



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

25 July 2016

PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II

Secretary
Department of Health

Dear **Secretary Ubial**:

The Formulary Executive Council (FEC) respectfully recommends disapproving the inclusion of **levobupivacaine 5 mg/mL solution for injection** in the Philippine National Formulary because after evaluating the documents submitted for reconsideration, it was noted that the proposed medicine has the same efficacy with the currently listed bupivacaine. Likewise, based on the three studies presented (i.e., pre-clinical study on sheep, randomized clinical trials on 14 male healthy volunteers and 60 pregnant women), there is insufficient evidence to support the claim on superior safety of levobupivacaine compared to bupivacaine. The Council deemed that the purported advantage in terms of safety profile is theoretical.

In the mean time that the evidence is insufficient, the recommendation to disapprove **levobupivacaine** still remains.

For your disposition, Ma'am.

Thank you and best regards.

Very truly yours,

For the Formulary Executive Council

Froilan A. Bagabaldo
ATTY. FROILAN BAGABALDO

Chair
Formulary Executive Council

Recommending disapproval:

Agnette P. Peralta
AGNETTE P. PERALTA, MSc, CESO III

OIC Undersecretary
Office for Health Regulation

Official disapproval of the above medicine:

Paulyn Jean B. Rosell-Ubial
PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II

Secretary of Health