

Guidance on the Early Access to Medicines Scheme (EAMS) abridged risk management plan (RMP)

*All EAMS applications require an EAMS RMP. The template below is for an abridged EAMS RMP and can be used in the case that there is an RMP approved for the product in an authorized indication in the UK that is relevant to the use through EAMS. This would usually apply for a drug authorized for marketing for which the important safety concerns can be expected to be the same to those in its use through EAMS.*

*The RMP approved for the authorized product in the UK must be submitted alongside the abridged EAMS RMP.*

*In the case where the drug does not have a marketing authorization in the UK in an appropriate indication[[1]](#footnote-2), the full EAMS RMP template should be used*

*In brief, the structure of the EAMS RMP is as follows*

*Part I: Product overview*

*Part II: Safety specification – only “Module SVIII - Summary of the safety concerns” is required in this Part*

*Part III: Pharmacovigilance Plan – this section is specific for EAMS*

*Part IV: Plans for further efficacy studies - This section must be completed in the event that any efficacy or effectiveness studies are required by MHRA as part of the terms of the positive opinion. If such post-opinion studies are not a requirement, a simple cross reference to the accompanying approved RMP for the marketing authorisation can be accepted.*

*Part V: Risk minimization plan – If routine risk minimization only is needed and no additional risk minimisation, a simple cross reference to the accompanying approved RMP for the marketing authorisation can be accepted.*

*Part VI: Annexes – Any annexes which are identical to those in the accompanying approved RMP for the marketing authorisation can be omitted and replaced with a cross reference to the relevant annex of the accompanying approved RMP.*

*Blue highlighting – indicates a notable difference compared with the EU RMP rev 2*

*In addition to the green text in the template below, please refer to MHRA guidance on pharmacovigilance procedures[[2]](#footnote-3), GVP V, the EU RMP rev 2 template and the* *[Guidance on applying to the EAMS](https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams) for further reference.*

Early Access to Medicines Scheme (EAMS) abridged risk management plan (RMP) template (version 1.1)

| Active substance(s) (INN or common name): |  |
| --- | --- |
| Pharmaco-therapeutic group(ATC Code): |  |
| Name of Opinion Holder or Applicant: |  |
| Medicinal product(s) to which this RMP refers: | *Indicate total number of products to which the RMP refers.* |
| Name and version number of the approved RMP that the EAMS RMP bridges to |  |

<Enter a version no>

<Enter a date>

Data lock point for this RMP Version number

<Enter a date>

Date of final sign off

Version number of last agreed RMP:

Version number

<Enter a version no>

QPPV Name

QPPV Signature

Table of Contents

[Table of Contents 3](#_Toc59634426)

[Part I: Product(s) Overview 4](#_Toc59634427)

[Part II: Safety specification 5](#_Toc59634428)

[Part II: Module SVIII - Summary of the safety concerns 5](#_Toc59634429)

[Part III: Pharmacovigilance Plan 6](#_Toc59634430)

[III.1 Routine pharmacovigilance activities 6](#_Toc59634431)

[III.2 Additional pharmacovigilance activities 7](#_Toc59634432)

[III.3 Table of on-going and planned additional PhV activities 7](#_Toc59634433)

[Part IV: Plans for further efficacy studies 8](#_Toc59634434)

[IV.1 Summary of Post-opinion efficacy development plan 8](#_Toc59634435)

[Part V: Risk minimisation measures 10](#_Toc59634436)

[V.1 Summary table of risk minimisation measures 10](#_Toc59634437)

[V.2 Details of Additional risk minimisation measures (if applicable) 10](#_Toc59634438)

[Part VI: Annexes 13](#_Toc59634439)

[Annex 1 – EudraVigilance Interface 13](#_Toc59634440)

[Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme 14](#_Toc59634441)

[Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan 15](#_Toc59634442)

[Annex 4 - Specific adverse drug reaction follow-up forms 16](#_Toc59634443)

[Annex 5 - Protocols for proposed and on-going studies in RMP part IV 17](#_Toc59634444)

[Annex 6 - Details of proposed additional risk minimisation activities (if applicable) 18](#_Toc59634445)

[Annex 7 - Other supporting data (including referenced material) 20](#_Toc59634446)

