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EUROPEAN UNION GOOD PHARMCOVIGILANCE PRACTICE (RISK MANAGEMENT PLAN)

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ABSTRACT

"Materials vigilance" protects patients from medical device malfunctions. Traceability tracks device life. Each state's medical device safety is its responsibility. Medical device risk classification. EU medical device markets need CE markings. "Notified body" issues 5-year certifications. Market and incidents are monitored. Rules boost efficiency and transparency. Medical device incident reporting increases safety. Local reporters must report incidents to ANSM. ANSM assesses the safety, efficacy, and quality of healthcare products nationally, centralises vigilance reports, and makes decisions. Medical device law is unified by European and global materials vigilance. Traceability aids medical device recalls. Traceability is the responsibility of each centre, not the manufacturer. CE labels are safe. IUDIs, standardised label data, barcodes, and terminology improve traceability. Create international databases

In this article Risk Management Process is explained and used when obtaining preliminary marketing authorization or making major changes to an existing product registration in the EU. In March 2017, the EU accepted a revised version of its Good Pharmacovigilance Practices (GVP) Guideline, Module V Risk Management Systems, which gives a framework for constructing more specified, achievable, and risk-proportionate RMPs. Using Module V of the GVP and its interpretation to analyse RMP risks.

Keywords: Good Pharmacovigilance Practice, Risk Management System, Risk Management Product, Modules V, Safety perspective

INTRODUCTION

In the approved indication, the target population's risk-benefit balance is positive (s). Severity, likelihood, patient impact, and public health impact vary for adverse drug reactions. There will be some unintended consequences found and characterised after the drug has been given the green light. A risk management plan (RMP) identifies, characterises, and minimises drug risks RMP:

1. Identification or characterization emphasis on important risks and missing information ("safety specification");
2. Planning pharmacovigilance to identify clinically significant risks and ill consequences ("pharmacovigilance plan");
3. Plan, implement, and evaluate risk reduction ("risk minimization plan") **[1]**.

STRUCTURE/PROCESS

Risk Benefits:

Benefits outweigh risks with drug risk management. RMP manages drug lifecycle risk. (3) DIR Identified, potential, and post-authorization safety data must inform risk management. Product-life RMPs should be updated (s). Adding and removing safety worries.

This document's risk classification guidance may reduce RMP safety concerns: Important potential risks may be removed from the RMP safety specification or reclassified when Diagnostic reports don't support original assumption, the individual impact is less than anticipated, or pharmacovigilance can't characterise the risk.

Considerable risks can be identified and removed from the safety specification once they have been fully characterised and properly managed (for example, for long-market products that are not subject to additional pharmacovigilance measures and/or risk minimization measures that recommend specific clinical measures). For the full integration of risk management into accepted clinical practise (e.g., B. participation in care and monitoring).

As the product grows, the classification of missing information may become meaningless if new information or pharmacovigilance initiatives cannot more properly characterise the product's safety profile. Pre-approval can't be utilised on populations that need additional information regarding risks and benefits. B. EU standard treatment practises may reduce risk (i.e., they could need to be substituted with more effective activities). risk-reduction (e.g. contraception) **[1]**.

Risk-Management Responsibilities:

Applicants are directly involved in risk management planning for medicines. An applicant/MA holder must have a risk management system; reviewing the product's safety profile after clinical use. The marketing authorisation holder should

monitor pharmacovigilance data to determine if there are new risks or if risks have changed [Dir Art 104(3)(e)] Characterized below: Hotfix the risk management system and RMP. PSURs (see GVP Subsystem VII) indicate a product's security profile. After initial applications, marketing authorization holders should check permitted products twice for safety concerns, pharmacovigilance, and risk minimization. PSUR after the first 5-year renewal.

This PSUR submission is expected 8-9 years after the marketing authorization is granted, when initial marketing authorization applications for generic products for the active substance are assessed. As a result, the medicinal product's safety profile can be reviewed and updated.

