



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

15 October 2018

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: **Human menopausal gonadotrophin (MHG, menotrophin) freeze-dried powder for injection, 75 IU FSH + 75 IU LH per ampul + 1 mL solvent (IM)**

Indication: For anovulation (including polycystic ovary syndrome) and controlled ovarian hyperstimulation for the purpose of inducing the development of multiple follicles in connection with assisted reproduction medicine [e.g.: in-vitro fertilization/ embryo transfer (IVF/ET) and intracytoplasmic sperm injection (ICSI)] in women. For insufficient spermatogenesis caused by hypogonadotrophic hypogonadism in men.

The product shall only be utilized by the requesting party – the **Armed Forces of the Philippines Medical Center (AFPMC)**, otherwise known as **Victoriano Luna Medical Center (VLMC)**. 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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