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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.

Adopted: 12 Oct. 2004

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