Plan Format and Content Overview (RMP)

RMP has 7 parts. The RMP must follow [IR Annex Itemplate]'s RMP delivery isn't guaranteed; see GVP Module VII for details. PSURs reflect the product's security profile. Once marketing permission applications are complete, marketers should double-check approved products **[2]**. **Table V.1** lists the RMP aspects.

Table V.1: RMP Components and Parts

Part I	Product(s) overview
Part II	Safety specification
Module SI	Epidemiology of the indication(s) and target population(s)
Module SII	Non-clinical part of the safety specification
Module SIII	Clinical trial exposure
Module SIV	Populations not studied in clinical trials
Module SV	Post-authorisation experience
Module SVI	Additional EU requirements for the safety specification
Module SVII	Identified and potential risks
Module SVIII	Summary of the safety concerns
Part III	Pharmacovigilance plan (including post-authorisation safety studies)
Part IV	Plans for post-authorisation efficacy studies
Part V	Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)
Part VI	Summary of the risk management plan
Part VII	Annexes

RMP part II knowledge should be equal to identified and potential risk and depend on the type of medicinal product, its risks, and its life cycle (DIR Art 8(3)). Article 14 (EC 1394/2007) establishes ATP RMPs (ATMP). Marketing ATMP must be employed by applicants/holders risk management plans, considering post-authorization followup needs. Before submitting the ATMP RMP, consult the authority. The Agency's website explains ATMP safety, efficacy, and risk management requirements.

The RMP should include all relevant medicines contender/MAH the same active ingredient(s). The RMP should be detailed without distracting from product risk management. The RMP's safety specifications shouldn't duplicate data from unless the portions are intended to be PSUR modules, somewhere within the dossier.

Based on data from pre-clinical, clinical, and post-marketing trials, the RMP should provide a unified overview and discussion of the most significant risks. Any RMP data should match other dossier sections. RMPs should link to non-clinical and clinical summaries. RMP submissions for newly approved items with sparse safety information may include safety data and discussion

Table V.2 shows where eCTD information in the RMP be examined. Initial marketing authorization applications, high variability, or historical data are referred to as "eCTD data." from previous submissions. In a centralised procedure, the RMP is an eCTD; in non-centralised procedures, it's a CTD. Depending on the competent authority, this Module's Read eCTD statistics as CTD data/submissions.

Table V.2: Shows where eCTD information in the RMP be examined

RMP Module	eCTD
Part I Product(s) overview	Module 2.3 Quality overall summary Module 3 Quality
Module SI Epidemiology of the indication(s) and target population(s)	Module 2.5 Clinical overview
Module SII Non-clinical part of the safety specification	Module 2.4 Non-clinical overview Module 2.6 Non-clinical written and tabulated summaries Module 4 Non-clinical study reports
Module SIII Clinical trial exposure	Module 2.7 Clinical summary Module 5 Clinical Study reports
Module SIV Populations not studied in clinical trials	Module 2.5 Clinical overview
Module SV Post-authorisation experience	Module 2.5 Clinical overview
Module SVI "Additional EU requirements for the safety specification"	Data not presented elsewhere in eCTD
Module SVII Identified and potential risks	Module 2.5 Clinical overview (including benefit-risk conclusion) Module 2.7 Clinical summary (SPC)
Module SVIII Summary of the safety concerns	Module 2.5 Clinical overview Module 2.7 Clinical summary
Part III Pharmacovigilance plan (including post-authorisation safety studies)	Module 2.5 Clinical overview Module 2.7 Clinical summary
Part IV Plans for post-authorisation efficacy studies	Module 2.5 Clinical overview Module 2.7 Clinical summary
Part V Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)	Module 2.5 Clinical overview Module 2.7 Clinical summary

Only RMP-referenced literature should be in Annex 7, if these are previously references or links in eCTD VB.4 outlines the RMP's modules and parts. This guidance may not apply to all medicines and may be missing topics. RMPs should be scientifically based and free of promotional elements.

List data lock point, List data lock point, Version and approval date should be listed here (opinion date). Module updates need a high-level rationale; assessment versions

don't. Last RMP sequence for eCTD submissions (e.g. closing sequence). The MAH/QPPV has evaluated and approved the RMP. APPs and has an electronic signature to show QPPV oversight.