[Annex 8 – Summary of changes to the risk management plan over time 21](#_Toc59634447)

Part I: Product(s) Overview

Administrative information on the RMP

|  |  |
| --- | --- |
| **Brief description of the product including:*** chemical class
* summary of mode of action
* important information about its composition *(e.g. origin of active substance of biological, relevant adjuvants or residues for vaccines*
 |  |
| **Indication(s) under EAMS** Current (if applicable)Proposed (if applicable) |  |
|  |
| **Posology and route of administration under EAMS** Current (if applicable)Proposed (if applicable) |  |
|  |
| **Pharmaceutical form(s) and strengths**Current (if applicable)Proposed (if applicable) |  |
|  |

Part II: Safety specification

<For full details of the Safety specification for this product, please refer to the approved RMP for the marketing authorisation in the UK: <drug name><version number and date of sign off>

Part II: Module SVIII - Summary of the safety concerns

A summary should be provided of each of the safety concerns identified in previous Modules of Part II.

This module is applicable for all initial applications.

Table SVIII.1 Summary of safety concerns

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

Part III: Pharmacovigilance Plan

*The Pharmacovigilance plan (PhV Plan) provides details of pharmacovigilance activities which are intended to identify and/or characterise safety concerns with a focus on use of the product under EAMS. What is required will depend upon the nature of the medicine, the target population, the number of safety concerns and where the medicine is in its life-cycle. A PhV Plan may also include details of studies to measure the effectiveness of risk minimisation measures for important measures where a formal study is required.*

*For products with a positive Opinion through EAMS, a means of proactive safety data collection, eg in the form of a registry, will be required. For further information on the registry requirements, please see the* *published guidance for applicants for the Early Access to Medicines Scheme (EAMS):* [*https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams*](https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams)*.*

*Depending upon the safety concerns, and areas to be investigated, a PhV Plan may include other types of epidemiological (non-interventional) studies (such as cohort, case control, drug utilisation etc.) but may also include interventional studies or more rarely pre-clinical activities (such as PK/PD, clinical trials, in vivo or in vitro studies). Further information on post authorisation safety studies is given in GVP Module VIII.*

III.1 Routine pharmacovigilance activities

Include a statement to describe the routine pharmacovigilance activities. This should confirm that a PSMF is in place and that adverse events/adverse drug reaction reports will be managed and reported in line with the Good Vigilance Practice Module VI, MHRA guidance on the exceptions and modifications to the EU guidance on GVP[[3]](#footnote-4) and the requirements on reporting for EAMS as described in the published guidance (<https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams#scientific-opinion>). The following statements should be included as applicable

<A pharmacovigilance system as described in the pharmacovigilance system master file is in place to support the pharmacovigilance tasks in relation to the product(s) concerned>

For an EAMS product with nationally licensed indication(s) in the UK (including in Great Britain and/or Northern Ireland):

<As per the Human Medicines Regulations 2012 as amended (HMR), regulation 188(1), all serious suspected adverse drug reactions (ADRs) are reported to MHRA within 15 calendar days of receipt and all non-serious suspected ADRs that occur in the UK are reported to MHRA within 90 calendar days of receipt. This includes suspected ADRs that arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure.>

For an EAMS product with no nationally licensed indication(s) in UK (the full RMP template should be used in this situation) :

<As per HMR regulation 170(3), all serious suspected ADRs are reported to MHRA within 15 calendar days of receipt>

*Additional requirements for reporting may be necessary:*

<The following additional pharmacovigilance reporting requirements apply:>

* <All suspected ADRs with a fatal outcome are reported to the MHRA within 7 calendar days of receipt, further information to be provided within 8 days>
* <All non-serious suspected ADRs are reported to MHRA within 90 calendar days of receipt>
* <other>

*Part III.1 should only include a brief description of the routine pharmacovigilance activities beyond adverse reaction reporting and signal detection (see examples in the GVP Module V, section V.B.6.1.).*

EAMS-specific forms for collection of adverse events should be provided in annex 3 as part of the pharmacovigilance protocol (see Module III.3).

*Where specific adverse reaction follow-up questions are used, their purpose and a description of the questionnaires used should be provided. The forms should be provided in Annex 4 of the RMP*

**III.1.1 Periodic update reporting**

Describe the timelines and frequency of periodic update reports.

