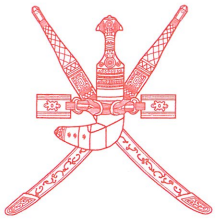
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....7.1..... dated 26/03/12 Regarding recall of Dimension Total Bilirubin (TBI) Flex reagent cartridge from Siemens Healthcare Diagnostics

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

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

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Circular No. 71 / 2020

01 - 8 1441 H

26 -3-2020

Ref: 52/2020

Recall of Dimension Total Bilirubin (TBI) Flex reagent cartridge from Siemens Healthcare Diagnostics

Source of Recall	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15112
Product	Dimension Total Bilirubin (TBI) Flex reagent cartridge-IVDs
Manufacturer	Siemens Healthcare Diagnostics
Local Agent	New Source
The affected products	Test Code: TBI Catalogue Number: DF167 Siemens Material Number: 10444957 All Lot Numbers
Reason for Recall	Siemens Healthcare Diagnostics has become aware that the United Kingdom Medicines and Healthcare products Regulatory Agency published an alert to healthcare professionals informing them that laboratory tests for bilirubin should be monitored for patients who take the drug eltrombopag due to the potential for discordant results. Eltrombopag may be used in the treatment of thrombocytopenia and/or aplastic anaemia. Siemens spiking studies have shown a positive bias in Total Bilirubin (TBI) results at a therapeutic concentration of eltrombopag. Interference has not been observed with the Direct Bilirubin (DBI) assay
Action	Healthcare is advising that for patients on eltrombopag therapy, use of Dimension TBI is not recommended. Siemens Healthcare advises that the Instructions For Use for the Dimension TBI assay assay will be updated as appropriate. The "Limitations of the Procedure" section in the Instructions For Use (IFU) for the Dimension TBI assay will be updated to indicate: "Use of this assay is not recommended for patients undergoing treatment with eltrombopag due to the potential for falsely elevated results". Siemens will provide further communication once the IFUs have been updated. Siemens is not recommending a review of previously generated results
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail: Med-device@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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