



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

04 May 2015

CERTIFICATION

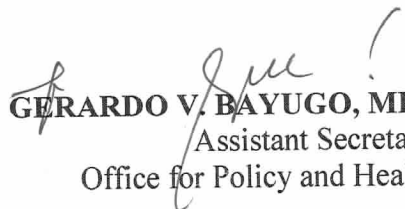
This is to certify the provisional exemption for one year, effective upon receipt of this certificate, of the following medicine:

Medicine: **Tolvaptan 15 mg tablet**

Indication: Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium $<125\text{mEq/L}$ or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH) and as adjunct treatment of volume overload in heart failure when adequate response is not obtained with other diuretics (loop diuretics).

The product shall only be utilized by the requesting party – the National Kidney and Transplant Institute, and the concerned proponent shall provide to the Formulary Executive Council (FEC) through the Pharmaceutical Division the following: (1) local safety profile; (2) surveillance report on adverse effects; and (3) impact study/outcomes of patients using the product. These shall be submitted after expiration of the validity.

For compliance and strict implementation.


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