SUBMISSION OF ADVERSE DRUG REACTION REPORTS ON COX-2 INHIBITORS AS PART OF SAFETY MONITORING

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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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