What is Risk Minimisation?

Risk minimisation measures are actions taken to prevent or reduce the occurrence of adverse drug reactions, or to reduce the severity or impact on the patient of adverse reactions that do occur.

The right medicine, at the right dose, at the right time, to the right patient (GVP, Module XVI)

Routine risk minimisation measures

All medicinal products are subject to routine risk minimisation measures, which should be detailed in the Risk Management Plan for the product, in accordance with Good Pharmacovigilance Practice (GVP) Module V. Routine risk minimisation activities relate to the Summary of Product Characteristics, the labelling, the pack size, the package leaflet and the product's legal status.

Additional risk minimisation measures

In some cases, routine risk minimisation measures are not sufficient to ensure safe and effective use of the medicinal product, in which case additional risk minimisation measures may be proposed by the Marketing Authorisation Holder. Such measures may include:

- Educational tools aimed at health care professionals
- Educational tools aimed at patients or carers
- Controlled access programmes
- Pregnancy prevention programmes
- Direct health care professional communications (DHPC)