Periodic reports should usually be submitted on a 3-monthly basis for the first year after positive scientific opinion. A one month period for preparation of the report is permitted, ie the first periodic report would have a data lock point at 3 months post-opinion and be submitted within 4 months post-opinion. A final periodic report is required following scientific opinion expiry and is to be submitted within 1 month after EAMS expiry.

For products that have had a positive EAMS opinion for 1 year or more, submission of periodic reports on a less frequent basis (e.g. 6-monthly) may be considered.

III.2 Additional pharmacovigilance activities

The plans for active pharmacovigilance for use of the product under EAMS, such as operation of a registry should be described here and the protocol provided in Annex 3.

*The Applicant should describe any other additional pharmacovigilance activities relevant to use of the product under EAMS, such as non-clinical, clinical or epidemiological (non-interventional or interventional) studies and explain why they are needed. e.g.:*

* *Long-term follow-up extensions of ongoing clinical trial(s);*
* *Cohort studies to provide additional characterisation of the long term safety of the medicinal product;*
* *Further effort to evaluate the missing data.*

Studies in the pharmacovigilance plan should relate to the safety concerns identified in the safety specification irrespective of whether the studies are to identify and characterise important risks/missing information, or to assess the effectiveness of additional risk minimisation activities using behavioural or safety outcome indicators.

A tabulated summary of on-going and completed pharmacovigilance studies should be provided in Annex 2.

Protocols for the registry and any other studies in the pharmacovigilance plan should be provided in Annex 3 of the RMP until completion of the study and submission to the MHRA of the final study report.

When any doubt exists about the need for additional pharmacovigilance activities, consultation with MHRA should be considered and please also refer to the [Guidance on applying to the EAMS](https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams). Further guidance on the conduct of post-authorisation safety studies (PASS) is provided in the GVP Module VIII.

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III.3 Table of on-going and planned additional PhV activities

This section should be a complete overview of all on-going and planned safety studies relevant to use of the medicinal product under EAMS and included in the Pharmacovigilance Plan, regardless of whether they were designed to assess the safety of the medicinal product, or the effectiveness of the risk minimisation measures.

Information on the study population should be part of the information provided in the study objectives as indicated in the example tabulation e.g. to evaluate the long term safety of adult/ paediatric/ adolescent/ elderly/ very elderly patients with Type 1 diabetes.

Clear milestones and due dates should be provided (e.g. submission of final study report by 31/01/2018). Final report due dates (and interim report due dates where appropriate) should be provided for all studies included in the table below.

If a study aims to evaluate the effectiveness of risk minimisation measures, this needs to be made explicit in the study summary of objectives.

Note: Regardless of other milestones, EAMS Opinion Holders are expected to provide updates on findings from registries/studies within the Periodic Reports and to provide an annual report with each EAMS renewal application.

1. On-going and planned additional pharmacovigilance activities

| Study/activity type, title; status (planned, on-going) | Objectives | Safety concerns addressed | **Milestones** (mandatory) | Due date (mandatory) |
| --- | --- | --- | --- | --- |
| 1. <E.g. CRUCIALCancer Registry at University College IdAho Liver unit(non- interventional cohort);*<On-going*>  | <E.g. To investigate long term survival, time to progression> | <E.g.* Bradycardia
* Thrombosis
* Leukopenia>
 | Protocol submission1 | DD/MM/YYYY |
| Final report | DD/MM/YYYY |
| Observational evaluation of safety of <product> in children and adolescent with high risk conditions*<Planned*> | To investigate the safety of <product> in high risk paediatric patients |  | Protocol submission1 | DD/MM/YYYY |
| Annual report | DD/MM/YYYY |

Part IV: Plans for further efficacy studies

*This section must be completed in the event that any efficacy or effectiveness studies are required by MHRA as part of the terms of the positive opinion. If such post-opinion studies are not a requirement, a simple cross reference to the accompanying approved RMP can be accepted and the section below need not be completed.*

IV.1 Summary of Post-opinion efficacy development plan

The purpose of this section is to have an overview of the planned and on-going efficacy studies. The results of the efficacy studies are also expected to contain safety data and might have an impact on the safety profile of the product(s).

