RAPID ALERT

DRAP ALERT No: I/S/01-25-04

UNREGISTERED SUPPLY OF LUCENTIS (RANIBIZUMAB) 10MG/ML SOLUTION FOR INJECTION PURPORTEDLY MANUFACTURED BY M/S. NOVARTIS PHARMA STEIN AG, SWITZERLAND.

Date: 2nd January, 2024

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

Problem Statement:

The firm M/s Novartis Pharma (Pakistan) Ltd, Karachi, has notified DRAP, regarding the supply of unregistered Lucentis Solution for Injection in the market across Pakistan. The firm has confirmed that they do not market any product under the name of Lucentis in Pakistan. Details of unregistered product are as under:

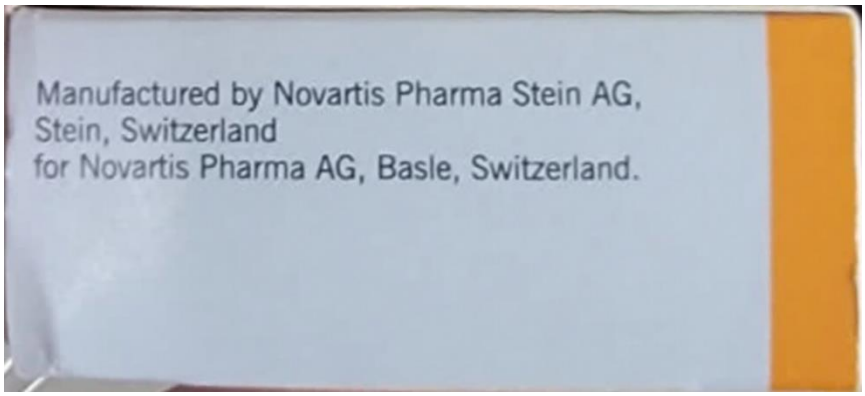
Product name	Batch/Lot No.	Stated Manufacturer	Mfg. date	Exp. date
LUCENTIS Solution for Injection, 10mg/ml (Ranibizumab)**,** (For Intravitreal Injection only)	SKVJ1	M/s Novartis Pharma Stein AG, Stein, Switzerland. -For Novartis Pharma AG, Basle, Switzerland.	07-2023	06-2026

Risk Statement:

Ranibizumab is a humanized monoclonal antibody fragment produced by recombinant DNA technology used in the treatment of Age-Related Macular Degeneration **(AMD)**. The unregistered supply of **LUCENTIS Solution for Injection (Ranibizumab)** in the market poses several risks, such as risks of contamination, incorrect formulation, or improper storage, leading to adverse reactions such as eye infections, retinal detachment, or even vision loss.

DRAP, Islamabad **+ 92 051 9255969** **gsms@dra.gov.pk**

Identification and details of unregistered product:



Lot Number : SKVJ1

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Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain to confiscate the mentioned product. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the supplier of such product should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product from the circulation.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use this product and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned product and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

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

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

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