



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 National Kidney and Transplant Institute, 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.

  
**ANNA MELISSA S. GUERRERO, MD, MPH (HTA)**

Division Chief  
Pharmaceutical Division  
Office for Health Regulations

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