



DD Month YYYY
EMA/699686/2015
Pharmacovigilance Risk Assessment Committee (PRAC)

<PRAC> <Rapporteur> <preliminary> <updated> non-interventional imposed PASS final study report <and RMP> assessment report

<Invented name> *For CAPs only*

<Active substance> or <combination of active substances>

Procedure no.:

Status of this report and steps taken for the assessment ¹			
Current step	Description	Planned date	Actual Date
<input type="checkbox"/>	Start of procedure		
<input type="checkbox"/>	PRAC Rapporteur preliminary assessment report (AR)		
<input type="checkbox"/>	MS/PRAC members comments		
<input type="checkbox"/>	PRAC Rapporteur updated assessment report following comments		
<input type="checkbox"/>	Oral explanation		
<input type="checkbox"/>	PRAC recommendation/ Request for supplementary information		
<input type="checkbox"/>	<PRAC Rapporteur preliminary assessment report (AR) on the responses to the RSI>		
<input type="checkbox"/>	MS/PRAC members comments		



Status of this report and steps taken for the assessment¹

<input type="checkbox"/>	<PRAC Rapporteur updated assessment report on the responses to the RSI following comments >		
<input type="checkbox"/>	<Oral explanation>		
<input type="checkbox"/>	<PRAC recommendation/ Request for supplementary information>		

¹ Tick the box corresponding to the applicable step – do not delete any of the steps. If not applicable, add n/a instead of the date

Procedure resources

PRAC Rapporteur	<Rapporteur Name>
PRAC Rapporteur Contact Person	Name: Tel: Email:
EMA Procedure Manager	Name: Tel: Email:
EMA Procedure Assistant	Name: Tel: Email:

Declarations

In order to facilitate the redaction of potentially commercially confidential information the assessor should confirm by ticking the below box whether the report contains any of the below data/information. This does not preclude the assessor from including this information if needed for the assessment; however, if the boxes are un-ticked, the EMA will review and redact the report accordingly prior to circulation to the MAH(s):

The assessor confirms that reference to ongoing assessments, development plans (including Scientific Advice/Protocol assistance) or pharmacovigilance inspections are not included in this assessment report.

Whenever the above boxes are un-ticked please indicate the section and page where the confidential information is located here:

General guidance

This template should be used by the PRAC Rapporteur for all non-interventional imposed PASS final study report assessments.

The template's structure of the scientific discussion follows the headings of the format of the final study report specified in Article 38 of the Commission Implementing Regulation No 520/2012 with the additional instructions of Module VIII of the Good pharmacovigilance practices. All headings and sub-headings of the template should be covered. Each section includes a Summary and a PRAC Rapporteur's assessment and Conclusion.

The text in italics and between brackets at the beginning of each section is intended to guide the assessor on the principle points to be considered for review. Please delete this text in the final assessment report. For detailed guidance on the scientific content and background on each section, please refer to:

- the Guidance for the format and content of the final study report of non-interventional post-authorisation safety studies:

(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2013/01/WC500137939.pdf). This format is mandatory for studies imposed as an obligation (categories 1 and 2 of studies mentioned in GVP Module V) and is recommended for all other PASS.

- the GVP Module VIII on Post-authorisation safety studies

(http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129137.pdf).

In every updated AR (following committee members comments or MAH's clarifications or responses to RSI), the overall assessment conclusion and actions (section 2) as well as the recommendations (section 3) should be amended as necessary.

Note to the Rapporteur/PRAC - send the report/comments

To: LIST-H-PHARMACOVIGILANCE@EUDRA.ORG

Cc: < LIST-H-CHMP@EUDRA.ORG > (for CAPs) and/or

< LIST-H-CMD-PHARMACOVIGILANCE@EUDRA.ORG

> (for NAPs); "<active substance >_107n-q@ema.europa.eu (procedure mailbox);

<EMAProceduralManager>@ema.europa.eu; <EMAProceduralAssistant> @ema.europa.eu

Subject: <Active substance>(<Invented name (for CAPs) >); <Procedure Number> PRAC Rapporteur's AR, PRAC members comments by <date>, <MS comments>

[Important: Do not edit this table. The TOC-field is to be updated automatically (place the cursor in the TOC-field and press F9)].

Table of contents

List of abbreviations

[Provide a list of relevant abbreviations used throughout the assessment report.]

