



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

18 April 2017

**CERTIFICATION**

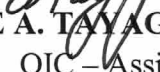
This is to certify the one (1) year provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following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

Medicine: **Levetiracetam 500 mg/5 mL concentrate for solution for IV infusion**

Indication: Control of generalized tonic-clonic status epilepticus, or focal motor status epilepticus, particularly in patients in whom other anti-convulsants are contraindicated (e.g., where severe hypotension or cardiac events are present, hepatic diseases, bone marrow disease); control of generalized tonic-clonic seizures or focal seizures when oral anti-convulsants cannot be administered.

The product shall only be utilized by the requesting party – the National Kidney and Transplant Institute (NKTi). 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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Office for Policy and Health Systems

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