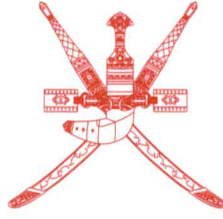


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَا جَمَانَا
وَزَارَةُ الصِّحَّةِ
الْمَدِيرَةُ الْعَامَّةُ لِلصِّدْقِ
وَالرِّيَاقَةِ الدَّوَلِيَّةِ
مَسْقَط

To

Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Disease Surveillance & Control
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. 67..... dated 22/08/19 regarding voluntary lot recall of Freeze-Dried Glutamate BCG Vaccine and diluent.

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. Muscat Pharmacy – to arrange recall of the mentioned lots 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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سلطنة عمان
وزارة الصحة
الديرة العامة للصحة
والرقابة الدوائية
مسقط

Circular No. 67 / 2019

20 -12-1440 H

22 -08-2019

Voluntary Lot Recall
Freeze-Dried Glutamate BCG Vaccine 0.5mg/ml, 20 dose with
diluent for Intradermal Use
Mfr: Eisai Co. Limited, Japan

Please be informed that M/s. Eisai Co. Limited, Japan, is voluntarily recalling certain lots of **Freeze-Dried Glutamate BCG Vaccine and Diluent** due to finding of foreign matters in its diluent (i.e. Isotonic Sodium Chloride Solution). Although the problem is related to the diluent, the company is recalling both **Freeze-Dried Glutamate BCG Vaccine** and the **diluent**. The affected lots being recalled in Oman are carrying Lot Nos: 1629, 1632, 1637, 1639, 1646, 1648 & 1651.

Kindly check your stock and return the available quantity, if any, to the local agent M/s. Muscat Pharmacy under intimation to us.

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.



Ph. Hussain Al Ramimmy
ACTG. DIRECTOR GENERAL