



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

02 August 2017

CERTIFICATION

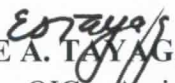
This is to certify the one (1) year provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following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

Medicine: Iloprost 10 mcg/mL inhalation

Indication: For the treatment of pulmonary hypertension in the following situations: (a) treatment of pulmonary artery hypertension (PAH) in the immediate post-operative period to prevent or treat pulmonary artery hypertensive crisis in shunt anomalies, valve surgeries or complex heart disease with severe but reversible pulmonary artery hypertension; (b) treatment of PAH for Functional class III patients with Eisenmenger Physiology and class IIb for Functional class IV patients with Eisenmenger physiology; and (c) as part of combination treatment for PAH.

The product shall only be utilized by the requesting party – the Philippine Heart Center (PHC). 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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