RAPID ALERT

DRAP ALERT NO. Nº I/S/07-23-27

FALSIFIED SOJOURN (SEVOFLURANE) LIQUID FOR INHALATION

Date: 24th July 2023

Target Audience:

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

Problem Statement:

The federal Inspector of Drugs, Quetta, took sample of suspected Sojourn liquid for inhalation from two different batches and sent it for analysis to the laboratory. The Central Drug Testing Laboratory, Karachi declared these samples as ***"Spurious"*** based on the analysis. The laboratory also identified the differences in the labeling and packaging of the falsified products in comparison to the authorized pack of registered products.
The detail of the product is as under:-.

Detail of Product	**Batch / Lot ***	**Mfg. Date**	**Exp. Date**	**Purported Manufacturer**	**Remarks**
Sojourn Liquid for Inhalation **Reg.No. 088891**	S0502C11	Mar-22	Mar-27	M/s Priamal Critical Care, Inc. USA	The sample is declared spurious for a non-complying identification test for Sevoflurane. Instead, lab identified chloroform in the samples.
	S0512C14	Mar-22	Mar-27		

***The differences noted in the labeling and packaging of sample products declared as spurious in comparison to the authorized product from the marketing authorization holder are summarized in a table as Annexure-I.**

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Risk Statement:

Sojourn (Sevoflurane) Liquid is an inhalational anesthetic agent which is indicated for use in the induction and maintenance of general anesthesia. It may lead to life-threatening reactions as the safety, quality, and efficacy of the product are unknown.

Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health facilities (Hospitals) in addition to markets and confiscate these batch(es) of products if available. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying these batches of the product. The remaining stock should be quarantined immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) in order to ensure the removal of these products.

Advice for Healthcare Professionals: -

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

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP 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 / General public: -

Consumers should not use this product and shall contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug 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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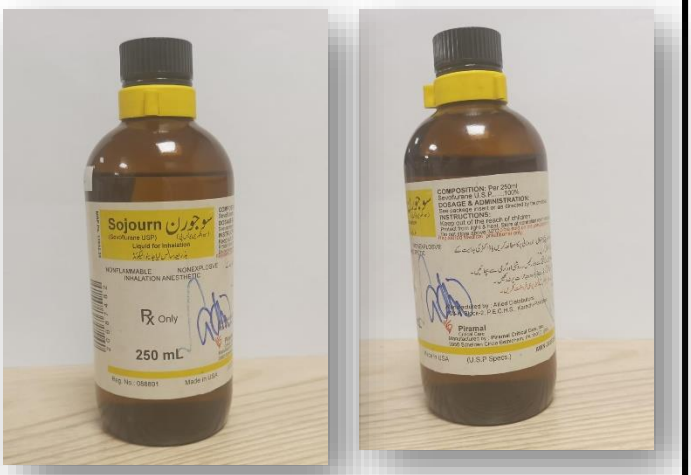
Annex-I

S. No.	Original pack of the manufacturer	Sample pack.
1.	There is a hyphen "-" between NONFLAMMABLE and NONEXPLOSIVE written under yellow panel	No hyphen between NONFLAMMABLE and NONEXPLOSIVE is observed in the given sample. The spelling for NONEXPLOSIVE is wrongly written as "NONEXPLOSVE" without "I"
2.	Font Size of information for composition, dosage and administration and instruction is smaller	Font Size of information for composition, dosage and administration and instruction is larger
3.	Marketed by: Allied Distributors.	Manufactured by Allied Distributors.
4.	Color of "Piramal" is Dark Green in logo.	Color of "Piramal" is Black in logo.
5.	The gap between MRP and Yellow Panel is sufficient and the Price is written in normal letters.	The gap between MRP and Yellow Panel is less and the Price is written in bold letters.
6.	R is correctly written in MRP Rs. 17032.35	P is written instead of R in MRP Ps. 17032.35
7.	Font Color is black light shaded for Lot No, Mfg Date and Exp Date.	Font Color is black dark shaded for Lot No, Mfg Date and Exp Date.
8.	The Bottom of Glass Bottle does not contain any alphabet or number.	The Bottom of Glass Bottle contain "PG" & "5"

FALSIFIED SPURIOUS PRODUCT



ORIGINAL PRODUCT

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