

**P-RMS <PRELIMINARY, (DRAFT) FINAL>
ASSESSMENT REPORT
Procedure number XX/H/PSUR/XXXX/XXX**

Active substance	
Innovator name of product in the P-RMS	
<for MRP products also procedure number>	
Pharmaceutical form(s)/strength	
MAH(s)	
HBD and DLP	
PSUR period	(day Month year- day Month year)
P-RMS	
Assessor	
Contact point	

TIME TABLE

Procedure Start Date	
Date of preliminary AR	
Deadline for comments to P-RMS	
Clockstop/ RFI / LoQ	
Procedure Restart Date	
Date of Draft Final AR	
Deadline for comments to P-RMS	
Date of Final AR	
Discussion at PhVWP	
DLP of the next PSUR submission and period of PSUR	

In addition to the innovator PSUR, the assessment report covers the following PSURs of additional products authorised in the P-RMS:

MAHs	MR procedure number (if applicable)	Period covered by the PSUR

The following PSURs of products not authorised in the P-RMS have been submitted as part of the worksharing procedure.

MAHs	MR procedure number (if applicable)	Period covered by the PSUR

INDICATIONS AUTHORISED IN THE P-RMS (INNOVATOR):

WORLDWIDE MARKETING AUTHORISATION STATUS AND UPDATE OF REGULATORY ACTIONS TAKEN FOR SAFETY REASONS (MAH, AUTHORITIES)

Has there been a change to the marketing authorisation status or have regulatory actions been taken for safety reasons? Yes No

If yes, specify:

SUMMARY OF PREVIOUS RELEVANT PhVWP/CHMP DISCUSSIONS *, IF ANY:

* During the period under review

CHANGES TO REFERENCE SAFETY INFORMATION

Is the CCDS the reference document? Yes No

If not, please indicate which document is used as reference document:

Date of the last reference document :

Which sections of the reference safety document have been changed during the period covered by the PSUR?

- posology and method of administration (4.2)
- contraindications(4.3)
- special warnings and precautions for use(4.4)
- interaction with other medicinal products and other forms of interaction(4.5)
- pregnancy and lactation (4.6)
- effects on ability to drive and use machines(4.7)
- undesirable effects(4.8)
- overdose (4.9)

Please specify the safety relevant changes:

Selected differences between RSI and proposed CSP:

SUSPECTED ADVERSE DRUG REACTIONS (INNOVATOR) DURING THE PERIOD

SERIOUS CASES AND ADRs

Total number of serious cases, incl. fatalities	
Number of fatal cases	

SUSPECTED ADVERSE DRUG REACTIONS, overview

TABLE OF ADVERSE DRUG REACTIONS (ADRs)					
System Organ Class (SOC)	Serious		Non-serious		Total
	Listed	Unlisted	Listed	Unlisted	
Blood and lymphatic system disorders					
Cardiac disorders					
Congenital and familial and genetic disorders					
Ear and labyrinth disorders					
Endocrine disorders					
Eye disorders					
Gastrointestinal disorders					
General disorders and administration site conditions					
Hepatobiliary disorders					
Immune system disorders					
Infections and infestations					
Injury poisoning and procedural complications					
Investigations					
Metabolism and nutrition disorders					
Musculoskeletal and connective tissue disorders					
Neoplasms benign, malignant and unspecified					
Nervous system disorders					
Pregnancy, puerperium and perinatal conditions					
Psychiatric disorders					
Renal and urinary disorders					
Reproductive system and breast disorders					
Respiratory thoracic and mediastinal disorders					
Social circumstances					
Skin and subcutaneous tissue disorders					
Surgical and medical procedure					

Vascular disorders					
Total					

TABLE OF SELECTED* SERIOUS UNLISTED ADRs :

Serious unlisted ADRs (MedDRA PT in agreed SOC order)	Number of serious unlisted ADRs

* Selection is within the discretion of the P-RMS

VALUABLE INFORMATION FROM PSURs FOR OTHER PRODUCTS AUTHORISED IN THE P-RMS

Do any of the PSURs for other products authorised in the P-RMS contain information not addressed in the PSUR for the originator product(s)?

Yes No

If yes, specify in table below:

TABLE OF SELECTED* SERIOUS UNLISTED ADRs IN OTHER PSURs AUTHORISED IN THE P-RMS

Serious unlisted ADRs (MedDRA PT in agreed SOC order)	Number of serious unlisted ADRs

* Selection is within the discretion of the P-RMS

Other information:

OVERALL ASSESSOR COMMENTS ON CASE REPORTS (INCL. LITERATURE CASES)

Describe and comment on ADRs of importance from individual case histories.

OVERALL ASSESSOR COMMENTS ON MAH SPONSORED STUDIES

Describe and comment on studies of relevance to safety of the product(s)

OVERALL ASSESSOR COMMENTS ON STUDIES FROM THE LITERATURE

Describe and comment on literature studies of relevance to safety of the product(s).

OVERALL ASSESSOR COMMENTS ON NEW INFORMATION REGARDING

Special populations:

Pregnancy/lactation:

Drug interaction:

Overdose:

Abuse or misuse:

Medication errors:

Long-term treatment:

Off label use:

COMMENTS ON ANY CHANGE OF THE RISK BENEFIT BALANCE

MAH conclusion:

Assessors conclusions and comments:

ACTION PLAN AND CONCLUSIONS

A CHANGES OF THE BENEFIT RISK BALANCE

Has the benefit risk balance changed?

No

Yes , please specify:

B CHANGES REQUIRED IN THE CSP

Is the CSP acceptable?

Yes No

If not, specify the necessary changes (specific wordings):

C REGULATORY ACTIONS * PROPOSED, IF ANY

* Regulatory options may include urgent safety restrictions, variations, suspension or revocation. Topics for close monitoring should be mentioned below in section E.

D SUMMARY OF COMMENTS FROM OTHER MSs

Member State	Comment	Agreed action e.g. updating CSP, close monitoring

E POINTS TO BE ADDRESSED IN THE NEXT PSUR

<E.g. agreed topic(s) for close monitoring / review to be included in next PSUR.>

F RFI / LoQ: REQUEST FOR FURTHER INFORMATION / LIST OF QUESTIONS

Questions to be addressed by the MAH:

MAH response:

P-RMS assessment and conclusion:

FINAL CONCLUSION (SUMMARY OF A-F)

DATE AND CONCLUSION OF PHWVP DISCUSSION CONCERNING THIS PSUR, IF ANY:

Annex I : CSP

In PAR: Proposed CSP with assessor comments, if any

In Draft FAR: Proposed CSP with assessor comments

In FAR: Agreed CSP

Annex II:

PATIENT EXPOSURE (one annex for each PSUR of products authorised in the P-RMS)

Patient exposure in this PSUR :

Methodology used for the exposure number calculation :

Defined Daily Dose
 patients/day
 number of prescriptions
 number of doses
 Other (please specify)

Comparison with previous PSUR, if information is available

Change in methodology used for calculation:
Yes No

Overall change in patient exposure:
Yes No

Increase Decrease

Annex III: COMMENTS ON THE PSUR (annex exclusively for innovator MAH)

Is the PSUR in accordance with international guidelines (CIOMS II, Volume 9A) ?

Yes No

If not, specify non-conformance with the guidelines