



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: **Idursulfase 2 mg/mL (6 mg/3 mL) concentrate solution per vial**

Indication: Enzyme Replacement Therapy (ERT) for Patients with Hunter syndrome or Mucopolysaccharidosis II (MPSII).

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

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