A synopsis of the protocol(s) of any efficacy or effectiveness studies required by MHRA should be provided in Annex 5.

1. Planned and on-going post-opinion efficacy or required effectiveness studies

| **Study (type and study number), status** (planned, on-going) | **Objectives** | **Efficacy uncertainties addressed** | **Milestone(s)** | **Due Date(s), if applicable (e.g. for studies required by MHRA)**  |
| --- | --- | --- | --- | --- |
| <E.g. missing pivotal clinical trial;*On-going*> |  |  | <E.g. Final report> | <DD/MM/YYYY> |
| <E.g. 5 year efficacy follow-up in cancer as a standard condition;*On-going*> |  |  | <E.g. Final report> | <DD/MM/YYYY> |

Part V: Risk minimisation measures

Any additional risk minimisation measure should be described in Table V.1. For each safety concern identified in module SVIII “summary of the safety specification” a summary of any routine and additional risk minimisation measures should be provided. Where none are proposed, then “none proposed” should be entered against the safety concern.

Further guidance on additional risk minimisation measures can be found in GVP Module XVI.

*If routine risk minimization only is needed and no additional risk minimisation, a simple cross reference to the accompanying approved RMP can be accepted and the sections below need not be completed.*

V.1 Summary table of risk minimisation measures

| Safety concern | Routine risk minimisation measures | Additional risk minimisation measures |
| --- | --- | --- |
|  | Only reference to the general information included in the treatment protocol is needed here (i.e. specific wording is not needed) | (where applicable)listing in line with section V.2 |

V.2 Details of Additional risk minimisation measures (if applicable)

*This section should present the additional risk minimisation measures. The proposed draft key messages of additional risk minimisation activities should be provided in the RMP Annex 6.*

*Select from following options:*

*Statement that there is no need for additional risk minimisation activities*

<Routine risk minimisation activities as described in Part V.1 are sufficient to manage the safety concerns of the medicinal product.>

*Or*

**<Additional risk minimisation 1>**

*Further extensive guidance on additional risk minimisation measures and on monitoring the effectiveness of risk minimisation activities is provided in GVP Module XVI, but examples of the materials most frequently used are included below:*

***Healthcare Professional and Patient/Carer Guide***

*The term guide can refer to any descriptive material that educates Healthcare Professional and/or patients/caregivers about specific risks, and/or their early symptoms, and/or the best course of action to be taken when these appear beyond the recommendation contained in the Treatment Protocols. A guide may also aim to raise awareness about an on-going (required) registry/study, as well as about the general value of reporting adverse events. Terms such as ‘brochure’, ‘leaflet’ should be avoided and the term ‘guide’ should be used instead.*

***Healthcare Professional training material***

*In case of complex medicinal products, guides may be supplemented with training materials. They are commonly used to train Healthcare Professional when new complicated administration procedures (e.g. intra-vitreal injections, imaging diagnostics, ATMPs, etc.) are introduced or diagnostic products are first made available, in order to minimise the potential risks associated with performing such procedures.*

***Prescriber checklist***

*Used to facilitate patient selection when initiating therapy or repeat prescription is issued, as appropriate. The checklist should remind prescribers of e.g. a restricted indication, contraindications, warnings and precautions needed for the use of a medicinal product particularly relating to important safety concerns in the SmPC and to facilitate the need for examination of specific aspects of the patient’s health before initiating treatment and/or during continuous monitoring as appropriate.*

***Patient diary***

*It is generally requested to record information on the recommended treatment (e.g. date and/or outcome of specific tests needed) to facilitate regular monitoring of the patient’s health status with respect to the medicinal product related safety concerns or particular signs and symptoms that can be discussed with the Healthcare Professionals. It is useful for the patient to read about precautions needed to minimise important risks.*

***Patient alert card***

*The aim of this tool should be to ensure that special information regarding the patient’s current therapy and its important risks (e.g. potential life-threatening interactions with other therapies) is held by the patient at all times and reaches the relevant healthcare professional as appropriate. The information should be kept to the minimum necessary to convey the key minimisation message(s) and the required mitigating action, in any circumstances, including emergency. Ability to carry with ease (e.g. can be fitted in a wallet) should be a key feature of this tool.*

