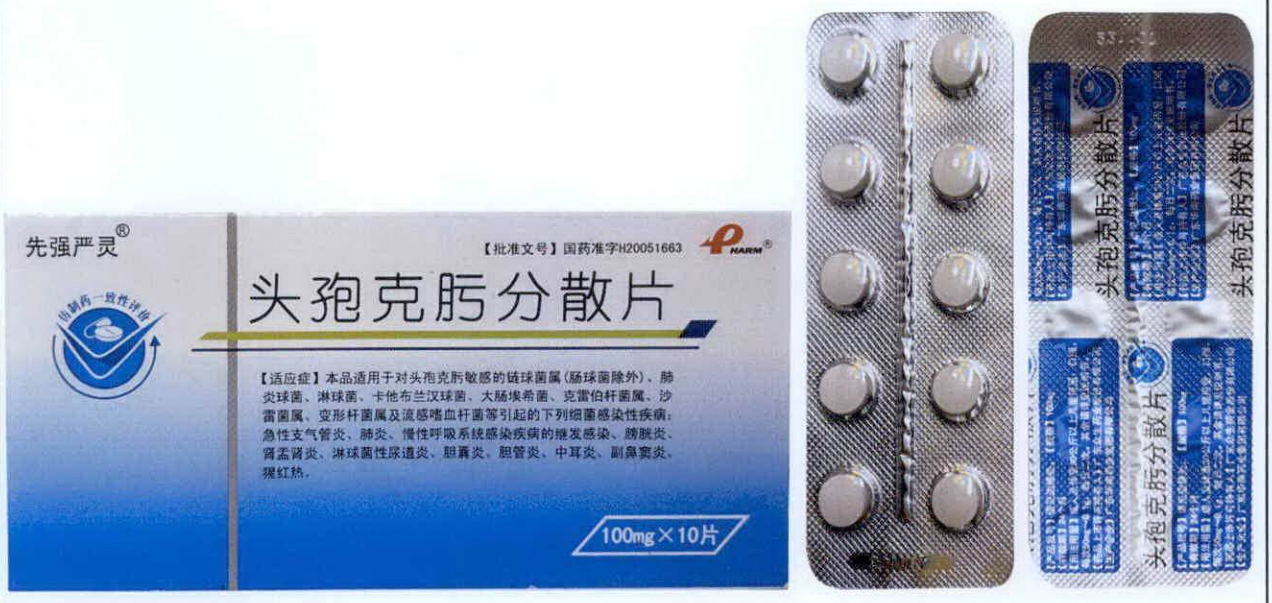
07 MAR 2024

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

SUBJECT : **Public Health Warning Against the Purchase and Use of the Unregistered Drug Products:**

1. **Pharm® Tuobaokewo Fenspian – Cefixime Dispersible Tablet [as reflected in package insert]**
2. **Levofloxacin Hydrochloride Ear Drops 5 mL**
3. **Vitamin B12 Injection 1mL: 0.25mg Ampoule**
4. **Fenhuangyi'An Zhusheye 2mL:0.5 g Ampoule**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



Pharm® Tuobaokewo Fenspian – Cefixime Dispersible Tablet [as reflected in package insert]

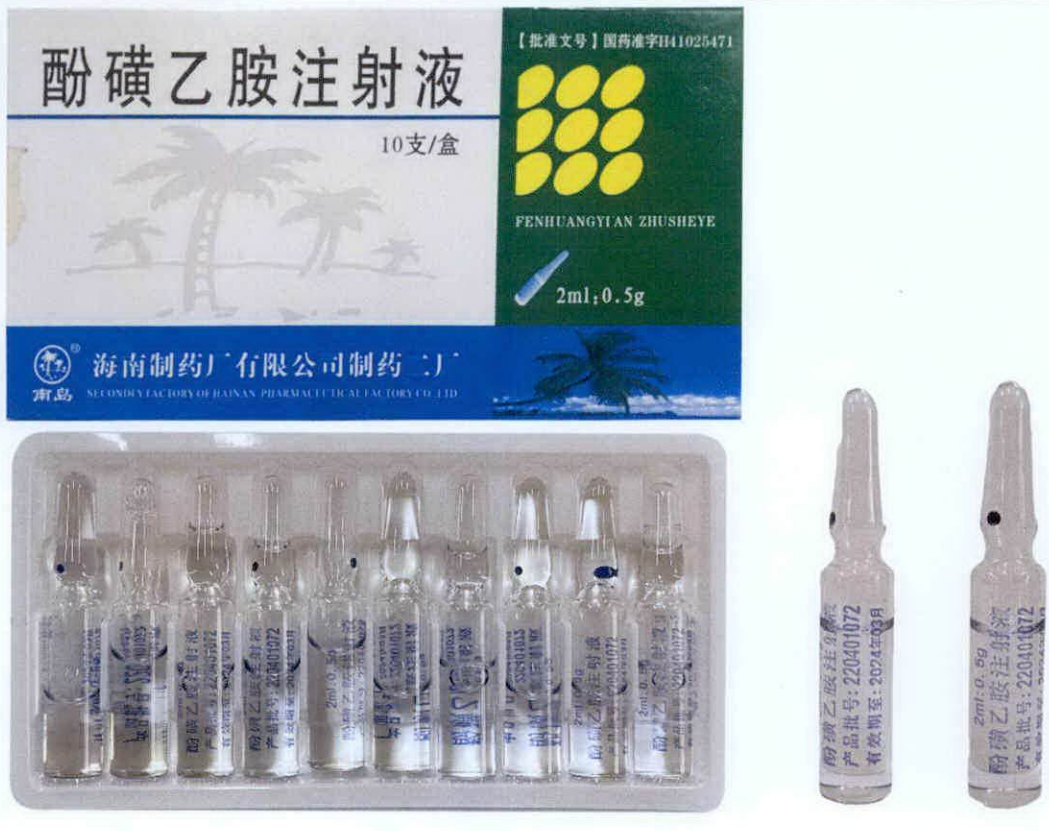
Figure 1. Unregistered drug product

Levofloxacin Hydrochloride Ear Drops 5 mL

Figure 2. Unregistered drug product

Vitamin B12 Injection 1mL: 0.25mg Ampoule
Manufactured by: Xinxiang Changle Pharmaceutical CO., LTD.

Figure 3. Unregistered drug product



Fenhuangyi 'An Zhusheye 2mL: 0.5 g Ampoule
by: Secondly Factory of Hainan Pharmaceutical Factory CO., LTD.

Figure 4. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product may pose potential danger or injury to health.

Pursuant to 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, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal feature** accessible at **https://verification.fda.gov.ph**.

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

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

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