



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

23 January 2017

**CERTIFICATION**

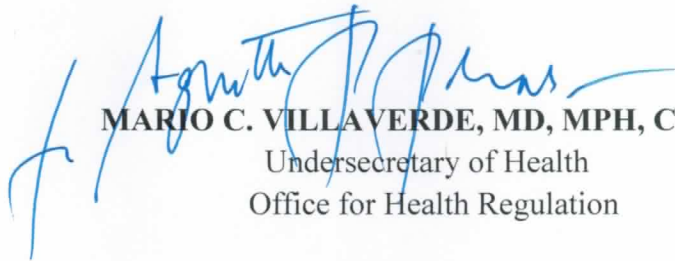
This is to certify the one (1) year provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following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

Medicine: **Laronidase 580 mcg/mL (2.9 mg/5 mL) concentrated solution per vial**

Indication: Enzyme Replacement Therapy (ERT) for Patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidoses I (MPSI) and for patients with the Scheie form who have moderate to severe symptoms.

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.

A handwritten signature in blue ink, appearing to read "Mario C. Villaverde", is written over the typed name and title.

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

PNFX-2017-002