***Pregnancy prevention programmes***

*A pregnancy prevention programme (PPP) is a set of interventions aiming to minimise pregnancy exposure during treatment with a medicinal product with known or potential teratogenic effects. The scope of such a programme is to ensure that female patients are not pregnant when starting therapy or do not become pregnant during the course and/or soon after stopping the therapy. It could also target male patients when use of a medicinal product by the biological father might have a negative effect on the pregnancy outcome. A PPP combines the use of educational tools with interventions to control appropriately access to the medicine. Therefore, the following elements should be considered individually and/or in combination in the development of a PPP.*

*• Educational tools targeting healthcare professionals and patients to inform on the teratogenic risk and required actions to minimise this risk e.g. guidance on the need to use more than one method of contraception and guidance on different types of contraceptives; information included for the patient on how long to avoid pregnancy after treatment is stopped; information for when the male partner is treated;*

*• Controlled access at prescribing or dispensing level to ensure that a pregnancy test is carried out and negative results are verified by the healthcare professional before prescription or dispensing of the medicinal product;*

*• Prescription limited to a maximum of 30 days supply;*

*• Counselling in the event of inadvertent pregnancy and evaluation of the outcome of any accidental pregnancy.*

Objectives:

*Include objectives including a list of risks addressed.*

Rationale for the additional risk minimisation activity:

*Include justification on why the particular additional risk minimisation is considered needed.*

Target audience and planned distribution path:

*Include very brief summary of planned communication plan.*

Plans to evaluate the effectiveness of the interventions and criteria for success:

*Specify how effectiveness will be measured and provide the criteria for judging success. Milestones for reporting should be included when effectiveness is evaluated using only routine pharmacovigilance activities.*

**<Removal of additional risk minimisation activities>**

<Rationale for the removal:>

*Include justification when an additional risk minimisation activity is proposed to be removed from the RMP.*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

Part VI: Annexes

Any annexes which are identical to those in the accompanying approved RMP can be omitted. A cross reference should be provided.

Annex 1 – EudraVigilance Interface

Not required

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

*List* ***all*** *studies included in the Pharmacovigilance Plan (current or in previously approved RMP versions).*

Table 1 Annex II: Planned and on-going studies

| Study*Include study short name, title and category number*  | Summary of objectives | Safety concerns addressed | **Protocol link****Milestones***Include link or reference to full protocol (included in RMP Annex 3 or eCTD).**Include planned submission dates of interim and final study report requested by the Competent Authorities.* |
| --- | --- | --- | --- |
| *e.g.:**LE observational cohort safety study* *(study LE123)* | *e.g. To evaluate over a minimum of 1 year the incidence of all-cause mortality and adverse events of special interest in patients with lupus erythematosus.* | *e.g.:**- serious infections (including non-serious and serious opportunistic**infections and PML)**- malignancies (including non-melanoma skin cancer)**- serious infusion**- hypersensitivity reactions**- serious psychiatric events (mood disorders, anxiety and suicide).* | *Link to protocol**Interim results:31 December 2016**Final study report submission: 15 July 2020*  |

Table 2 Annex II: Completed studies

| Study*Include study short name, title and category number*  | Summary of objectives | Safety concerns addressed | Date of Final Study Report submissionLink to report*Include date of report submission or state the reason for not submitting the results.**Include link or reference to full Final Study report (included in eCTD).* |
| --- | --- | --- | --- |
| *e.g.:**An open-label, multicentre evaluation of the long-term safety and efficacy of drug A in the prevention and treatment of bleeding episodes in previously untreated patients with acquired haemophilia A**A123* | *e.g. To evaluate the long-term safety in subjects with acquired haemophilia A* | *e.g.**- Long-term safety**- Safety profile in patients ≥ 75 years* | *27 May 2015**Link to final study report* |

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

*Annex 3 should include protocols of studies in the pharmacovigilance plan. A description of the proactive safety data collection (i.e. registry) for use of the product under EAMS should be included here.*

*This annex may include the electronic links or references to other modules of the eCTD dossier where the protocols are included, instead of the full protocol documents.*

