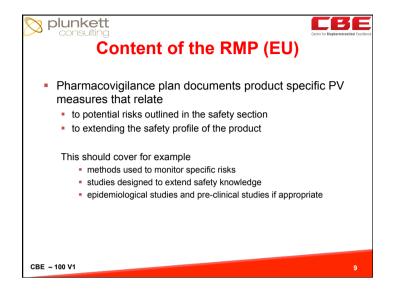
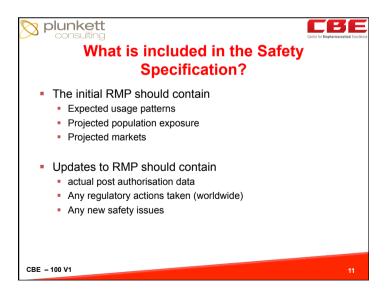
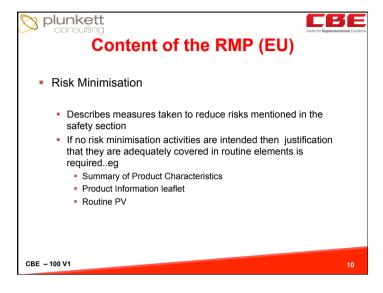


CBE







What is included in the product specific Pharmacovigilance Plan? Summaries of completed studies since the last RMP update (as defined in the Safety section) Summary ongoing studies should include relevant: protocols and protocol amendments contracts with external organisations Interim reports that have been provided to relavnt authority(s)

Procedures are in place for notification of Adverse Events

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What is included in the Risk Minimisation plan?

- Should contain:
 - Criteria for verifying the success of proposed risk minimisation measures
 - Proposed review periods of the measures
 - A summary of any relevant reports that have been generated (which should be provided on request to inspectors)

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In Summary a Risk Management Plan......

Outlines the risk management system for a medicine once it is available for use

Comprises:

- · Known safety profile
- Identified and potential safety concerns and where appropriate how they will be mitigated
- Missing safety information where this is known or can be predicted and how this will be managed

Focuses on

- Monitoring Pharmacovigilance Plan
- Minimising risks associated with the use of the product Risk Minimisation Activities

Provides:

- · Coverage of the life cycle of the product
- Assurance that all risks related to the use of a medicine have been considered and acted upon

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Common issues with RMPs (MHRA)

- Tend to focus more on what is known rather than identifying areas where information is lacking
- The relevance of the epidemiology to the target population is often not sufficiently considered
- The PV plan often emphasises routine PV rather than focusing on product specific measures
- Insufficient time is allowed to develop study protocols
- Justification is often not provided by MAH when it considered that extra measures were not required in the risk-minimisation section
- Plans for monitoring success of RMPs is often lacking

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