PSUR Report - DrugX (ID: 101)

Report Generated: 24-Jul-2025

Compliance: Indian CDSCO Standards & ICH E2C(R2)

Executive Summary

This PSUR report has been generated for DrugX (Product ID: 101) based on actual uploaded data. The AI-powered analysis is temporarily unavailable due to service quotas, but this report contains all your real data.

Key Safety Statistics:

- Total Adverse Events: 2
- Authorized Countries: 2
- Estimated Patient Exposure: 43,000
- Clinical Studies: 1
- Regulatory Actions: 1

1. Title Page

Product Name: DrugX

Product ID: 101

INN: Compound A

Dosage Form: Tablet

Strength: 500mg

PSUR Period: 24-Jul-2025

Reporting Company: Pharma Pulse System

2. Executive Summary

This report summarizes the safety profile of DrugX based on data from 2 countries where the product is authorized.

Key Findings:

- Total adverse events reported: 2
- Patient exposure estimated at: 43,000 patients
- Regulatory actions taken: 1

3. Introduction

Product: DrugX (Compound A)
Dosage Form: Tablet
Strength: 500mg

The product is currently authorized in 2 countries worldwide.

4. Worldwide Marketing Authorization Status

Total Authorized Countries: 2

Countries with Authorization:
- India
- USA

Marketing Status Distribution:
- Approved: 2

5. Update on Actions Taken for Safety Reasons

Total Regulatory Actions: 1

Action Types:
- Label updated to include headache: 1 action(s)

6. Changes to Reference Safety Information

Based on the adverse events data, no significant safety signals were identified.

7. Estimated Patient Exposure

Total Estimated Patients: 43,000

Regional Distribution:
- India
- USA

Estimation Methods:
- Sales: 1 estimate(s)
- Prescription Volume: 1 estimate(s)

8. Presentation of Individual Case Histories

Total Adverse Events: 2

Outcome Distribution:

- Recovered: 1 case(s)
- Recovering: 1 case(s)

Age Distribution:

- 0-17: 0 case(s)
- 18-64: 2 case(s)
- 65+: 0 case(s)
- Unknown: 0 case(s)

Gender Distribution:

- Male: 1 case(s)
- Female: 1 case(s)

9. Studies

Total Clinical Studies: 1

Completed Studies: 1

Study Status Distribution:

- Completed: 1 study/studies

10. Other Information

Recent Events (2023+): 2 adverse events

Recent Actions (2023+): 1 regulatory actions

Additional safety information from literature review and post-marketing surveillance would be included in a complete assessment.

11. Overall Safety Evaluation

Based on the available data:

- Adverse Event Rate: 2 events reported from 43,000 exposed patients
- Regulatory Oversight: 1 regulatory actions taken
- Study Evidence: 1 completed clinical studies available

Assessment: The safety profile appears acceptable based on current data.

12. Conclusion and Appendices

Summary:

- Product is authorized in 2 countries
- 2 adverse events reported from 43,000 patients
- 1 regulatory actions implemented
- 1 clinical studies on record

Recommendation: Continue monitoring safety profile with regular PSUR updates as per regulatory requirements.

Report Generation Information:

- Generated by: Pharma Pulse System (Enhanced Data Mode)
- Date: 24-Jul-2025
- Standards: CDSCO & ICH E2C(R2)
- Data Source: User-uploaded CSV files (actual data)

Note: This report uses your actual uploaded data. AI-enhanced analysis will be available once OpenAI service quotas are restored.