

Republic of the Philippines
Ministry of Health
OFFICE OF THE MINISTER
Manila

April 5, 1978

ADMINISTRATIVE ORDER
NO. 342 s. 1978

SUBJECT: Banning Tetracyclines for Children Under 8 Years Old

There are well known toxic effects of tetracyclines especially during childhood up to the age of 8 years. Tetracyclines are deposited in calcifying areas in bones, in deciduous teeth and in nails. The risk of staining developing teeth is greater when given to neonates and babies prior to first dentition. Pigmentation of the permanent dentition may develop if the drug is given between the ages of 2 months and 5 years, when the teeth are being calcified. Tetracyclines when given in therapeutic doses to young infants or to women during the later stage of pregnancy are deposited in the skeleton of the human fetus and young child causing rarefaction of the bones. Tetracyclines may cause increased intracranial pressure and tense bulging of the fontanels (pseudotumor cerebri) in young infants, even when given in the usual therapeutic dose.

In the interest of consumer protection and as a guidance to pharmaceutical manufacturer, distributor and retail outlets, the following order are hereby promulgated:

ORDERS

1. Pharmaceutical preparations containing Chlortetracycline, Oxy tetracycline, Tetracycline, Demeclocycline, Rolitetracycline, Methacycline, Doxycycline, Minocycline and other tetracycline derivatives in the form of syrup (mixture or suspension) or drops particularly intended for pediatric use are no longer certifiable.
2. Henceforth, the registration of the above-mentioned pharmaceutical preparations are hereby recalled and cancelled.
3. For the orderly phasing out of stock which have been distributed to retail outlet prior to the issuance of the Order all stocks should have been recalled and withdrawn by the manufacturer or distributor before June 30, 1978.

Recommended by:

(SGD.) ARSENIO M. REGALA
Administrator

Approved:

CERTIFIED TRUE COPY:
(SGD) GREGORIA V. BAUTISTA
Chief, Records Section
Dept. of Health
hbm 4/11/78

(SGD) CLEMENTE S. GATMAITAN, M.D., MPH
Secretary of Health

IMPORTANT: - The Regional Health Director is requested to disseminate copies of this Administrative Order to all personnel and offices concerned under his region. PLEASE COMPLY.