PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/02-23-12

RECALL OF CHLOROQUINE 5ML INJECTION (B. NO. 201238)
(MANUFACTURED BY M/s. SHANXI SHUGUANA PHARMA CO LTD CHINA)

Date: 23rd 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:

Drug inspector Quetta took the sample of Chloroquine 5ml Injection Bach No. 201238 which has declared as **Misbranded** by Provincial Drug Testing Laboratory, Quetta.

Detail of the product is as under:

Product Name	**Manufactured by**	**Remarks**
Chloroquine 5ml Injection (Reg#061824) **Batch No. 201238** Mfg. Date: 12-20 Exp. Date: 12-23	M/s. Shanxi Shuguana Pharma Co Ltd, China **Sole Agent:** M/s Mehran International, Karachi.	The sample portion of "Inj. Chloroquine 5ml" ampoule is printed with delible ink which is easily removable. The label should be printed with indelible/irremovable ink/printing

Risk Statement:

Chloroquine is used to prevent and treat of Malaria and Amebiasis. Improper labels **due to delible printing of label may lead to misleading information,** accidentally administering the wrong medication or wrong dose, may cause a patient to experience a negative health outcome. Further it may lead to **adverse reactions including but not limited to Allergic reactions, Cardiac effects,** Nausea, Vomiting, Abdominal cramps, Headache, and Diarrhea.

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

Action Initiated: -

The sole agent / registration holder has been directed to **immediately recall** the defected batch of product from the market by Secretory Provincial Quality Control Board, Quetta. 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, Provincial Health Departments and States) have also increased 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، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
92 51 9107404
gsms@dra.gov.pk