EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU Part VI: Summary of the risk management plan by product

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

Data lock point for this module	<Enter a date>
Version number of RMP when this module was last updated	<Enter a version no>

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

[1]Please note that under section VI.1.4 Summary table of Risk Minimisation Measures "Copy table from Part V: 5.2" should have read "Copy table from Part V: V.3"

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A separate RMP Part VI should be provided for each product in the RMP.

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Copy table from Part I: SVIII

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

VI.1.2 Table of on-going and planned studies in the Post-authorisation Pharmacovigilance Development Plan

Copy table from III.5.1.

Study / activity Type, title and category (1-3)	**Objectives**	**Safety concerns addressed**	**Status (planned, started)**	**Date for submission of interim or final reports (planned or actual)**
<E.g. CRUCIAL Cancer Registry at University College IdAho Liver unit (non-interventional cohort, 3)>	<E.g. To investigate long term survival, time to progression, safety profile and QoL in patients with primary liver cancer or solid tumour metastases>	<E.g. Bradycardia, thrombosis, leukopenia, use in patients with renal impairment, long term safety>	<E.g. Protocol submitted to PRAC>	<E.g. Interim reports planned June 2013, 2017 Final study report Dec 2020>
<E.g. Validation of antibody test (non-clinical, 3)>	<E.g. Comparison of Supertest kit with current gold standard>	<E.g. Development of antibodies>	<E.g. Planned start March 2013>	<E.g. Final study report December 2013>

VI.1.3 Summary of Post authorisation efficacy development plan

Copy table IV.3 from Part IV

Study (type and study number)	**Objectives**	**Efficacy uncertainties addressed**	**Status**	**Date for submission of interim or final reports**

VI.1.4 Summary table of Risk Minimisation Measures

Copy table from Part V: V.3.

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

(Maximum 150 words per indication)

Abbreviated lay language version of RMP Part II Module I.

VI.2.2 Summary of treatment benefits

The summary of treatment benefits should be in lay language and non-promotional. The text should not exceed a maximum of 200 words (up to 300 if multiple indications). The following should be considered for inclusion:

- *Describe briefly each pivotal study, including total participant numbers (randomised figure where applicable). Explain the primary endpoint in lay language.*
- *If there are multiple indications, use bullet points to separate the studies per indication. If there are several studies for one indication with a similar design, in some cases these may be described together and the total patient numbers combined to stay concise.*
- *For each study, describe the primary endpoint results directly after the description of the study (either in the same paragraph, or a separate paragraph if needed). When using percentages, give patient numbers in brackets.*

<E.g. The average survival time for patients in the main study treated with 475 mg of drug x in addition to drugs y and z increased by 19.5 months to 55.5 months compared with treatment 2 (36 months) and 17 months (57.5 months) compared with treatment 3 (40.5) months.>

VI.2.3 Unknowns relating to treatment benefits

(1 short paragraph per indication of 50 words maximum)

A short summary of the applicability of efficacy to all patients in the target population can be provided in lay language. This should be a précised version of Part IV IV.1 written for the lay reader. It should describe very briefly any relevant parts of the target population where experience is limited and whether efficacy is expected to be different in these people – e.g. factors such as age, sex, race, and organ

impairment. If there is evidence that efficacy is either enhanced or reduced (e.g. ACE inhibitors and the Afro-Caribbean population) this should be stated.

<E.g. In the main and supporting studies nearly all patients were white Caucasians aged between 52 and 86 with most patients aged over 65. There is no evidence to suggest that results would be any different in non-white patients or in younger patients unable to tolerate high dose chemotherapy.>

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
<Safety concern in lay language (medical term)>	<Brief summary in lay language>	<Whether risk can be minimised or mitigated, and how>
<E.g. Damage to the nerves in hands and feet (peripheral neuropathy)>	<E.g. Approximately one in two people treated with x will experience some form of nerve damage which may increase to three out of four people after 12 months of treatment. The nerve damage varies from mild tingling and altered sensation to irreversible disabling damage in the most severe cases. Early symptoms usually resolve or improve upon dose adjustment or discontinuation of therapy. >	<E.g. Yes, by monitoring for early symptoms >
<E.g. Blood clots (thromboembolic events {TEE})>	<E.g. These may affect the arteries or veins. In the veins this may lead to a painful swelling of the legs (deep vein thrombosis) and very occasionally life threatening or fatal clots in the lungs. Clots in the arteries may lead to a heart attack or stroke – particularly in patients who already have problems with their arteries. Patients with cancer who are being treated with oestrogen are already at higher risk of blood clots so it is difficult to assess what extra risk is caused by x.>	<E.g. Yes with preventative anti-thrombotic medicines >

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
<E.g. Secondary primary cancers>	<E.g. Patients treated with X may be at an increased risk of developing new cancers. There are theoretical mechanisms and more patients treated with X developed new cancers than those not treated with X, but this could also be due to the fact that they live longer.>

Missing information

Risk	What is known
<E.g. Limited information on use in patients with kidney impairment>	<E.g. X itself is not eliminated to any significant extent by the kidney so it is unlikely that kidney impairment will lead to problems. Some of its metabolites are eliminated by the kidney so it is recommended that patients with severe renal impairment are monitored carefully. >

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for X can be found in the X's EPAR page

<This medicine has no additional risk minimisation measures>

<This medicine has special conditions and restrictions for its safe and effective use (additional risk minimisation measures). Full details on these conditions and the key elements of any educational material can be found in Annex II of the product information which is published in X's EPAR page; how they are implemented in each country however will depend upon agreement between the manufacturer and the national authorities.

These additional risk minimisation measures are for the following risks:

Safety concern in lay terms (medical term)

Risk minimisation measure(s)
Objective and rationale
• Summary description of main additional risk minimisation measures – key points
<E.g. Damage to the nerves in hands and feet (peripheral neuropathy) Healthcare Professional and patient education Objective and rationale

Risk minimisation measure(s)
Patients and HCPs to understand the risk of peripheral neuropathy and the procedures related to the appropriate management of this risk to minimise its occurrence and its severity. Proposed action: HCP educational materials to be provided to prescribing physicians and pharmacists including advice on: Use of electromyogram prior to and during treatment Importance of adherence to dosing recommendations Management of neuropathy including dose reduction and treatment discontinuation Direct HCP communication prior to launch ('Dear HCP' letter). Patient booklet will inform patients what the symptoms of nerve damage are and the importance of informing their HCP if any occur>

VI.2.6 Planned post authorisation development plan

From combined summary tables in Part III and Part IV

List of studies in post authorisation development plan

Study / activity (including study number)	Objectives	Safety concerns / efficacy issue addressed	Status	Planned date for submission of (interim and) final results

Studies which are a condition of the marketing authorisation

<None of the above studies are conditions of the marketing authorisation>

< <study(ies)> <is><are> <a> condition<s> of the marketing authorisation

Mention all studies in the table (including specific obligations) which are conditions of the MA.

VI.2.7 Summary of changes to the Risk Management Plan over time

Table 1. Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
	At time of authorisation dd/mm/yyyy	Identified Risks Potential Risks Missing information	
<E.g. 7.0>	<E.g. 17/08/2012>	<E.g.Allergic conditions added as an identified risk Hypersensitivity	<E.g. The previous term hypersensitivity was updated to allergic conditions to include

Version	Date	Safety Concerns	Comment
		removed as an identified risk Severe infection added as an identified risk Convulsions added as a potential risk>	angioedema and urticarial>