*A table of contents should be provided.*

Annex 4 - Specific adverse drug reaction follow-up forms

**Table of contents**

**Follow-up forms**

*Provide the specific adverse drug reaction follow-up forms in full.*

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

*This section should include links or references to other parts of the eCTD dossier, where the protocol for a required efficacy or effectiveness study was submitted. This information is meant to facilitate the assessment by maintaining an overview of the post-authorisation efficacy and safety development plans.*

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

**<Draft/approved> key messages of the additional risk minimisation measures**

*Key messages are included before grant of positive scientific opinion for review and assessment. Final versions must be agreed with the MHRA before the product is made available to patients via EAMS.*

*If the product requires a revision of the key messages post-opinion, an amended set of key messages can be proposed for assessment in Annex 6 by the Marketing authorisation holder (tracked changes).*

Prior to the <launch><use> of <PRODUCT NAME> via EAMS the Opinion Holder must agree about the content and format of the <educational> <controlled access> <pregnancy prevention> <other> programme, including communication media, distribution modalities, and any other aspects of the programme, with the MHRA.

The <educational> <controlled access> <pregnancy prevention> <controlled distribution> <other> programme is aimed at *<describe main objectives of programme>*

The Opinion Holder shall ensure that all <healthcare professionals> <and> <patients/carers> who are expected to <prescribe> <dispense><use> <PRODUCT NAME> have access to/are provided with the following educational <package> <message to be disseminated through professional bodies>:

* <Physician educational material>
* <Patient information pack>
* <Other *(if any other audience is targeted it should clearly described)>*

**Physician educational material**:

* <The treatment protocol – information for healthcare professionals>

*In addition to the Treatment Protocol select all tools that apply:*

* <Guide for healthcare professionals>
* <Healthcare professionals training material>
* <Prescriber checklist>
* <Patient alert card>

*Based on the choice on the above listing, select all relevant elements and edit as required.*

* **Guide for healthcare professionals**:
* <Relevant information of the safety concern(s) addressed by the aRMM (e.g. seriousness, severity, frequency, time to onset, reversibility of the AE as applicable)>
* <Details of the population at higher risk for the safety concern addressed by the aRMM (e.g. contraindications, risk factors, increased risk by interactions with certain medicine)>
* <Details on how to minimise the safety concern addressed by the aRMM through appropriate monitoring and management (e.g. what to do, what not do, and who is most likely to be impacted according to different scenarios, like when to limit or stop prescribing/ingestion, how to administer the medicine, when to increase/decrease the dosage according to laboratory measurements, signs and symptoms)>
* <Key message to convey in patients counselling >
* <Instructions on how to handle possible adverse events>
* <Information about the <name of> <study> <registry> and the importance of contributing to such a study>
* <Remarks on the importance of reporting on specific adverse reactions, namely: < adverse reaction 1, adverse reaction 2 etc…>
* <Other to be specified>
* **Healthcare professionals training material**:
* <Information on <product name>, including the approved indication according to the SmPC>
* <Detailed description of the administration procedures of <PRODUCT NAME>>
* <Patient’s preparation for the procedure and subsequent monitoring>
* <Management of early signs and symptoms of selected safety concerns, namely: safety concern 1, safety concern 2, etc.>
* <Other to be specified>

*For diagnostic products, select additional information:*

* <Limitations of <PRODUCT NAME> use, interpretation errors, safety information and the results of clinical trials informing on the diagnostic use of <PRODUCT NAME>>
* <Review of the imaging reading criteria, including method of image review, criteria for interpretation, and images demonstrating the binary read methodology>
* <Demonstration cases with correct imaging interpretation by an experienced reader and a number of clearly positive and negative cases as well as less clear-cut cases>
* **Prescriber checklist**:
* <Lists of tests to be conducted for the initial screening of the patient>
* <Vaccination/treatment course to be completed/withdrawn before/after treatment>
* <Premedication, general health, and pregnancy and contraception checks immediately before/during/after treatment>
* <Monitoring activities during treatment and for X years after last treatment>
* <A specific reference to the fact that the patient has been informed and understands the <potential> <teratogenic> risks of <specify risk(s)> and the measures to minimise them>
* <Other to be specified>
* **Patient alert card**:
* <A warning message for healthcare professionals treating the patient at any time, including in conditions of emergency, that the patient is using <PRODUCT NAME>>
* That <PRODUCT NAME> treatment may increase the <potential> risk of: <Risk 1, Risk2, etc.>
* Signs or symptoms of the safety concern and when to seek attention from a healthcare professional
* Contact details of the <PRODUCT NAME> prescriber

