Risk Management Plan [RMP]

A risk management plan provides a detailed description of the activities and interventions in place to prevent or minimise risks of using a medicine. Risk management plans outline how more knowledge about the safety and efficacy of a medicine will be generated, what are the risk factors for developing side effects, and how risk-minimisation measures will be monitored.

Risk management plans must be submitted by companies at the same time they apply for marketing authorisation in the European Union, although they must be continually updated and revised throughout the medicine’s lifetime. Risk management plans can also be requested by the EMA at other times, or whenever there is concern that a risk may be affecting the balance of benefits and risks for a particular medicine.