The EU regulatory network and its governance structure have developed specific guidance to support stakeholders, including the pharmaceutical industry and regulatory authorities in Member States involved in the reporting, evaluation and prevention of medication errors. This guide is complementary to the guideline on GVP and other existing guidelines published by the Agency.

The Heads of Medicines Agencies (HMA) endorsed the final two-part guide in November 2015, taking into account comments from a two-month public consultation.

The first part of the guide clarifies specific aspects related to recording, coding, reporting and assessment of medication errors in the context of EU pharmacovigilance activities with the objective of improving reporting and learning from medication errors for the benefit of public health:

The second part of the guide clarifies key principles of risk management planning in relation to medication errors and describes the main sources and categories of medication errors and how the risk of such errors can be minimised throughout the product life cycle:

The addendum to the guide provides a strategy to minimise the potential risk of medication errors associated with high strength insulin products (i.e. higher than the EU-wide standard of 100 units/ml concentration) and fixed combinations of insulin with another non-insulin injectable blood glucose lowering agent:

The guide takes into account the recommendations of a stakeholder workshop on medication errors held in 2013 and is a key deliverable of the resulting action plan agreed by the HMA.

Reference

Conducting & Reading Research in Kinesiology

How to Be a Researcher: A strategic guide for academic success