**The patient information pack**:

* Treatment protocol – information for patients

*In addition to the Treatment Protocol, select all that applies:*

* <A patient/carer guide>
* <A patient diary>

*Based on the choice on the above listing, select all relevant elements and edit as required. The suggested key elements are not strictly supposed to be used only for the related specific tool (see example below):*

* **Patient/carer guide**:
* <A description of the <potential> <teratogenic> risks(s) associated with the use of <PRODUCT NAME> namely: <Risk 1, Risk2, etc.>
* <A description of the correct use of <product name> and the <potential> risks associated with its use, namely: <Risk 1, Risk2, etc.>
* <Detailed description of the modalities used for the self-administration of <PRODUCT NAME>>
* <A description of the <early> sign and symptoms of the <potential> risk of <specify risk(s)>
* <A description of the best course of action if sign and symptoms of those risks present themselves (e.g. How to reach your doctors)>
* <Recommendations for the planning of the monitoring schedule>
* <Information about the <name of> <study> <registry>>
* <Remarks on the importance of reporting on specific adverse reactions, namely: < adverse reaction 1, adverse reaction 2 etc…>
* <Other to be specified>
* **Patient diary**:
	+ <A record on the recommended treatment <date> <outcome of specific test(s)> to facilitate regular monitoring of the patient´s health status to product related <Risk 1, Risk2, etc.> or <particular symptoms that can be discussed with the Physician etc.>>
	+ <A description of precaution(s) needed to minimise <Risk 1, Risk2, etc.> associated with the use of <PRODUCT NAME>>

*For pregnancy-related risks, select additional information:*

* <Recommendation not to take <PRODUCT NAME> in case of pregnancy>
* <For women of child bearing potential recommendation to use effective contraception methods>
* <Recommendation for regular pregnancy testing>

Annex 7 - Other supporting data (including referenced material)

*Only key literature referenced in the RMP should be included in the format of electronic links or references if already included in other modules of the dossier.*

Annex 8 – Summary of changes to the risk management plan over time

*A list of all significant changes to the Risk Management Plan over time*

|  |  |  |
| --- | --- | --- |
| **Version** | **Approval date****Procedure** | **Change** |
| <e.g. 7.0> | <At the time of positive opinion> <procedure number> dd/mm/yyyy | *Add high level description of major changes:*<Safety concerns>*Important Identified/Potential Risk/Missing information 1: Added/ Removed/ Reclassified* <Pharmacovigilance Plan>*Study 1:* * *Added as a new safety concern <Important identified risk 1> has been identified and need to be further characterised*
* *Due date postponed due to difficulties with patient recruitment*
* *Removed as study has been completed and obligation has been fulfilled*

<Post-authorisation efficacy plan><Risk minimisation measures>*Additional risk minimisation 1:* * *Added/ Modified to increase the patient´s awareness on the signs and symptoms relevant to the early recognition of increased plasma levels in patients with specific polymorphism*
* *Added to inform the healthcare professionals about the new available information regarding heart failure*

<Annexes>* *Annex 4: Specific adverse drug reaction follow up forms 1 added*
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1. An appropriate indication would concern a population in whom the safety profile is likely to be relevant to that in the EAMS use, such that the important safety concerns would usually be expected to be the same for both the authorised product and the EAMS application. [↑](#footnote-ref-2)
2. <https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures/guidance-on-pharmacovigilance-procedures>; <https://www.gov.uk/government/publications/exceptions-and-modifications-to-the-eu-guidance-on-good-pharmacovigilance-practices-that-will-apply-to-uk-mahs-and-the-mhra> [↑](#footnote-ref-3)
3. https://www.gov.uk/government/publications/exceptions-and-modifications-to-the-eu-guidance-on-good-pharmacovigilance-practices-that-will-apply-to-uk-mahs-and-the-mhra [↑](#footnote-ref-4)