Pharmacovigilance by ELC

Qualified Person Responsible for Pharmacovigilance (QPPV)

Key activities of EU QPPVs

1 Oversight of quality system and single point of contact

- Responsible for all EU QPPV activities listed in Pharmacovigilance system master file, including acting as a 24-hour contact point
- Management of Standard Operating Procedures (SOPs) and quality systems
- Responding in a timely and accurate manner to requests from EMA/PRAC/Authorities
- Having an overview of MAH's medicinal product safety profiles and any emerging safety concerns

2 Global safety database

- Overview of validation status of the database
- Overview of Individual Case Safety Reports (ICSRs)

3 Exchange of safety data/information to MAH

- On receipt of any safety reports, sending information on to the MAH pharmacovigilance team within one working day

4 Reconciliation/compliance between parties

- Providing reconciliation every six months, and ensuring monthly compliance on an ongoing basis

5 PSURs

- Review and approval of Periodic Safety Update Reports (PSURs) and Addendum to the Clinical Overview (ACOs) prior to submission to regulatory authorities

6 Reference safety documents

- Retaining permanent access to the most up-to-date Reference Product Information (RPI) & applicable Summary of Product Characteristics (SmPCs)
- Quarterly review of safety variation trackers or urgent safety restrictions

7 XEVMPD maintenance

- Providing relevant support and training for XEVMPD maintenance

8 Medical information and product complaints

- On receipt of any quality complaints, sharing information with the MAH within one working day
- Overview of medical information system

9 Signal Management

- Part of Validating all signals
- Part of an ad-hoc joint safety review committee meeting with safety and regulatory representatives

10 Risk Management System

- Review and approval of Risk Management Plan (RMP)

11 Pharmacovigilance system master file

- Authority over Pharmacovigilance system master file
- Acting as notification point of contact for changes to the PSMF

12 Document retention and training

- Ensuring proper archival arrangements are available with the MAH
- Ensuring appropriate training to the PV team as and when needed

ELC Group provides a full range of services to support EU QPPVs, ensuring that all requisite pharmacovigilance activities are taken into account and offering key services to help QPPVs meet their responsibilities.

Concept to Safety

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