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web within the european union eu there is a requirement to submit a risk management plan rmp for a proposed new drug at the time of submission of the marketing authorisation application maa an rmp may also be needed for existing products when there is a significant change to the maa

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web publication of risk management plan rmp summaries analysis of the experience of the 1 year pilot phase presented by juan garcia burgos and caroline voltz outline background on rmp summaries and pilot phase objectives of the analysis results conclusions and way forward why produce a summary of the risk management plan