Risk minimisation measures

These are public health interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient should adverse reactions occur. Risk minimisation measures aim to optimise the safe and effective use of a medicinal product throughout its life cycle. Planning and implementing risk minimisation measures and assessing their effectiveness are key elements of risk management. Routine risk minimisation involves the use of the tools such as the Summary of Product Characteristics (SmPC), the package leaflet, the labelling, the pack size and design, and the legal (prescription) status of the product.

The majority of safety concerns may be adequately addressed by routine risk minimisation measures, but for some risks however, additional risk minimisation measures are necessary to manage risk and/or improve the benefit-risk balance of a medicinal product.