



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

23 January 2017

CERTIFICATION

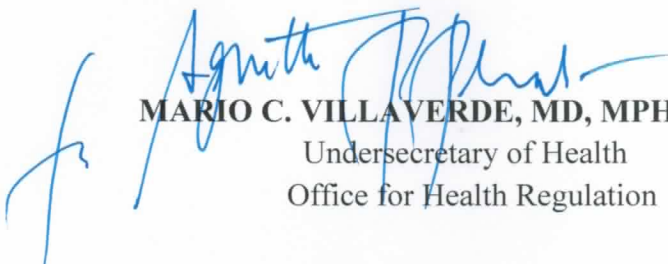
This is to certify the one (1) year provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following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


MARIO C. VILLAVERDE, MD, MPH, CESO I
Undersecretary of Health
Office for Health Regulation

PNFX-2017-004