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. 02 / 2019

25 -04-1440 H

02 -01-2019

ALL PRIVATE DRUG STORES AND LOCAL MANUFACTURERS

After Compliments,

Sub: Drug Safety update that warrant revision of Pack Insert of registered products containing Hydrochlorothiazide

Reference to the EMA PRAC recommendation on Signals adopted at the PRAC meeting between 3-6/9/2018 related to the increased risk of non-melanoma skina cancer (NMSC) following higher cumulative doses of hydrochlorothiazide (HCTZ). This is to inform you that all Marketing Authorisation Holders are requested to revise the package insert (PIL) of their hydrochlorothiazide containing products that are registered and / or to be registered in Oman and to submit the variation application for this change to the Drug Control Department within 3 months from the date of this circular.

Yours faithfully,

Ph. Ahmed Al Harbi
Director of Drug Control

Cc: DG – for kind inf.
Section Head (Registration of Human Medicines)

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om