

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

12 July 2018

FRANCISCO T. DUQUE III, MD, MSc

Secretary
Department of Health

Dear Secretary Duque:

The Formulary Executive Council (FEC) respectfully recommends the **DISAPPROVAL** of the inclusion of **exemestane 25 mg tablet** in the Philippine National Formulary (PNF) based on the review of available evidence and consultation with local specialists. On 23 May 2016, the proponent (i.e., Philippine Society of Medical Oncology (PSMO)) presented to the FEC the updates on hormonal treatment of breast cancer, wherein it was pointed out that using the National Comprehensive Cancer Network (NCCN) evidence blocks, the utilization of anastrozole and exemestane in breast cancer risk reduction strategy for post-menopausal women have almost the same level of evidence in terms of safety, efficacy, and consistency. It was likewise reported that based on the guidelines of the American Society of Clinical Oncology (ASCO) and European Society of Medical Oncology (ESMO), aromatase inhibitors (AIs) (both non-steroidal and steroidal) and tamoxifen are valid options for postmenopausal women. This recommendation was also reflected in the draft Clinical Practice Guidelines for Stages 0-IIIB Breast Cancer at First Diagnosis developed by the Breast Cancer Medicines Access Program Technical Working Group of the Department of Health.

On 23 May 2018, the FEC deliberated on the inclusion of the said drug based on the results of the initial review of clinical trials conducted by the Health Technology Assessment unit (HTA) Unit under the DOH - Health Policy Development and Planning Bureau (HPDPB), which was supplemented by several rounds of consultation with local specialists. The said review showed that exemestane has comparable clinical effectiveness with the other AIs (e.g., letrozole and anastrozole) and tamoxifen in the treatment of early-stage breast cancer. The only significant difference between the therapies is the observed adverse events, mainly bone thinning for all AIs, which can be prevented by intake of calcium and bisphosphonate therapy. With regard to the cost, exemestane remains to be the most expensive option among all AIs at the current price of Php 376.24 per tablet.

The Council noted that tamoxifen and letrozole are already included in the PNF, hence given the limited added clinical benefit and its higher cost relative to the other treatment options, the Council recommended the **DISAPPROVAL** of the inclusion of exemestane in the PNF.

Please be informed that the above recommendation was posted on the website of the Pharmaceutical Division for 30 days to accommodate any comment or appeal from the stakeholders prior to final decision-making.

For your disposition, Sir.

Thank you and best regards.

Very truly yours,

For the Formulary Executive Council

Recommending approval of the FEC recommendation:

Finla a. Bagataldo ATTY. FROILAN BAGABALDO

Formulary Executive Council

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health

Health Regulation Cluster

Approval of the FEC recommendation:

FRANCISCO 7. DUQUE III, MD, MSc