



BUREAU OF FOOD AND DRUGS
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

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BUREAU CIRCULAR
No. 4-a s. 2004

**SUBJECT Different Brand names for narcotic/Opioid Analgesic Drugs for
Cancer Pain**

Cancer Pain treatment should follow the accepted 3-step analgesic ladder based on WHO recommendation. Regular dosing is required to prevent re-emergence of pain and to minimize expectation of pain. The analgesic ladder is composed of 3 steps namely:

1. non-opioid analgesic like aspirin, paracetamol and nonsteroidal anti-inflammatory drugs.
2. less potent opioid analgesids like codeine and dihydrocodeine plus a non-opioid analgesic
3. potent opioid analgesic such as morphine sulfate which is the drug of choice for moderate to severe cancer pain. The other potent opioid analgesics which are considered alternative to morphine and maybe given on a long term basis are:
 - a. Fentanyl
 - b. Oxycodone
 - c. Hydromorphone

This directive applies to oralopioid analgesic preparations as stated in nos. 2 & 3. These oral preparations maybe available in immediate and modified extended/sustained release. Individualization of dosage by gradual adjustment is recognized as important. There maybe patients that receive modified release (with supposed duration of action up to 12 hours). However, breakthrough pain may occur so that the standard/immediate released tablets maybe given pending modification of the dose of the sustained release tablet. One example of cancer pain management is first titration with immediate release preparation and only transferring to modified release formulations once the optimum analgesic dose has been achieved. When transferring a patient, the same total 24-hour immediate release dose is given as two equal 12-hourly modified doses with the first dose given 4-hours after the last immediate release hours. Any breakthrough pain during titration or as a result of loss of analgesic control should be treated with immediate release preparation. Such case illustrates the need to use 2 types of dosage forms.

Such need however runs contrary to Bureau Circular No. 08 s. 2003 which prohibits the use of different brand names. In order to correct this situation and for the reasons specified below, the narcotic/opioid drugs with immediate and extended releases will be permitted to have 2 different brand names. Said reasons are:

1. to avoid confusion during drug administration and thereby prevent possible emergence of serious adverse reactions
2. compliance to Philippine Drug Enforcement Agency (PDEA) ruling: one prohibited drug per prescription
3. for correct dispensing at the drugstore level.

For information and immediate compliance of all concerned.

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