



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

25 October 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: **Gadoteric acid 0.5 mmol/mL solution for injection in vials (5 mL, 10 mL, 15 mL and 20 mL) or pre-filled syringes (15 mL and 20 mL)**

Indication: Contrast medium for magnetic resonance imaging (MRI) in central nervous system (CNS) and whole body indications including angiography.

The product shall only be utilized by the requesting party – the Philippine Children's Medical Center (PCMC). 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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