Title:

End – to – End Pharmacovigilance ICSR Processing using Ms Word and Ms Excel.

Tools used

- Ms word (preparation of ICSR narrative, Case documentation and safety summaries.)
- Ms Excel (Data entry and Tabulation of ADR details.
- CIOMS 1 form and Med watch form 3500 (For ADR reporting for study and Academics reference purpose only.

Drug used for Reference

- Cetrizine

Work flow Formatting

- Project Initiation and PV understanding
- Case Intake and Case – log creation
- ICSR Formatting
- Triaging
- Regulatory reporting
- Conclusion

Project Initiation and PV Understanding

Studied Pharmacovigilance fundamentals, understanding regulatory concepts such as adverse event, serious and non serious, ICH seriousness criteria and CIOMS reporting format.

Case Intake and Case – log creation

- Created a case log sheet in Ms excel
- Assigned unique case numbers
- Recorded cases received form (Health care, professionals, consumer's, literature pharmacist Email reports.
- Coding Summary.xlsx

ICSR Formatting

Case Information

Case Number = 001

Data receiver = 23-10-2025

Country = India

Patient Information

Name = x.xxxxxx Age = 45 Sex = Male Weight = 68 kg

Reporter Information

Name = x.xxxxxx Age = 42 Sex = Male Weight = 60kg

Suspect product (s)

Drug name = Cetrizine

Dose = One Tablet (strength not found)

Route = Not reported

Indication = Allergic symptoms' and upper respiratory tract information.

Therapy dates = Not reported

Medication = Not reported

Adverse event description

Chronological description of events; the patient took Cetrizine at Night and cause dizziness.

Laboratory Diagnostic Findings; Not reported

Action Taken; Not reported

Outcome; Recovered

Triaging

Validity assessment

Identifiable Patient = Yes

Identifiable reporter = Yes

Suspect drug = Yes

Adverse event = Yes

Conclusion = Valid ICSR

Duplicate Assessment

Patient / drug/ event / time frame = No

Conclusion (Duplicate / Non Duplicate) = Non Duplicate

Serious Analysis

Death =

Life Treating =

Hospitalization =

Disability =

Congenital anomaly =

Medical important =

Non serious = Yes

Regulatory reporting

Med watch 3500 = https://mail.google.com/mail/u/0/#inbox?projector=1

Conclusion

This is self reported spontaneous case concerning a 45 years old man who experience somnolence and dizziness following administrating of Cetrizine for Allergic symptoms. The patient reported taking one tablet of suspected drug at Night and experienced, the event on the same day, Information regarding (Strength Dosage form), and action taken not reported.