



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

17 April 2018

CERTIFICATION

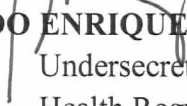
This is to certify the **one (1) year** provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following medicine:

Medicine: **Insulin glargine rDNA 100 IU/mL, 3 mL vial**

Indication: Once daily subcutaneous administration for the treatment of: (a) adult and pediatric patients with type I diabetes mellitus; and (b) adult patients with type II diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

The product shall only be utilized by the requesting party – the Armed Forces of the Philippines Medical Center (AFPMC). Likewise, the concerned proponent shall provide the Formulary Executive Council (FEC), through the Pharmaceutical Division, the following documents at the end of exemption validity: (1) local efficacy and safety profile; (2) surveillance report on adverse effects; (3) registry of patients; and (4) impact study/outcomes of patients using the product.

For compliance and strict implementation.


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Health Regulation Cluster

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