



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

02 April 2019

**CERTIFICATION**

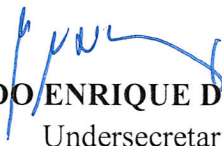
This is to certify the **one (1) year** provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the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

Medicine: **Alglucosidase Alfa 50 mg lyophilized powder for concentrate solution per vial**

Indication: Long-term Enzyme Replacement Therapy (ERT) in patients with a confirmed diagnosis of Pompe disease.

The product shall only be utilized by the requesting party – the Institute of Human Genetics, National Institutes of Health (NIH-IHG). 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.

  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**  
Undersecretary of Health  
Health Regulation Team

PNFX-2019-004