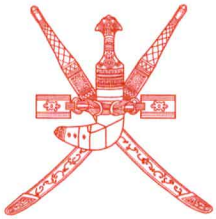
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 60 **/2020**

21 -07-1441H
16 -03-2020

To: ALL PRIVATE DRUG STORES & LOCAL MANFACTURERS

After Compliments,

Pharmaceutical Products containing Ranitidine.

Based on the recommendation of the Pharmacovigilance Joint Technical Committee in its meeting no.1/2020 dated 28/1/2020 & further to our circular no 74/2019 dated 26/9/2019 regarding the above subject. This to inform you that the companies are requested to conduct their own laboratory testing on Ranitidine containing products and to confirm to us if the levels of DMA & NDMA found in their products were above or within the FDA acceptable limits (daily intake 96 nanograms per day or 0.32ppm) along with supportive documents. The response should be within 3 months from the date of this circular.

Dr. Mohammed Hamdan Al Rubaie
Director General

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

Cc: DDC
DPVD
DQCL
SH (Reg of Human Medicines)

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