



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

05 September 2019

**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: **Mitomycin C 10 mg powder for injection vial**

Indication: Chemotherapeutic agent used in the trans-arterial chemoembolization (TACE) of hepatocellular carcinoma

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.

  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**

Undersecretary of Health  
Health Regulation Team

PNFX-2019-009