



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

12 November 2018

CERTIFICATION

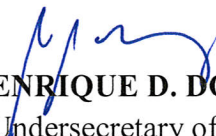
This is to certify the **one (1) year** provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the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

Medicine: **Sodium benzoate 2 gm in 10 mL injection (IV)**

Indications: Acute and maintenance treatment of hyperammonemia in patients with urea cycle disorders (UCD) involving deficiencies of the following enzymes: carbamyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), arginosuccinic acid synthetase (AS), arginosuccinase (AL), arginase, and N-acetylglutamase synthase (NAGS).

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.


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Undersecretary of Health
Health Regulation Team

PNFX-2018-032