



7 November 2012
EMA/715019/2012
Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU part V: Risk Minimisation Measures

| | |
|--|--|
| Active substance | |
| Product(s) concerned (brand name(s)): | |
| MAH/Applicant name | |

Data lock point for this module

<Enter a date>

Version number of RMP when this module was last updated

<Enter a version no>

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices: Risk Management Systems.



Each safety concern identified in module SVIII "summary of the safety specification" should be addressed. If no risk minimisation measures are proposed, then "none proposed" should be entered against the objective.

If several components make up one risk minimisation measure (e.g. a pregnancy prevention plan may have educational material for health care professionals and patients, algorithms for deciding on child-bearing potential, patient reminder cards etc.) these should be grouped together.

For each safety concern, provide details of what criteria will be used to judge whether risk minimisation measures are a success e.g. fewer than 2 pregnancy reports in period y, no cases of liver failure reported, drug utilisation study showing <5% off-label use etc.

Further guidance on risk minimisation measures can be found in GVP Module XVI and CIOMS IX.

V.1 Risk minimisation measures by safety concern

| | |
|--|--|
| Safety concern | |
| Objective(s) of the risk minimisation measures | |
| Routine risk minimisation measures | (Proposed) text in SmPC <E.g. Dose reduction for in section 4.2 of the SPC..... Warning in section 4.4 to..... Listed in section 4.8> |
| | Comment (e.g. on any differences between SmPCs) |
| | Other routine risk minimisation measures <E.g. Prescription only medicine Use restricted to physicians experienced in the treatment of.....> |
| Additional risk minimisation measure(s) (repeat as necessary) | Objective and justification of why needed. |
| | Proposed actions/components and rationale |

| Effectiveness of risk minimisation measures | |
|---|--|
| How effectiveness of risk minimisation measures for the safety concern will be measured | <i>If a study is planned, this should also be included in Part III.2 Additional PhV activities to assess effectiveness of risk minimisation measures</i> |
| Criteria for judging the success of the proposed risk minimisation measures | |
| Planned dates for assessment | |
| Results of effectiveness measurement | Provide latest assessment at each update of the RMP. For risk minimisation measures where formal studies are planned, any results should be mentioned in Part III.2 with the implications discussed here and any remedial actions in V.2 |
| Impact of risk minimisation | |
| Comment | |

V.2 Risk minimisation measure failure (if applicable)

List the safety concerns and risk minimisation measures which are judged to have failed.

| Safety concern | Risk minimisation measure |
|-----------------------|----------------------------------|
| | |
| | |

V.2.1 Analysis of risk minimisation measure(s) failure

When risk minimisation measures for a safety concern are thought to be inadequate, a root cause analysis of where it is failing should be undertaken

| Safety concern | |
|------------------------------|----------|
| Risk minimisation measure(s) | |
| Component 1 | Analysis |
| Component 2 etc. | Analysis |
| Discussion | |

V.2.2 Revised proposal for risk minimisation

Based on the analysis of why the risk minimisation activities were inadequate, a proposal should be made for new (or revised) risk minimisation measures for the safety concern

| | |
|---|---|
| Safety concern | |
| Objective(s) of the risk minimisation activities | |
| Routine risk minimisation activities | Synopsis of (proposed) text in SmPC |
| | Comment (e.g. on any differences between SmPCs) |
| | Other routine risk minimisation activities |
| Additional risk minimisation measure(s) (repeat as necessary) | Objective and justification of why needed. |
| | Proposed actions/components and rationale |
| Comment on how revised proposals will address failings | |
| Effectiveness of risk minimisation measures | |
| How effectiveness of risk minimisation measures for the safety concern will be measured | <i>If a study is planned, this should also be included in Part III: Additional PhV activities to assess effectiveness of risk minimisation measures</i> |
| Criteria for judging the success of the proposed risk minimisation measures | |

V.3 Summary table of risk minimisation measures

| Safety concern | Routine risk minimisation measures | Additional risk minimisation measures |
|----------------|--|---------------------------------------|
| | From V.1 "proposed text in SmPC" and "other routine risk minimisation measures" | From V.1 (list) |
| | <E.g. Dose reduction for in section 4.2 of the SPC..... Warning in section 4.4 to..... Listed in section 4.8 Prescription only medicine Use restricted to physicians experienced in the treatment of.....> | |