VB4. RMP PART I "Product (s) Overview"

This should provide RMP administrative details and a product overview (s). Current and accurate information about the ongoing application should be presented for the marketing authorization. Include:

Substance(s), pharmacotherapeutic group(s), and dosage If acknowledged on the time of utility, the names of the predicted destiny advertising authorization holders with inside the reference Member State for mutual recognition/decentralized procedures. Approving (central, mutual recognition).

An.eCTD hyperlink ends.in product statistics pr imarily based totally at the indication. Dose (pertains to most important populace only; no duplication of phase 4.2 of the SmPC); pharmaceutical bureaucracy and concentrations; if the product is concern to extra manage with inside the EU; authorised and proposed and, if applicable, pharmaceutical bureaucracy and concentrations (after final touch of the preliminary authorization utility or with RMP updates).

VB5. RMP PART II "Safety Specification"

Safety specification discusses the medicinal product(s)' safety profile and risk-management areas. Identify dangers, possible risks, and gaps in knowledge. It should also address after authorization, the risk-benefit ratio should be improved by identifying at-risk individuals (both when used on- and off-label) and any unresolved safety issues that warrant further study. It directs risk minimization and pharmacovigilance. The terms SI-SV, SVII, and SVIII are equivalent in the ICH-E2E.SVI implements EU-mandated RMPs. When compiling the safety specification, applicants/MA holders should follow the provided structure.V.C.1.1 outlines marketing authorization application requirements.

VB.5.1. GENERAL CONSIDERATION FOR GENERIC PRODUCTS AND ADVANCE AUTHENTIC MEDICINAL ITEMS

VB.5.1.1. Generics:

RMP safety standards apply to generic drugs. Applicants must propose and justify the safest RMP. If justified a new generic medicine applicant may add or remove reference product safety concerns when their differences in the product's characteristics from the reference product, such as a dangers associated with a disintegrant present only in some products, or when there is a more recent

comprehension of the current safety profile. containing the reference product).

VB.5.1.2. Products for Advanced Therapy:

According to Regulation (EC) No 1394/2007, some pharmaceuticals designed for human use are advanced treatment pharma. This regulation applies to products made using gene therapy, somatic cell therapy, and tissue engineering.

The properties of these products may result in risks to living donors, germ line alterations, and vector transmission. These risks must be thought about when creating ATMPs (see V.B.5.8).

VB.5.2. RMP PART II, MODULE SI "Epedimiology of the Indication(s) and Target Population(s)"

This RMP module must take into account illness outcome, prevalence, and incidence (i.e. indications), and relevant co-morbidity, stratified by age, gender, and ethnicity when relevant. Describe risk factors and treatments. Emphasize the EU indication's epidemiology. Regional epidemiology. This section should describe target population unfavourable situations, how often they occur, and what they resemble like. The text ought to predict, interpret, and reduce risks. Short, non-promotional text is needed.

VB.5.3. RMP PART II, MODULE SII "Non Clinical part of the Safety Specification"

This RMP module should include a statement of non-clinical safety findings, such as toxicity (serious issues with acute or repeat-dose toxicity), safety pharmacology, encompassing reproductive/developmental toxicity, genotoxicity, and carcinogenicity; cardiovascular system toxicity, including QT interval prolongation; and other toxicity-related data or information.

According on the treatment, the entire community, and prior knowledge about analogous drugs or procedures, a significant non-clinical safety finding may be made. Discuss organ system toxicity and human relevance. Discuss safety-relevant quality aspects (e.g. genotoxic impurities). If a product is for childbearing women, reproductive, developmental toxicity data should be mentioned. RMP module SVIII should include non-clinical safety findings that risk the target population. When a non-clinical safety finding isn't relevant for humans, a brief explanation is required, but it won't be carried forward as a safety concern to SVII and SVIII.

Non-clinical or clinical studies are required. This section's contents should reflect module SVII. Apply. Non-clinical evidence could jeopardize this component's safety after approval. Non-clinical safety concerns without post-marketing data can be addressed.

