



Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City



Date: 12 October 2004

Bureau Circular
No. 14 s. 2004

SUBJECT : Submission of adverse drug reaction reports on COX-2 inhibitors as part of safety monitoring.

The Bureau of Food and Drugs, after careful evaluation on the recent voluntary withdrawal of **ROFECOXIB (VIOXX)** from the Philippine market by its local company Merck Sharp & Dohme Philippines, has determined that all concerned pharmaceutical establishments with COX-2 inhibitors are required to monitor and submit adverse drug reaction reports on serious cardiovascular events including heart attacks and strokes.

Accordingly, the following COX-2 inhibitors shall be monitored and establishments should submit a monthly adverse drug reactions reports for 3 years:

- (1) Celecoxib
- (2) Valdecoxib
- (3) Meloxicam
- (4) Etoricoxib

For strict and immediate compliance.

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