**Good pharmacovigilance practices**

**Rules are underpinned by guideline modules**

The rules of the new regulation are underpinned by a number of guideline modules (Good Vigilance Practice – GVP modules), each addressing different major elements in the new legislation.

The GVP modules have been prepared by teams consisting of experts from the European Medicines Agency (EMA) and from the national authorities in the EU Member States.

**Good pharmacovigilance practices (GVP)** are a set of measures drawn up to facilitate the performance of pharmacovigilance in the European Union (EU). GVP apply to marketing-authorisation holders, the European Medicines Agency and medicines regulatory authorities in EU Member States. They cover medicines authorised centrally via the Agency as well as medicines authorised at national level.

**Guideline on GVP**

The guideline on GVP is divided into chapters that fall into two categories:

- modules covering major pharmacovigilance processes;
- product- or population-specific considerations.

Each chapter is developed by a team consisting of experts from the European Medicines Agency and from EU Member States.

The guideline on GVP is a key deliverable of the 2010 pharmacovigilance legislation.

GVP modules I to XVI cover major pharmacovigilance processes.


The rules of the new regulation are underpinned by a number of guideline modules (Good Vigilance Practice – GVP modules) and apply to marketing-authorisation holders, the European Medicines Agency and medicines regulatory authorities (NAMMD) in EU Member States.