VB.5.4. RMP PART II, MODULE SIII "Clinical Trial exposure"

Initial RMP submission or major update due to new exposure data should include summary information on clinical trial patients (e.g. tables/graphs) (e.g. in a new indication). Without new clinical trial exposure data, this section is fine. Population size should include patients and exposure time. This requires classification. Age, gender, indication, dose, and risk stratifications. Children's data should be sorted by age (e.g., ICH-E113), and so should older people's. Aggregate data unless warranted.

Tables and graphs need totals. Age, gender, and ethnicity tables should only cover experiment participants (for example, an open-label extension study). Different table totals? When the RMP is given a fresh indication, pharmacological form, or route of administration, clinical trial data should be combined across all purposes.

RMP II V.B5.5 "Population not studied in Clinical Studies"

Module RMP should describe missing-data populations. When accessible and appropriate, information on low exposure of special populations (pregnant women, nursing mothers, Renal, hepatic, cardiac, genetic polymorphisms, immune-compromised patients) should be included. Describe renal, hepatic, or cardiac dysfunction and polymorphism.

If there is insufficient information and the product will be utilised in unstudied groups, state this in the RMP. Excluded groups should only appropriate for permitted and intended purposes ("on-label") and if their use poses clinically substantial risks. Target groups and clinical trial participants may be affected more by trial settings than inclusion/exclusion criteria. RMP SIV missing subpopulations. If omitted populations pose a clinical danger, include it.

RMP PART II VB.5.6 "Post Authorization expirience"

Post-marketing information should be included in this RMP module if it's accessible from non-EU countries where the product is already approved or from other approved products made by the same marketing authorization holder. Risk management planning requires post-authorization experience. No more PSURs. When relevant to module SVII's risk identification discussion, address how the medicine is utilised in practise, Off-label and in particular populations. Summarize data on usage in non-EU markets for indications not approved in the EU, and address the implications for EU approval, if applicable for SVII.

VB.5.7 CONTAINS MODULE SVI of RMP PART II, "EU Safety Creteria"

EU-RMP should address illegal use in addition to ICH-E2E safety topics (see GVP Annex IV) [DIR Art 71(2)].. "Identified and potential risks"

This RMP module should recognise hazards and information gaps (safety concerns). Module SVII should include intentional or accidental overdose where there is a short therapeutic window, dose-related toxicity, or a considerable risk of purposeful overdose (e.g. in depression). Important overdose RMP module SVIII should deal threats and risk minimization should be advocated in RMP part V, when overdose injury happened during clinical trials. Medication mistakes are unexpected failures in medication treatment that affect patients. Discuss pharmaceutical mishaps during product development and clinical trials. What happened? Annex 2 of the Medication Error Prevention Guide lists errors and their repercussions. The updated RMP should address infectious agent transmission from manufacturing processes or materials and post-marketing medication concerns. Live attenuated vaccines can sicken immunocompromised people.

Risks associated arising from off-label use of the commodity should be considered for inclusion in the protection specified requirements when differences in safety concerns between the target and off-label societies are anticipated. Module XVI and P.III discuss embryo/fetal teratology. administration-related hazards, such as transdermal patches with leftover active component or radioactive diagnostics (e.g. transdermal patches).

Applicants should consider specific concerns while defining ATMP RMP safety requirements (see Safety and Efficacy Guideline). Section SVII of Risk Management of Advanced Therapy Medicinal Products identifies safety concerns in the original RMP submission. RMP section filled out with the first marketing authorization (MA) application or post-authorization and should include any safety concerns. The original RMP should "seal" this portion.

"Risk judged significant for inclusion in the list of safety concerns" and "Risk not considered important for inclusion in the list of safety issues "Discuss risk severity, frequency, and impact in this RMP section. Causes of non-safety hazards **[3]**.

