PHARMA DEVILS

PHARMACOVIGILANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Periodic Safety Update Report (PSUR)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. OBJECTIVE:

To describe the steps associated with the production of Periodic Safety Update Reports (PSUR's) for the products of …… and all affiliated companies/subsidiaries. This also defines, in detail, the process that shall be followed by …… authoring PSUR's. All process followed shall be in accordance with applicable regulatory guidelines.

2. SCOPE:

This SOP applies to all employees/vendors involved in PSUR creation process at or on behalf of ……. This pertains to scheduling, preparing and writing, producing, and distributing PSUR's in accordance with applicable reporting regulations.

3. RESPONSIBILITY:

3.1. Pharmacovigilance Department:

3.2. Pharmacovigilance Officer In-charge (PVOI):

Review, approval and submission of PSUR of …….. Review, training and effective implementation of this SOP.

4. ACCOUNTABILITY:

PvOI

5. PROCEDURES:

5.1 PSUR Calendar Preparation

5.1.1 Respective regulatory affairs department shall inform PV department for any new marketing authorization/application granted by their respective regulatory authority.

5.1.2 PV (Officer/ Executive) shall prepare PSUR submission calendar as per format "PSUR Calendar" as shown in Annexure I as per respective regulatory authority requirements.

5.2 PSUR Preparation:

5.2.1 According to the PSUR Calendar, PSUR data lock point shall be considered.

5.2.2 PV (Officer/ Executive)/Designee shall prepare PSUR.

5.2.3 PSUR shall contain the following titles:

- Title page
- Introduction
- Current worldwide marketing authorization status
- Update of actions taken for safety reason
- Changes to reference safety information like PIL, CCDS & SMPCS
- Estimated Patient exposure
  - Cumulative subject exposure in clinical trials
  - Cumulative and interval patient exposure from marketing experience in India
  - Cumulative and interval patient exposure from marketing experience from rest of the world
- Presentation of individual case histories

- Line listing of individual cases received from India
- Line listing of individual cases received from rest of the world
- Cumulative summary tabulations of Serious Adverse Events (SAEs) from clinical trials
- Cumulative and interval summary tabulations from post marketing data sources

- **Studies**
  - Summaries of significant findings from clinical trials during the reporting period
  - Findings from non-interventional studies
  - Information from other clinical trial sources
  - Findings from non-clinical studies
  - Finding from literature
- **Other information**
  - Lack of efficacy in controlled clinical trials
  - Late-breaking information
  - Overview of signals: new, ongoing or closed
- **Overall safety evaluation**
  - Signal and risk evaluation
  - Benefit evaluation
  - Benefit-risk analysis evaluation
- Conclusion
- Appendix to the PSUR

  To estimate patient exposure, sales data of the product shall be requested to marketing team business development team/relevant department /marketing company

5.2.4 Safety Information shall be included from reported clinical trial (if applicable), literature and spontaneous ICSR's entered in electronic safety database.

5.3. PSUR Review:

5.3.1. Prepared PSUR shall be reviewed for quality check by the assigned reviewer from PV department.

5.3.2. The reviewer shall review the PSUR and fill up PSUR review checklist to ensure quality and accuracy of information incorporated in the PSUR as per format "PSUR Review Checklist" as shown in Annexure II.

5.4. PSUR Submission

5.4.1. Final PSUR shall be submitted along with PSUR Check List for Regulatory submission.

5.4.2. As per Indian Regulatory Authority PSUR shall be submitted as per local regulatory recommended timelines. PSUR due for a period must be submitted within 30 calendar days of the last day of the reporting period.

5.4.3. Acknowledgement of PSUR submission to regulatory authority shall be documented.

6. DISTRIBUTION:

Not Applicable

7. REFERENCES:

Not Applicable

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8. ABBREVIATIONS:

CCDS	Company Core Data Sheet
DLP	Data Lock Point
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
MAH	Marketing Authorization Holders
NA	Not Applicable
PI	Package Insert
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PvOI	Information Summary of Product
RSI	Reference Safety Information
SPC	Summary of Product Characteristics
SOP	Standard Operating Procedure

9. ANNEXURES:

S.No.	Title	Annexure No.	Format No.
1.	PSUR Calendar	I	
2.	PSUR Checklist	II	

10. REVISION HISTORY:

Revision No.	Effective Date	Reason for change	CC No.
00		New SOP	Nil

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ANNEXURE I
PSUR CALENDER

S.No.	Generic Name	Brand Name	Strength	Marketing Authorization No.	Marketing Authorization date	PSUR No.	Market Launch Date	Reporting Period	Due Month for submission	Submitted on	Reason for deviation (if any)	Maintain By

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ANNEXURE II
PSUR CHECKLIST

S.No.	PSUR Section	Review Activity	Complied		Comment
			Yes	No	
1.0	Title Page	Name of the product (strength) Verified			
		Review period verified			
		International Birth date/ Date of approval of new drug verified			
		Approved indication verified			
		MAH name and address verified			
2.0	Executive Summary	Introduction, Marketing approval Status, Action Taken and Proposed for Safety Reason, Patient Exposure, Overall Evaluation and Conclusion verified			
3.0	Introduction	Product Introduction verified			
4.0	World-wide Market Authorization Status	Marketing Authorization details verified			
5.0	Update of Regulatory Authority or Marketing Authorization Holder actions taken for safety Reasons	Any updates on actions taken for safety reasons from regulatory authority			
		Any updates on actions taken for safety reasons by MAH			
6.0	Changes to reference safety information	Changes made in new contraindications, Precautions, Warnings, ADRs, or interactions sections of PI/SMPC/RSI captured			
7.0	Patient exposure	Patient exposure during clinical trial verified			
		Market experience sales data verified			
8.0	Presentation of Individual case Histories	Presentation of cases in line listings and summary tabulations verified			
9.0	Studies	Summaries of significant findings from clinical trials during the reporting period verified			
		Finding from non-interventional studies verified			
		Information from other clinical trial source verified			
		Findings from non-clinical studies verified			
		Findings from literature verified			
10.0	Other information	Efficacy-related information, late breaking information, overview of signal etc. verified			

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S.No.	PSUR Section	Review Activity	Complied		Comment
			Yes	No	
11.0	Overall safety evaluation	Signal and risk evaluation, Benefit evaluation, and Benefit-Risk analysis evaluation verified			
12.0	Conclusions	Conclusion verified			
13.0	Appendices:				
13.1	Reference Safety Information	Updated (PI/SMPC/RSI) attached			
13.2	Line-listing	Line-listing verified for its contents			
13.3	Summary Tabulation	Summary Tabulation verified for its contents			
13.4	Other information (if applicable)	Other document verified			