



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

06 December 2018

CERTIFICATION

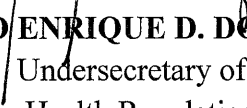
This is to certify the **one (1) year** provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the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

Medicine: **Polymyxin B sulfate 500,000 units powder for solution for injection, 5mL vial**

Indication: Treatment of infections of the blood stream caused by susceptible strains of *Pseudomonas Aeruginosa*. It may be indicated in serious infections caused by susceptible strains of the following organisms: *Haemophilus influenzae*; *Escherichia coli*; *Aerogenes*, specifically bacteremia; *Klebsiella pneumoniae*, specifically bacteremia.

The product shall only be utilized by the requesting party – the Philippine General Hospital (PGH). 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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Health Regulation Team

PNFX-2018-038