



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

12 November 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: **Carglumic acid 200 mg dispersible tablets**

Indications: For the treatment of the hyperammonaemia due to the following: (a) N-acetylglutamate synthase primary deficiency; (b) isovaleric acidaemia; (c) methymalonic acidaemia; and, (d) propionic acidaemia.

The product shall only be utilized by the requesting party – the **Institute of Human Genetics, National Institutes of Health (NIH-IHG)**. The exemption of the above product is granted while awaiting the implementation of the Republic Act No. 10747, otherwise known as the "*Rare Disease Act of the Philippines.*" 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-2018-033