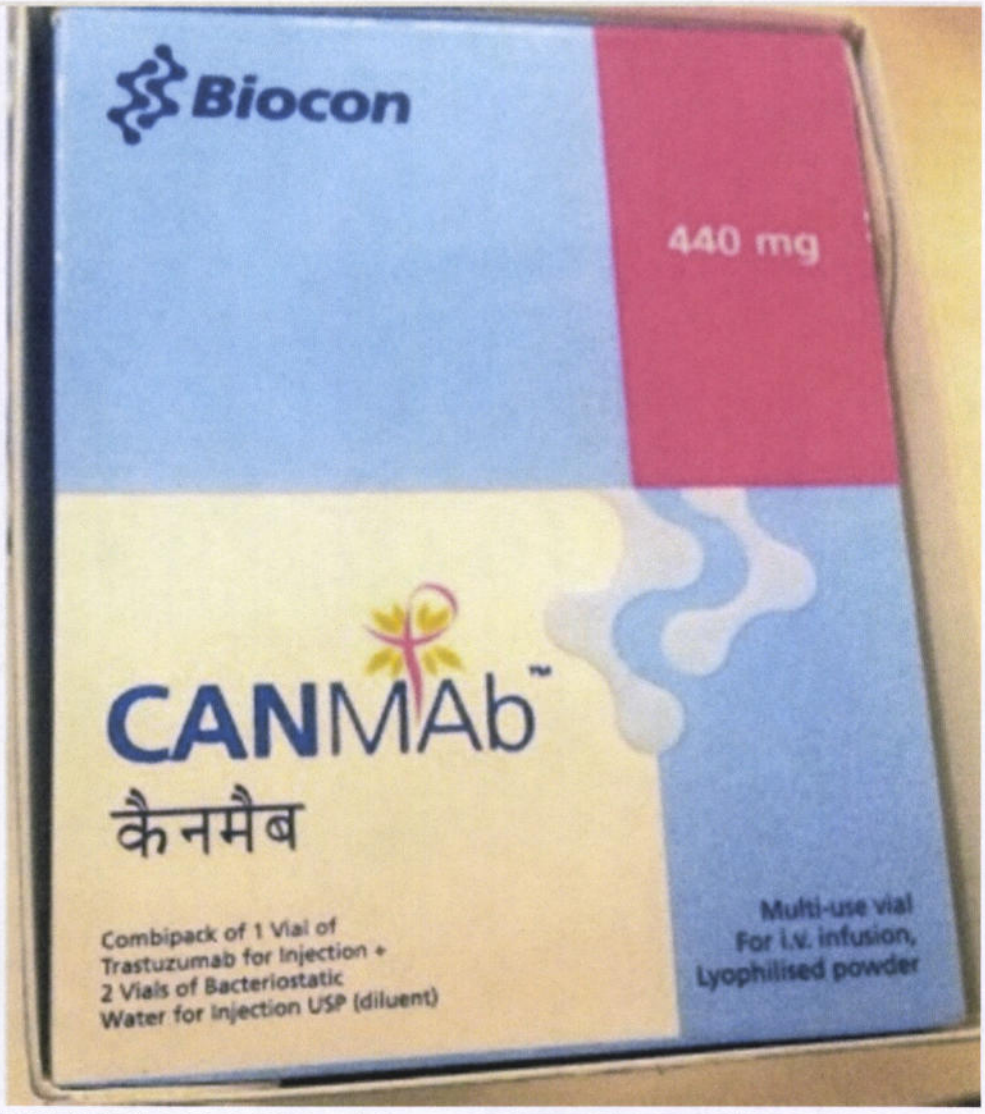
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

04 SEP 2015

FDA ADVISORY
NO. 2015-064

SUBJECT: **Public Health Warning Against the Use of the Unregistered Drug Product "Trastuzumab (CANMAb) 440 mg Lyophilised Powder for I.V. Infusion"**

The Food and Drug Administration advises the public against the use of the following unregistered drug product:



TRASTUZUMAB (CANMAB) 440 mg LYOPHILIZED POWDER FOR I.V. INFUSION
Marketing Authorization Holder: Biocon

Figure 1.Unregistered Drug Product

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug product. This poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Officers of the Field Regulatory Operations Office (FROO) are hereby ordered to seize the aforementioned unregistered drug product found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified product. Anyone found selling the said product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this product is not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration and testing are measures that the government undertakes to ensure the quality, safety and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN:20150807111901

[1] Pursuant to DPO 2015-1845