1. Background information on the procedure

In order to fulfil the obligation to submit the results of an imposed non-interventional PASS in accordance with Article 107p of Directive 2001/83/EC, <The Marketing Authorisation Holder/consortium><insert name of company/ consortium> submitted on <insert full date> a PASS final study report to the European Medicines Agency (EMA) for <active substance>.

[List only the CAPs involved in the procedure i.e. those concerned by the PASS final study report]

Centrally authorised medicinal product(s):	Active substance(s)	Marketing authorisation holder(s):
XXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXX

<For an overview of the nationally authorised products covered in the context of this final study report, please see appendix to this assessment report.>

<An update to the RMP resulting from the data presented in this PASS final study report was submitted.>

<An update to the Product Information resulting from the data presented in this PASS final study report was submitted.>

PASS information

[If the final study report follows the format of the "Guidance for the format and content of the final study report of non-interventional post-authorisation safety studies", the corresponding table can be copied here.]

Title	<i>[Informative title including a commonly used term indicating the study design and the medicinal product, substance or drug class concerned]</i>
Version identifier of the final study report	<i>[Number (note: this version identifier is needed in case of resubmission of the final study report based on comments from the competent authority)]</i>
Date of last version of the final study report	<i>[Date]</i>
EU PAS register number	<i>[Registration number in the EU PAS register]</i>
Active substance	<i>[List of pharmacotherapeutic group(s) [ATC code(s)] and active substance(s) subject to the study]</i>
Medicinal product	<i>[List of centrally authorised medicinal product(s) and/or, if possible, of nationally authorised products subject to the study]</i>
Product reference	<i>[Reference number(s) of centrally authorised products and/or, if possible, of nationally authorised products subject to the study]</i>
Procedure number	<i>[If applicable, Agency or national procedure number(s), e.g. EMA/X/X/XXX]</i>
Marketing authorisation holder(s)	<i>[Marketing authorisation holder(s) which initiated, managed or financed the study]</i>
Joint PASS	<i>["Yes" or "No"]</i>
Research question and objectives	<i>[Summary of the research question and main objectives- max. 150 words]</i>
Country(-ies) of study	<i>[List of countries where the study has been conducted]</i>
Author	<i>[Name and contact details of the main author of the final report of the study]</i>

2. <Preliminary> <Final> assessment conclusions and actions

[Important: If additional data was submitted as part of responses to the RSI or comments from Member States/EMA were received please update this section as necessary.]

[Overall summary and discussion of the PASS final study report, based on the Rapporteur/PRAC Assessment.

Provide an overall conclusion(s) deriving from the study and, if applicable, discuss any need for additional information and revision of the final study report before a final conclusion can be formulated.

This assessment should include a conclusion on the impact of the study results on the benefit-risk balance of the concerned medicinal product(s). In case the assessment concludes that the marketing authorisation should be varied, suspended or revoked, a justification should be provided.

Any impact on the RMP or the need for further studies or risk minimisation measures, monitoring or signal evaluation should be reflected in this section, including clear expectations for follow-up actions.]

<The benefit-risk balance of the concerned medicinal product(s) remains unchanged.>

[In case of recommendation to vary the marketing authorisation only]

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

*[In case a variation to change the product information or the conditions of the marketing authorisation is recommended, the scientific grounds need to be clearly documented i.e. a short summary of the evidence/data underlining the proposed changes should be included here. This should give the scientific motivation for the recommendation of the variation in a **concise manner (recommended maximum size of ½ page)**, as this text should be copied as the **scientific conclusions for the grounds for the variation in Annex IV to the CHMP opinion (and therefore published on the EMA website in all languages)**.*

<Therefore, in view of available data regarding the PASS final study report, the PRAC <Rapporteur> considered that changes to the <product information> <conditions of the marketing authorisation> were warranted.

3. <Preliminary> <Final> Recommendations

[Important: If additional data was submitted as part of responses to the RSI or comments from Member States/EMA were received please update this section as necessary.]

Based on the PRAC <Rapporteur> review of the PASS final study report version <X>, the PRAC <Rapporteur> considers <by consensus/majority decision> that:

[Choose one of the following options:]

[Option 1 - variation (changes to the product information or the conditions of the marketing authorisation)]

< the risk-benefit balance of medicinal products containing the active substance <name of active substance> concerned by the PASS final report remains unchanged but recommends that the terms of the marketing authorisation(s) should be varied as follows: >

[Option 2 - suspension]

< the risk-benefit balance of medicinal products containing the active substance <name of active substance> concerned by the PASS final report is negative and recommends the suspension of the marketing authorisation(s) on the following grounds: >

[Option 3 - revocation]

< the risk-benefit balance of medicinal products containing the active substance <name of active substance> concerned by the PASS final report is negative and recommends the revocation of the marketing authorisation(s) on the following grounds. >

[Option 4 - Request for supplementary information (RSI)]

< the risk-benefit balance of medicinal products containing the active substance <name of active substance> concerned by the PASS final report is subject to a request for supplementary information detailed in Section 12 in the Annex, before a recommendation can be made.

