Pharmacovigilance by ELC

What is a Safety Variation?

Summary of Product Characteristics and Package Leaflets (SmPCs/ PLs) are a key part of the MA of all medicines, and the basis of information for healthcare professionals on how to use a medicine safely and effectively. They are kept updated throughout the lifecycle of a medicine as new efficacy or safety data emerge.

What is a Safety Variation?

This is an update and implementation of SmPCs/PLs concerning particularly products, via variations with respect to – but not limited to – posology, contraindications, special warnings and precautions for use and undesirable effects.

When SmPC / PIL needs to be updated

- Competent Authority requested
- PRAC recommendation
- Identified through PSUR
- Identified through signal evaluation

WHO...

- does the change? — RA team
- submits the variation? — MAH
- reviews & approves the change? — Regulatory Head and EU QPPV
- Once approval granted — EU QPPV & PV personnel informed

Additional role of EU QPPV

Review of safety variations on a quarterly basis to ensure compliance with timelines. Any non-compliance found will be investigated and CAPA put in place.

ELC Group provides a full range of support to the EU QPPV and also ensure that all of the requisite pharmacovigilance activities are duly taken into account.

Concept to Safety

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