VB.5.8.1. RMP PART II, MODULE SVII SECTION "New Safety Conserns and Reclassification with Submission of an updated RMP"

During post-authorization, new product risks should be reported in the dossier's safety section, together with an assessment of whether they should be judged substantial and added to the RMP's safety specification (using Signal, benefit-risk, or safety variation evaluations). V.B.5.8.3 should identify extra hazards, not the RMP. When a risk is decreased or excluded, safety data should be justified. This section may describe a previous regulatory request **[4, 5]**.

VB.5.8.2. RMP PART II, MODULE SVII: Identified Risks, Anticipated Risks and Missing information"

Discrepancies in RMPs for different products (such as fixed dose combos) should raise safety concerns. RMP covers all product stages. Data on major hazards and concerns Risk, hypothesised mechanism, evidence source(s), and evidence strength (scientific basis for suspecting association). Periodicity, absolute risk, hazard ratio, severity, reusability, long-term effects, and quality of life; patient variables, dose, at-risk period, additive or synergistic factors. Health risk-benefit analysis Tedium (if a risk can be managed through routine or additional efforts beyond PI information); (e.g. absolute risk in relation to target population size and actual number of affected individuals, or overall population result).Incomplete data display Missing (MedDRA) information; Proof of the target population's safety profile; Describe a dangerous or understudied population **[6]**.

RMP PART II MODULE SVIII, VB.5.9, "Summary of Safety problems"

This RMP module should offer a list of safety issues. Important threats, potential dangers, and missing information **[7]**.

PART III of the RMP is "Pharmacovigilance strategy" (VB.6). Part III of the RMP describes the applicant/pharmacovigilance MAH's plan. Designed for deciding if a prospective danger is confirmed as an identified risk or rejected, characterising safety issues in detail, including severity, frequency, and risk factors, and determining the efficacy of risk-reduction strategies.

PART V OF THE RMP INCLUDES RISK MANAGEMENT.

The pharmacovigilance plan should focus on RMP module SVIII safety. Competent authorities and the applicant or marketing authorization holder should discuss pharmacovigilance needs and milestones early on. Regular and additional pharmacovigilance exist. Part III of the RMP, "Routine Pharmacovigilance Activities "DIR and REG require pharmacovigilance for all drugs. Novel product risk assessment uses signal detection. Pharmacovigilance master file describes these activities (see GVP Module II).

PRAC, CHMP, CMDh, or national responsible bodies may encourage collecting, collating, assessing, and reporting complaints of side effects that varies from pharmacovigilance criteria (see GVP Module I). This is prevalent if recommendations call for testing (including in a structured style). In these cases, the applicant's usual pharmacovigilance activities should be changed per PRAC, CHMP, CMDh, and the national competent body. The pharmacovigilance strategy

should explain this. Sending tissue or blood samples to a lab for antibody detection is pharmacovigilance. This RMP part should go beyond signal identification and event reporting.

Forms Tracking Adverse Reaction (VB.6.1.1)

The regular pharmacovigilance section should define when an applicant or marketing authorization holder must use particular Special interest allergic response interview questions. RMP annex 4 should include these forms. Multiple applicants/marketing rights holders should use identical questionnaires to send a uniform message, offer significant data for report analysis, and reduce the burden on healthcare providers. Marketing authorisation holders must furnish questionnaires upon request (s).

Pharmacovigilance Activities VB.6.1.2

Include the expanded passive supervision, observed vs. expected findings, cumulative detrimental event evaluations **[8]**.

VB.6.2 "Additional Pharmacovigilance Activities"

This RMP section should be used to identify supplementary pharmacovigilance initiatives to better understand risk-benefit. Pharmacovigilance techniques are rare. Non-clinical, non-interventional investing-ations. Long-term drug safety can be determined via a cohort study or long-term clinical trial follow-up. If more pharmacovigilance is needed, consult a professional. The pharmacovigilance strategy identifies risks, gathers missing data, and evaluates risk-reduction actions. They must be realistic, address safety standards, and avoid advertising.

