



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

18 September 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: **Ticagrelor 60 mg and 90 mg film-coated tablet**

Indication: The 60 mg tablet is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction, and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event. On the other hand, the 90 mg tablet is indicated for the prevention of thrombotic events (cardiovascular death, MI, and stroke) in patients with Acute Coronary Syndromes (ACS), unstable angina, non-ST elevation myocardial infarction (NSTEMI) or ST elevation MI (STEMI) including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).

The product shall only be utilized by the requesting party – the **Philippine Heart Center (PHC)**. 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

P N F X - 2 0 1 8 - 0 2 8