Safety specification

The safety specification of a medicinal product is a summary of the important identified risks of a medicinal product, important potential risks, and important missing information. It should also address the populations potentially at risk, and any outstanding safety questions which may benefit from further investigation to refine understanding of the benefit risk profile during the post-authorisation period. In the RMP, the safety specification will form the basis of the pharmacovigilance plan, and the risk minimisation plan. It is one of the three pillars of the risk management plan.