The responses timetable to the Request for Supplementary Information will be 30 days, unless indicated below at Rapporteur's request:

60 days (36 days to assess)>

[if Option 1 – variation- is chosen, fill in the following information as applicable]

[The scope of changes to the SmPCs and Package leaflets should be highlighted here. Alternatively, if extensive changes are proposed, a detailed description of the new text underlined and deleted text marked as strikethrough can be presented in an Annex].

Update of section X and X of the SmPC to add <the adverse reaction x with a frequency y> <to add a warning on...>. The Package leaflet is updated accordingly.

The following changes to the product information of medicinal products containing the active substance <name of active substance> are recommended:

Summary of Product Characteristics

[Add sections as relevant]

- Section 4.4

A warning should be <added> <revised> as follows:

<Exact wording of final warning>

- Section 4.8

<The following adverse reaction(s) should be added under the SOC <name of SOC> with a frequency <frequency>:

< The frequency of the adverse reaction <name of ADR> should be changed to <very common> <common etc...>

- Section x.y

Package Leaflet

[Add sections as relevant, ensuring that the above proposed changes to the SmPC are adequately reflected in lay terms in the package leaflet]

[In cases changes to the conditions of the marketing authorisation are recommended, these should also be highlighted here. Alternatively, if extensive changes are proposed, a detailed description of the new text underlined and deleted text marked as strikethrough can be presented in an Annex]

<The following changes to the conditions of the marketing authorisation(s) of medicinal products containing the active substance <name of active substance> concerned by the PASS final report are recommended:

[For CAPs should be structured as follows]

- **Annex II <CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT>**

- **<OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES>**
- **Annex 127a CONDITIONS OR RESTRICTION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

[For NAPs should be structured as follows]

<The marketing authorisation holder (s) shall complete the below conditions, within the stated timeframe: >

[if Option 2 - suspension - is chosen, fill in the following information]

Grounds for suspension

The conditions imposed to lift the suspension of the marketing authorisation are as follows:

Conditions to lift the suspension

[if Option 3 -revocation - is chosen, fill in the following information as applicable]

Grounds for revocation

[For CAPs if the RMP was updated with this submission]

At time of preliminary AR only: If the RMP could be acceptable with revisions required before recommendation:

<The PRAC Rapporteur considered that the RMP could be acceptable provided an updated RMP and satisfactory responses to the <request for supplementary information> detailed in annex is

Or at time of PRAC recommendation

<The PRAC <Rapporteur> considered that the RMP is acceptable. <In addition, minor revisions were recommended to be taken into account at the next RMP update>.

[For NAPs, if applicable]

<In addition, the MAH(s) which have an RMP in place should submit an updated RMP <at the next RMP update> <within x months> in order to address the following issues: >

4. <Other considerations>

< The recommendations proposed by the PRAC <Rapporteur> in this report merit careful consideration by <CHMP><CMDh>, as they propose e.g. important restrictions of use and/or substantial modifications in the Product Information or Annex II.>

Annex: <preliminary> <updated> <revised> Rapporteur assessment comments on PASS final study report <and RMP>

[This section should summarise the information provided by the marketing authorisation applicant/holder in the PASS final study report. It should be concise with relevant information presented in tables (where appropriate) to facilitate easy access and understanding.

Following circulation of the PRAC Rapporteur's Assessment report to PRAC members, comments received should be integrated in the discussion.

If the final study report has been resubmitted, the amendments to the final study report should be summarised and highlighted, and the comments and assessments should address whether the amendments respond to the objections/questions issued by the PRAC and relevant committees.]

1. Abstract

[The abstract is the text to be made public by the Agency according to Article 26(1)(h) of Regulation (EC) No 726/2004 via the EU PAS Register. The Agency should check if the abstract: (1) has been structured in accordance with the "[Guidance for the format and content of the final study report of non-interventional post-authorisation safety studies](#)", (2) is consistent with the results and the discussion of the full report, (3) does not promote the use of the drug. Attention should be given to the legibility of the text and clarity of the conclusions.

