PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/02-23-14

RECALL OF OSCAL-D TABLETS (B. NO. 6904)

(MANUFACTURED BY M/s. ARIES PARMACEUTICALS (PVT.) LTD., PESHAWAR)

Date: 24th February 2023.

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- General Public

Alert Summary:

Federal Government Analyst, CDL Karachi has declared the Batch No. 6904 of product **"Oscal-D Tablets"** as of **substandard** quality. Details of the product are given as under:

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Product Name	**Manufactured by**	**Remarks**
Oscal-D Tablets (Reg#073235) **Batch No. 6904** Mfg. Date: 07-22 Exp. date: 07-24	Ms. Aries Parmaceuticals (Pvt.) Ltd., Peshawar.	The sample is of sub-standard quality (on basis of assay test the result of which does not comply with acceptance criteria).

Risk Statement:

Oscal-D Tablets may be used to treat conditions caused by low calcium levels such as osteoporosis, osteomalacia/rickets, hypoparathyroidism and latent tetany. **Inaccurate use of the product may lead to adverse reactions including but not limited to** irregular heartbeat, weakness, drowsiness, headache, dry mouth or a metallic taste in your mouth or muscle or bone pain. Impact of use of substandard product on basis of assay test may leads to low to no therapeutic effect etc.

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Action Initiated: -

The manufacturer has been directed to **immediately recall** the defected batch of product from the market. All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and **stop** supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this affected batch of product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link

Advice for Consumers / General public: -

Consumers should stop using this product bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موئثر اور معیاری اشیائے علاج

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