Pharmacovigilance studies should follow applicable regulations and GVP Module VIII instructions. Only study protocols included in the pharmacovigilance strategy and Officials can request improvements. RMP appendix 3 part C needs pharmacovigilance methodologies (or electronic links or references in other sections of the eCTD dossier). Annex RMP 3 part C has protocols for category 3 investigations. Once completed study reports are submitted to the relevant body for evaluation, RMP annex 3 protocols should be deleted (see V.B.10.3.).All pharmacovigilance strategies should contain report-submission milestones. PASS methods can be used to get scientific advice from the EMA or national authorities.

RMP SECTION VB.6.3 "Summary table of Extra pharmacovigilance Activities"

RMP covers pharmacovigilance. Some MA requirements are fundamental to the product's risk-benefit profile (category 1 studies in pharmacovigilance) or are specific in a conditional or exceptional MA (category 2 studies in the pharmacovigilance plan). IR Annex III

describes non-invasive PASS (see GVP Module VIII).

Safety or risk issues may require more RMPs. pharmacovigilance (category 3 studies in the pharmacovigilance plan). Tables should categorise activities **(see Table V.3.)**.

Table V.3: Extra pharmacovigilance attributes

	Type of activity	In annex II of MA (CAPs only)	Study category (PhV plan)	Status	Supervised under	
					Article 107m	Article 107 n-q
Imposed PASS	"Interventional"*	Yes, in annex IID	1	Mandatory and subject to penalties	No	No
	Non-interventional	Yes, in annex IID			Yes	Yes
Specific obligation	"Interventional"*	Yes, in annex IIE	2	Mandatory and subject to penalties	No	No
	Non-interventional	Yes, in annex IIE			Yes	Yes
Required	"Interventional"*	No	3	Legally enforceable	No	No
	Non-interventional	No			Yes	No

***Directive 2001/20/EC governs clinical interventional studies. Non-clinical interventional studies must follow legal and ethical requirements for animal GLP protection. Unless authorised by the Agency or a national responsible body, studies necessary outside the EU should not be included in the RMP**

Non-required studies should not be included in the RMP's pharmacovigilance plan. This doesn't preclude reporting safety concerns from such studies as required by law approval. Planned or ongoing PASS for the originator product is also required for generics (registries may need to include often these patients treated with the drug). Product registration holders are incentivized to set up joint PASS, such as for registries or where a referral results in an imposed PASS for all authorised medicinal products containing a particular chemical in a given indication **[9]**.

VB.7. RMP PART IV "Plans for Post Authorization Efficacy Studies"

This RMP component should list post-authorization efficacy studies (PAES) mandated by a conditional or exceptional marketing approval. Leave RMP Part IV blank if no studies are necessary.

VB.8. RMP PART V "Risk minimisation (Including Evaluation of Effectiveness Minimisation Activities)"

RMP Part V should address safety risk minimization. Different indications or target populations may require risk minimization plans. Different indications, safety concerns, and target populations; patient supply legality. Evaluate risk-reduction measures' need and effectiveness (see V.B.8.). Module XVI and Addendum I

– Educational Materials provide guidance on risk minimization and effectiveness.

RISK REDUCTION ROUTINES

Every medicine has routine risk minimization activities. These include the product's summary, labelling (Inner and outside container), flyer, pack size(s), constitutional right. Product formulation eliminates the risk.

SUMMARY OF PRODUCT CHARACTERISATION (SmPC) AND PACKAGE LEAFLET (PL)

Summary of product specifications and package booklet reduce risk inform healthcare professionals and patients in a controlled and standardised format. The Summary of Product Characteristics Guideline explains how to present information. Both the SmPC.

PLs recommend minifying. Section 4.8 of the SmPC or Section 4 of package inserts lists possible negative effects to help patients and healthcare professionals make an informed treatment decision. Sections 4.2 and 4.4 of the SmPC, as well as Sections 4.1, 4.3, 4.5, 4.6, 4.7, 4, 9, and 2 and 3 of the package insert, are examples of routine risk minimization procedures that suggest clinical risk management actions. testing before treatment, reviewing lab levels throughout medication, watching for signs and symptoms, changing dosage or terminating treatment if negative effects occur. After treatment, wash your hands and use contraception. Reduce RA.