The abstract should provide the context or background for the study and should state the study's purpose, basic procedures (selection of study participants, settings, measurements, analytical methods), main results (i.e. information on the size of the study population, effect sizes and their statistical significance for the main study objectives), and principal conclusions. The conclusions should emphasize the important aspects of the study or observations, note important limitations, and avoid interpretation of the findings not supported by the results.

The abstract may be made public by the Agency in accordance with Article 26(1)(h) of Regulation No 726/2004. For this purpose, the marketing authorisation holder <has submitted><should submit> it to the EU PAS Register.

2. Milestones

Summary

[Copy here the table of section 5 of the final study report (Milestones).]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comment on any difference between planned and actual dates of study milestones and the explanation provided.]

<Text>

3. Rationale and background

Summary

[Summarise section 6 of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

*[Comment only on any difference between initially planned and actual rationale and background and the justifications provided (which have not previously been assessed), including an assessment of the impact of these on the validity of study results. Reference should be given to the previous assessment of the study protocol and to the final approved protocol. If no differences have been found write **<No difference observed from the final approved protocol>**]*

<Text>

4. Research question and objectives

Summary

[Summarise section 7 of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

*[Comment on any difference between initially planned and actual research question and objectives and the justifications provided, including an assessment of the impact on the validity of study results. Reference should be given to the previous assessment of the study protocol and to the final approved protocol. If no differences have been found write **<No difference observed from the final approved protocol>**]*

<Text>

5. Amendments and updates

Summary

[Summarise section 8 of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comment whether any substantial amendment and update to the study protocol after the start of data collection had impact on the validity of study results as initially planned in the final endorsed study protocol.]

<Text>

6. Research methods

Summary

[Summarise section 9 of the final study report.]

<Text>

PRAC Rapporteur's Assessment

[This section refers to the study protocol which usually does not require assessment except when changes to the endorsed version are provided. For each sub-heading mentioned in section 9 of the final study report (i.e. study design, setting, subjects, variables, data sources, bias, study size, data transformation, statistical methods, quality control) the assessors should only check and comment on any difference between initially planned and actual research methods employed in the conduct of the study. If available, justifications for any difference provided by the MAH and potential impact on the validity of the study results should be carefully assessed. Reference should be given to the previous assessment of the study protocol and to the final approved protocol. If no differences have been found write <No difference from the final approved protocol observed>].

<Text>

7. Results

7.1. Participants

Summary

[Summarise section 10.1. of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comments on the study participants section should mainly (but not only) take into account the following aspects:

- A clear accounting of study subjects who entered each stage of study (e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing followed and analysed) with an explanation for non-participation at every stage should be provided*
- Exact number of subjects included in analyses of different objectives or hypotheses should be clearly presented*
- In the case of a systematic review or meta-analysis, the number of studies screened, assessed for eligibility and included in the review (with reasons for exclusion at each stage) should be presented.]*

<Text>

7.2. Descriptive data

Summary

[Summarise section 10.2. of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comments on the descriptive data section should mainly (but not only) take into account the following aspects:

- Important characteristics of study subjects (e.g. age, sex, study site, categories of matching variables), potential confounders and/or other variables potentially relevant to the study question should adequately presented (by exposure or outcome categories if relevant) in table(s), with missing data for each variable of interest*

- *In case of cohort studies follow-up time (e.g. average and total) amount should be provided. In case of a systematic review or meta-analysis, descriptive information should include characteristics of each study from which data were extracted (e.g. study size, follow-up).]*

<Text>

7.3. Main results

Summary

[Summarise sections 10.3, 10.4 and 10.5. of the final study report with sub-headings as appropriate.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comments on the main results section should mainly (but not only) take into account the following aspects:

- *The analyses for different study objectives or hypotheses should be clearly separated*
- *The absolute numbers of outcome events in each exposure category should be provided*
- *The results should be clearly and adequately presented, including unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval)*
- *If relevant, estimates of relative risk should be translated into absolute risks*
- *Sensitivity analyses should be performed if planned in the statistical plan*
- *Unplanned analyses, such as sub-group analyses or investigation of alternative exposure categories, should be clearly identified and the reasoning behind them explained*

*Comments should be also provided if some specific result presented in this section is likely to be affected by potential source of biases. **For a full overview of the biases encountered in the final study report, please refer to [Section 8](#)***

