

File

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

May 19, 1982

ADMINISTRATIVE ORDER
No. 2408 s, 1982



Subject: Banning Neomycin in Anti-diarrheal Preparations.

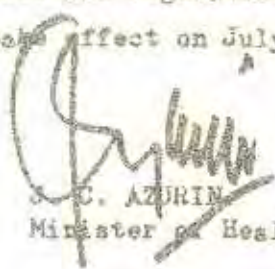
For many years, it has been known that Neomycin can cause serious adverse effects including renal damage, ototoxicity and neuro-muscular blockade. Ototoxicity involving the cochlear portion of the eighth cranial nerve is usually irreversible and may progress insidiously after the drug is discontinued. Enough absorption can occur to produce deafness particularly in patients with renal impairment. Deafness may occur even with conventional doses. Loss of hearing usually develops during the course of treatment however, it may not become apparent to the patient until sometime after therapy has been stopped, because of the time required for the defect to progress into the range of sound used in conversation. Risk of both ototoxicity and nephrotoxicity is greater in persons with decreased renal function.

Most cases of diarrhea are found to be resistant to Neomycin. Its constant use promotes pseudomembranous colitis in infants and children.

ORDER

1. Anti-diarrheal preparations containing Neomycin in dosage form for oral administration are no longer registrable.
2. Henceforth, the registration of the above-mentioned preparations are hereby recalled and cancelled.
3. For the orderly phasing out of stocks which have been distributed as retail outlet prior to issuance of this Order all stocks should have been cancelled and withdrawn by the manufacturer or distributor before June 30, 1982.

This Order supersedes all orders, rules and regulations or parts thereof inconsistent herewith and shall take effect on July 1, 1982.


J. C. AZURIN
Minister of Health