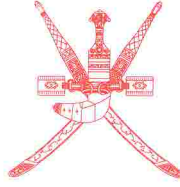


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عُمان
وزارة الصحة
المديرية العامة للصيرورة
والرقابة الدوائية
مسقط

To:

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. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
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
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....76..... dated 27/11/18
regarding the Batch recall of Paracetol 10mg/ml Intravenous Infusion (Mfr:
Pharmaceutical Solution Ind., KSA)

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- 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
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU
- M/s. Waleed Pharmacy – to arrange recall of the above batches and let us know the total quantity recalled, customers and the method of disposal of the recalled quantity, within ONE week. Please submit this information to Department of Pharmacovigilance & Drug Information through online e-portal (submission type 'Recall').

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Circular No. 76 / 2018

19 -03-1440 H

27 -11-2018

Recall of Batches

Paracetol 10mg/ml Intravenous Infusion

Batch Nos. 127751 & 126772

M/s. Pharmaceutical Solution Ind. (PSI), Kingdom of Saudi Arabia

Please be informed that we have decided to recall the following batches of Paracetol 10mg/ml Intravenous Infusion from M/s. Pharmaceutical Solution Ind., Kingdom of Saudi Arabia, due to recall of these batches in the country of origin because of the presence of some black particles in the solution.

Batch Nos: 127751 & 126772

Please do not dispense the above mentioned batches which should be returned to the local agent M/s. Waleed Pharmacy.

The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.



Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL