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Guideline on good pharmacovigilance practices Module V-Risk management systems (Revision 2): Updates and feedback

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The concept of benefit-risk balance has evolved in the realm of public health and the pharmaceutical industry, giving rise to robust risk management systems, as mechanisms by which to help promote a favorable benefit-risk balance to regulators, Healthcare Professionals (HCPs) and patients. In addition to supporting the submission dossier for a Marketing Authorization Application (MAA), the EMA Risk Management Plan (RMP) serves an important role for promulgating risks of marketed products to stakeholders, including the public. Guideline on Good Pharmacovigilance Practices (GVP) Module V–Risk Management Systems (Revision 2) and the corresponding revision to the RMP template, have improved the regulatory framework and scope of the RMP, giving rise to an enhanced document that is more focused yet comprehensive. The adoption and implementation of the revised guideline and template have been coupled with generally positive feedback from regulators, notwithstanding challenges that accompany change.

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