<Text>

7.4. Adverse events/adverse reactions

Summary

[Summarise section 10.6. of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comments on the adverse events/adverse reactions section should mainly (but not only) take into account the following aspects:

- Is there an adequate presentation of solicited adverse events and reported adverse reactions in tabular format?*
- Are relevant and serious adverse events/reactions discussed?*
- Was causality assessment performed and presented in an adequate way, if relevant?*
- Are reported adverse events already included in the Summary of Product Characteristics?]*

<Text>

8. Discussion

Summary

[Summarise section 11 of the final study report, using sub-headings as appropriate.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comment on the main aspects of the study discussed by the MAH in the final study report:

Key results: *they should be provided in relation to each of the study objectives with a particular focus on the safety concern(s) which triggered the initiation of the study, and discussed on the basis of the aspects mentioned below:*

- **Interpretation:** *criteria for assessment should mainly consider whether:*

a) limitations of the study has been taken into account (see below)

b) the interpretation arise logically from the main results or is far-fetched,

- c) the interpretation focus on positive results from primary and/or only secondary/subgroup analyses
 - d) the results are substantiated by the MAH based on previous findings and/or relevant scientific literature
 - e) mechanistic/pharmacological/physiological explanation has been provided to support the observed findings
 - f) alternative explanations to the observed findings have been considered
- **Limitations:** the discussion on the limitations of the study should take into account:
- a) circumstances that may have affected the quality or integrity of the data (e.g. methods of data collection, low response rate, missing or incomplete data)
 - b) sources of potential biases (e.g. Selection bias, information bias, channelling/confounding by indication, exposure/outcome misclassification) and methods to control them (e.g. validation, imputation, sensitivity analyses)
 - c) robustness of the statistical analysis, including any multiplicity issue;
- **Generalisability:** the discussion on the generalisability of results should take into account data source, characteristics of the study population, inclusion and exclusion criteria. Findings from previous studies and/or relevant scientific literature might also be used to support the generalisability of the study results and discussions/conclusions from the initial assessment of the protocol may be useful for this section.

<Text>

8.1. Other information

Summary

[Summarise section 12 of the final study report and any additional information arising from the evaluation of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Provide an assessment of this additional information and of its impact on the study results and their interpretation.]

<Text>

9. Conclusions

Summary

[Summarise section 13 of the final study report.]

<Text>

PRAC Rapporteur's Assessment and Conclusions

[Comment on the MAH's main conclusion(s) derived from the study and on its evaluation of the impact of the results on the benefit-risk balance of the concerned medicinal product(s)]

<Text>

[In case a RMP was submitted (for CAPs) please fill in section 10]

10. Update of the Risk Management Plan

For Centralised Authorised Products (CAPs) RMP updates can be submitted together with a non-interventional imposed PASS final study report when the changes to the RMP are a direct result of data presented in the report. In this case, sections relative to the RMP assessment should be completed.

If further to the assessment, the Rapporteur identifies that the RMP updates are not a consequence of the data submitted, it should be flagged in order to remind the MAH of the correct procedural framework to be used for RMP update.

For nationally authorised medicinal products (i.e. authorised through MRP, DCP or National procedures) RMP updates should not be submitted and assessed together with a non-interventional imposed PASS final study report. Any RMP update should be submitted via a variation procedure to the relevant National Competent Authority for assessment.

This section should be completed if an update of the RMP was submitted further to this non-interventional imposed PASS final study report. Topics should focus on the changes made to the RMP subsequent to data arising from this submission.

Any new information which has been included in the RMP should be detailed in this section. The following 'minimum' information should be included in the assessment report, but additional details can also be included where considered helpful.

10.1 Summary of safety concerns

[Copy and paste the summary of safety concerns (table 3) from Part II Module SVIII. Ensure any updates to the table are clearly marked.]

The MAH identifies the following safety concerns

Table 1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	<> List
Important potential risks	<> List
Missing information	<> List

Having considered the updated data in the safety specification

<The PRAC Rapporteur><The assessor> agrees that the safety concerns listed by the MAH are appropriate>

or

<The PRAC Rapporteur><The assessor> considers that the following issues should be addressed : >

<The PRAC Rapporteur><The assessor> considers that> <should also be <a> safety concern(s)>

<<The PRAC Rapporteur><The assessor> considers that the following should not be <a> safety concern(s)>

[If the second option is chosen, the issues to be addressed must be included in the List of Questions]

10.2 Pharmacovigilance Plan

[Copy and paste table III.5.1 of the RMP if it is populated. Ensure any updates to the table are clearly marked.]

