Republic of the Philippines
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

17 May 2016

JANETTE LORETO GARIN, MD, MBA-H
Secretary
Department of Health

Dear **Secretary Garin:**

After evaluating the application for inclusion of the below listed medicines in the Philippine National Formulary (PNF), the Formulary Executive Council (FEC) respectfully recommends the **DISAPPROVAL** of the said requests:

1. **Clevudine 30 mg capsule**

   This is not included in the World Health Organization Guidelines for the Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection (March 2015). There was a clinical trial conducted in South Korea on the use of clevudine for Hepatitis B, wherein safety issues were seen. There were spontaneous reports of myopathy in patients who took clevudine for a long period of time. Hence, its market authorization in South Korea was withdrawn.

2. **Abiraterone acetate 250 mg tablet**

   In the randomised, double-blind, placebo-controlled phase 3 study by Ryan, et al. (2015), it was found that the median overall survival was longer by 4.6 months in the abiraterone + prednisone group (34.7 months; 95% CI: 32.7 -36.8) compared to the placebo + prednisone group (30.3 months; 95% CI: 28.7 - 33.3). Likewise, abiraterone significantly decreased time to opiate use for prostate cancer-related pain by 10 months (**abiraterone:** 33.4 months; 95% CI: 30.2 -39.8 vs. **placebo:** 23.4 months; 95% CI: 20.3 - 27.5). In terms of safety profile, greater toxicity was observed in the abiraterone group as manifested by the increased Grades 1 and 2 adverse events (hypokalemia, hypertension, fluid retention) as well as Grades 3 and 4 adverse events (hypertension, cardiac disorders, increased level of alanine aminotransferase and aspartate aminotransferase).

   Its prohibitive cost of Php 775 per tablet or Php 3,100 per daily dose (Php 93,000 per month), does not justify the additional 5 months of delay in progression of the disease.

References:

3. Ryan, C., et al. (2015). Abiraterone acetate plus prednisone versus placebo plus prednisone in chemotherapy-naive men with metastatic castration-resistant prostate cancer (COU-AA-302): final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 study. *The Lancet Oncology* , 152-160.
4. Price offer submitted by Janssen (17 February 2016)

Please be informed that the above list was posted for 30 days in the website of the Pharmaceutical Division to accommodate any comment or appeal from the stakeholders.

For your disposition, Ma'am.

Very truly yours,

For the Formulary Executive Council

ATTY. FROILAN BAGABALDO
Chair
Formulary Executive Council

Recommending disapproval:

KENNETH HARTIGAN-GO, MD
Undersecretary of Health
Office for Health Regulations

Official disapproval of the above medicines:

JANETTE LORETO GARIN, MD, MBA-H
Secretary of Health