VB.8.1. RMP PART V SECTION "Risk minimisation Plan"

For each specified safety risk, the RMP should include: Daily risk minimization activities, such as proposed; Additional risk reduction activities, including objectives, justification, and effectiveness measurement.

VB.8.2. RMP PART V SECTION "Summary of Risk minimisation Measures"

This RMP should list risk-reduction activities by safety concern (e.g., SmPC section number, list of educational materials). EMA's Guidance on EU Risk Management Plan Format should summarise pharmacovigilance acts **[10]**.

VB.9. RMP PART VI "Summary of the Risk Management Plan"

Reg 26(1)(c), DIR 106(c), IR 31(1) Each RMP summary must include critical elements. The RMP applicant/holder must provide Part VI. The Agency should post the RMP summary per Part VI. and other public assessment documents on the EMA website when the European Commission decides.

This drug's EPR. A summary of the RMP for nationally-approved medicines should be posted on national websites. When the full RMP changes, the summary should be updated. Important changes include new

important risks or safety changes or removals; Adoption or removal of risk minimization measures or initiatives recommending clinical risk indicators; pharmacovigilance plan (new studies, completed studies) Read RMP summaries. The summary should be written clearly to me*et al*l needs7. Avoid avoiding technical terms. The document's purpose and relationship to other product information should be explained (SmPC, PL, labelling).Part VI of the RMP should match parts II, III, IV, and V. Include: The approved medicine; Safety concerns and missing info Additional risk-reduction measures;Pharmacovigilance enhancements **[11]**.

VB.10. RMP PART VII "Annexes to the Risk Management Plan"

RMP annexes (if applicable). If the RMP applies to multiple medicines, the annexes should be relevant. Highlight RMP aspects not applicable to all medicines (e.g., appendix 4 follow-up form may only apply to causative active substance goods).

VB.11. CORRELATION BETWEEN RISK MANAGEMENT PLAN AND PERIODIC SAFETY UPDATE REPORT

RMP and PSUR are post-approval safety documents. The documents' main goals and when they're needed differ, despite some overlap. PSUR's main purpose is RMP is both pre- and post-authorization set of indicators as complementary documents.

When submitted together, the RMP and PSUR should match. When a new signal or risk is found in the PSUR, the RMP can be updated. The Pharmacovigilance Plan and Risk Minimization Plan should be updated **[12]**.

V.4-Table Risk Management Plan and Security Update Report provide similar information (however, they may not have the same format and may not be interchangeable)

V.4-Table Risk Management Plan and Security Update Report

RMP section	PSUR section
Part II, module SIII –"Clinical trial exposure"	Sub-section 5.1 "Cumulative subject exposure in clinical trials"
Part II, module SV –"Post-authorisation experience"	Sub-section 5.2 "Cumulative and interval patient exposure from marketing experience"
Part II, module SVII – "Identified and potential risks" and part II, module SVIII – "Summary of the safety concerns"	Sub-sections 16.1 "Summaries of safety concerns" and 16.4 "Characterisation of risks"
Part V – "Risk minimisation measures", section "Evaluation of the effectiveness of risk minimisation activities"	Sub-section 16.5 – "Effectiveness of risk minimisation (if applicable)"

VB.12.RECORDKEEPING, QUALITY SYSTEMS

The MA applicant/holder is responsible for the RMP's accuracy and scientific integrity. QPPV should control the content. The MA holder must update the RMP and follow GVP Module I's quality principles. The holder of a marketing authorization should track RMP submissions and changes. Pharmacovigilance inspectors may audit RMPs and related documents **[13]**.

CONCLUSION

Product teams can develop a functional RMP and use a data-driven methodology on GVP Module V (Rev 2) ideas. Industry stakeholders and EU HAs can improve risk management by discussing about GVP Module V. (Rev 2). Other parties can strengthen their RMP operations by using Janssen's knowledge base. Practitioners can benefit patients lengthy by sharing whatever they've gained from clients.

ACKNOWLEDGEMENT:

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