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BANNING AND WITHDRAWAL OF TROVAFLOXACIN (TROVAN) FROM THE MARKET

BFAD ADMINISTRATIVE ORDER NO. 1, S. 2000, January 03, 2000

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The World Health Organization has released information regarding the risks posed by the use of the drug Trovafloxacin, a recently-approved fluroquinolone antibiotic. Cases of serious hepatic events have been reported including cases in which patients died or required a liver transplant. Data gathered from the reported cases suggest that the onset and the severity of the liver injuries are unpredictable.

In the light of the new information concerning the safety of the subject drug and upon the recommendation of the National Drug Committee (NDC) of the Department of Health, it is hereby ordered that all drug products containing trovafloxacin shall no longer be registrable.

Furthermore, the registration of all Trovafloxacin (Trovan) products are hereby recalled and cancelled. All stocks in the different drug distribution channels should be withdrawn immediately.

This regulation is issued for the safety and protection of the consumers.

Adopted: 03 Jan. 2000

(SGD.) ALBERTO G. ROMUALDEZ, JR. M.D.
Secretary of Health

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