Table 1. Ongoing and planned studies in the PhV development plan

Activity/Study title (type of activity, study title [if known] category 1-3)*	Objectives	Safety concerns addressed	Status Planned, started,	Date for submission of interim or final reports (planned or actual)

*Category 1 are imposed activities considered key to the benefit risk of the product.
Category 2 are specific obligations

Category 3 are required additional PhV activity (to address specific safety concerns or to measure effectiveness of risk minimisation measures)

Comment on whether the studies are in the correct category (most studies will be in category 3).

The PRAC Rapporteur, having considered the updated data submitted, was of the opinion that

<routine pharmacovigilance remains sufficient to identify and characterise the risks of the product>

or

< the proposed post-authorisation PhV development plan is sufficient to identify and characterise the risks of the product>

or

< the proposed post-authorisation PhV development plan is not sufficient to identify and characterise the risks of the product and the <MAH><MAA> should propose PhV studies/activities as detailed in section 9.1

Or if nothing has been proposed

<the <MAH> should propose a post-authorisation PhV development plan>

The PRAC Rapporteur also considered that

[Choose one of the following]

< routine PhV remains sufficient to monitor the effectiveness of the risk minimisation measures>

or

< the study(ies) in the post-authorisation development plan remain<s> sufficient to monitor the effectiveness of the risk minimisation measures >

or

<the <MAH> should propose a study to monitor the effectiveness of <> *[state which additional risk minimisation measures should be studied]*

10.3 Risk minimisation measures

[The RMP may cover more than one medicinal product. In some circumstances risk minimisation measures may be specified per product, or certain risks may not be relevant to all products. Copy and paste table from section V.3 of the RMP. Ensure any updates to the table are clearly marked.]

Table 2. Summary table of Risk Minimisation Measures

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
	Dose reduction for in section 4.2 of the SPC..... Warning in section 4.4 to.....	

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
	Listed in section 4.8 <i>Prescription only medicine</i> Use restricted to physicians experienced in the treatment of.....	

The PRAC Rapporteur, having considered the updated data submitted, was of the opinion that

[choose one of the following]

<the proposed risk minimisation measures remains sufficient to minimise the risks of the product in the proposed indication(s)>

Or if there needs to be some other risk minimisation measures (either routine or additional) added

<the proposed risk minimisation measures are not sufficient to minimise the risks of the product> and supplementary risk minimisation measures are required relating to:

[List safety concerns and ensure questions added to List of Questions].

Or (when the risks cannot be brought to a satisfactory level)

the proposed risk minimisation measures are not sufficient to minimise the risks of the product in the proposed indication(s)

10.4 MAH's Summary of the RMP

[Refer to the MAH's RMP summary in section VI that includes key elements of the RMP in lay language and consider whether there are any updates to the RMP which need to be reflected in this section.

Consider whether:

- *any updates to the following sections are balanced and suitable for publication:*
 - *VI.2.1 Overview of disease epidemiology*
 - *VI.2.2 Summary of treatment benefits*
 - *VI.2.3 Unknowns relating to treatment benefit*
- *tables in Part VI have been updated appropriately*
- *the summary of updates to the RMP over time is accurate and has been updated appropriately (including whether this current update qualifies for inclusion in the table).]*

<The summary of the RMP <requires><does not require> revision following the conclusion of the

procedure.>

[specify]

10.5 RMP Annexes

[Check to see whether annexes have been updated accordingly and comment on this.]

The RMP annexes have <not> been updated appropriately <and the following further changes are recommended>:

[specify]

11. <Member States and EMA comments>

[Important: If comments from Member States or EMA were received please update Sections 2 and 3 as necessary.]

<text>

12. <PRAC>< Rapporteur> Request for supplementary information>

[Provide for each main section of the final study report a list of comments based on the Annexed AR requiring additional information or clarification.]

12.1 <Major comments>

12.2 <Other concerns>

13. <Assessment of the responses to the request for supplementary information>

[Important: If additional data was submitted as part of responses to the RSI please update Sections 2 and 3 as necessary.]

MAH response

[Summarise the responses provided by the MAH]

PRAC Rapporteur's Assessment

[Provide an assessment of this additional information and of its impact on the study results and their interpretation.]

<Text>

PRAC Rapporteur's Conclusion

<Text>

Appendix: Overview of the nationally authorised products for which PASS results were submitted