



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: **Ethiodized oil 10 mL ampule**

Indication: Selective hepatic intra-arterial use for imaging tumors in adults with unknown hepatocellular carcinoma (HCC); a vehicle to carry and localize the chemotherapeutic agent inside the tumor and as microembolic agent for tiny tumor vessels in transarterial chemoembolization (TACE) using lipiodol-based regimens.

The product shall only be utilized by the requesting party – the National Kidney and Transplant Institute (NKTII). 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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