

RESTRICTION OF SALE AND DISTRIBUTION OF MISOPROSTOL (CYTOTEC)

BFAD (DOH) MEMORANDUM CIRCULAR NO. 9, s. 1994, May 06, 1994

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The Bureau of Food and Drugs (BFAD) has approved the clinical indication for Misoprostol (Cytotec): the treatment and prevention of Gastritis induced by Nonsteroidal Anti-inflammatory Drugs (NSAID). However, the BFAD has received reports and complaints of the abuse/misuse of Cytotec as abortifacient. In order to stop such Illegal activity, the BFAD is mandated to restrict the sale and distribution of Cytotec.

The BFAD shall limit the sale and dispensing of Cytotec prescription drug to Tertiary Hospital Pharmacies and big drugstore chains.

Pursuant to the mandate of Republic Act No. 3720, known as the Foods, Drugs and Devices, and Cosmetics Act as amended by Executive Order No. 175, s. 1987 and consistent with Republic Act No. 6675, known as the Generics Act of 1988, paragraph 2.2.2.3 of Administrative Order No. 56, s. 1989 provides as a requirement for a retail outlet for Non-Prescription Drugs, that the BFAD shall require a Special Drugstore Record Book for Cytotec Prescriptions.

This record shall list down the Name and Address of the Patient, the quantity dispensed to the customers and the dispensing physician.

This directive shall take effect immediately.

Adopted: 6 May 1994

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Director

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