



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

14 April 2015

**CERTIFICATION**

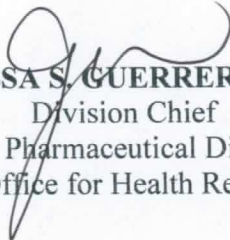
This is to certify the provisional exemption for one year, effective upon receipt of this certificate, of the following medicine:

Medicine: **Bedaquiline fumarate 100 mg tablet**

Indication: Indicated for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDRT-TB) in adults (>18 years) patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

The product shall only be utilized by the Disease Prevention and Control Bureau- National Tuberculosis Program, and the concerned proponent shall provide to the Formulary Executive Council (FEC) through the Pharmaceutical Division the following: (1) local safety profile; (2) surveillance report on adverse effects; and (3) impact study/outcomes of patients using the product. These shall be submitted after expiration of the validity.

For compliance and strict implementation.

  
**ANNA MELISSA S. GUERRERO, MD, MPH (HTA)**  
Division Chief  
Pharmaceutical Division  
Office for Health Regulation

PNFX-2015-019