



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. **2016-063**

20 JUN 2016

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

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

1. Phenytoin (Dilantin) Capsules 100 mg (Manufactured by Pfizer Limited – Pfizer Centre, Patel Estate, off. S.V. Road, Jogeshwari (W), Mumbai 400 102 at C-4/13, MIDC, Bhosari, Pune 411 026)
2. Digoxin (Lanoxin) Tablet 0.25 mg (Imported by A. Menarini (Thailand) Limited, Bangkok)
3. Methimazole (Tapazole) Tablet 5 mg (Manufactured by OLIC (Thailand) Limited – Ayutthaya, Thailand)

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

 <p><b>Phenytoin (Dilantin) Capsules 100 mg</b> Manufactured by Pfizer Limited – Pfizer Centre, Patel Estate, off. S.V. Road, Jogeshwari (W), Mumbai 400 102 at C-4/13, MIDC, Bhosari, Pune 411 026</p>	 <p><b>Digoxin (Lanoxin) Tablet 0.25 mg</b> Manufactured by Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany for Aspen Global Inc. Imported by A. Menarini (Thailand) Limited, Bangkok</p>
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Figure 1. Unregistered Drug Products



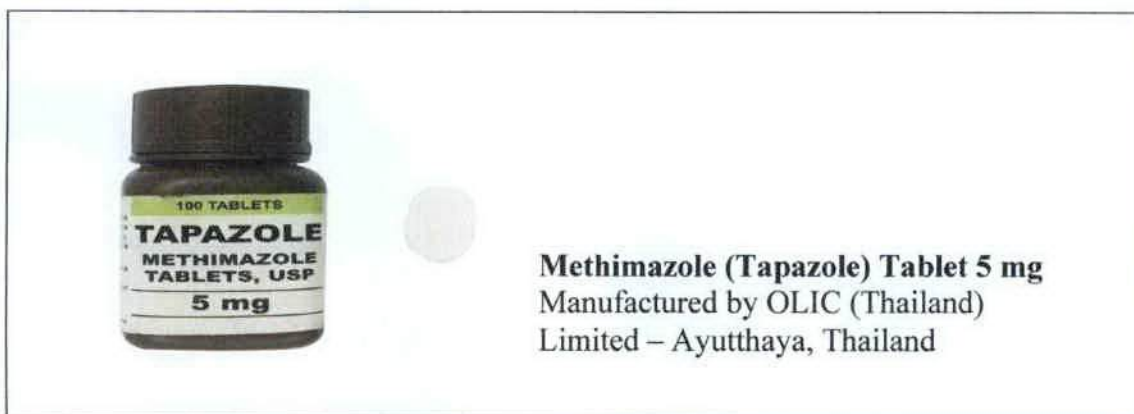


Figure 2. Unregistered Drug Product

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug products. These pose 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, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

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

Likewise, all local government units and law enforcement agencies are requested to ensure that these products are 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 e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [report@fda.gov.ph](mailto: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](http://www.fda.gov.ph/adr-report-new) and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
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