



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

01 December 2015

CERTIFICATION

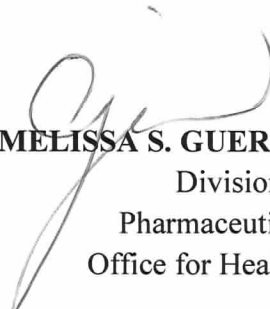
This is to certify the provisional exemption for one year, effective upon receipt of this certificate, of the following medicine:

Medicine: Terlipressin acetate 1 mg lyophilized powder for IV injection

Indication: Type 1 Hepatorenal Syndrome, characterized by spontaneous acute renal insufficiency, in patients suffering from severe cirrhosis with ascites

The product shall only be utilized by the requesting party – the Philippine General Hospital, and the concerned proponent shall participate in the local study: **“Prospective, Multi-center Observational Study of the Efficacy and Safety of Terlipressin for the treatment of Type 1 Hepatorenal Syndrome.”** The result of the study shall be submitted to the Formulary Executive Council (FEC) through the Pharmaceutical Division after expiration of the validity.

For compliance and strict implementation.


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Division Chief
Pharmaceutical Division
Office for Health Regulations

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