BIO-MED PRIVATE LIMITED
C-96, SITE NO. 1
BULANDSHAHR ROAD
INDUSTRIAL AREA
GHAZIABAD - 201 009 (U.P.) INDIA

SOP No. : BM/PV/003
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DATE	30/03/17	31/03/17	01/04/17

Department : PHARMACOVIGILANCE

SOP TITLE : STANDARD OPERATING PROCEDURE FOR THE PREPARATION OF PERIODIC SAFETY UPDATE REPORT (PSUR) FOR ALL HUMAN VACCINES PRODUCED IN BIOMED (P) LTD.

1. PURPOSE:-

The purpose of this SOP is to provide instructions for the preparation of periodic safety update report for all products manufactured at Bio – Med (P) Ltd.

2. SCOPE:-

This SOP shall provide a detailed procedure required for the preparation of product safety update report for all the products manufactured at Bio-Med (P) Ltd.

3. RESPONSIBILITY:-

3.1 Pharmacovigilance Personnel is responsible for preparation of PSUR.

3.2 Pharmacovigilance Head is responsible for review the PSUR.

3.3 QA In - charge is responsible for approval of PSUR.

4. GUIDELINES:-

4.1. PSUR are important pharmacovigilance documents. They provide an opportunity for organization to review the safety profile of their products and ensure that the SmPC and Package Leaflet are up to date.

4.2. The Bio Med Pvt. Ltd. shall furnish Periodic safety update report in order to –

4.2.1. Report all the relevant new information from appropriate sources;

4.2.2. Relate these data to patient exposure;

4.2.3. Summarize the market authorization status in different countries and any significant variations related to safety.

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4.2.4. Indicate whether changes should be made to product information in order to optimize the use of the product.

4.2.4.1. Ordinarily all dosage forms and formulations as well as indications for new drugs should be covered in one PSUR. Within the single PSUR separate presentations of data for different dosage forms, indications or separate population need to be given.

4.2.4.2. All relevant clinical and non-clinical safety data should cover only the period of the report (interval data).

4.2.4.3. The PSURs shall be submitted every six months for the first two years after approval of the drug is granted to the applicant. For subsequent two years – the PSURs need to be submitted annually.

4.2.4.4. PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period.

5. PROCEDURE:-

A PSUR should be structured as follows:

5.1. Title Page:

The title page of PSUR should capture the name of Biological product (s); reporting interval; approved Indication of Biological Products; date of approval of new drug; date of marketing of new drug; organization (s) name (s) and address (es).

5.2. Introduction:

This section of PSUR should capture the reporting interval; biological product (s) – mode (s) of action, therapeutic class (es), dose (s), route (s) of administration, formulation (s); a brief description of the approved indication (s) and population (s).

5.3. Current Worldwide Marketing Authorization Status:

This section of PSUR should capture the brief narrative overview including details of country where the product is currently approved along with date of first approval, date of marketing and if product was withdrawn in any of the countries with reasons thereof.

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5.4. Actions Taken in Reporting Interval for Safety Reasons:

This section of PSUR should include a description of significant actions related to safety that have been taken during the reporting interval, related to either investigational uses or marketing experience by the organization, sponsor of a clinical trial(s), regulatory authorities, data monitoring committees, or ethics committees.

5.5. Changes to Reference Safety Information:

This section of PSUR should capture any significant changes to the reference safety information within the reporting interval. Such changes might include information relating to contraindications, warnings, precautions, adverse drug reactions (ADRs), overdose, and interactions; important findings from ongoing and completed clinical trials and significant non-clinical findings.

5.6. Estimated Patient Exposure:

This section of PSUR should provide the estimates of the size and nature of the population exposed to the biological product. Brief descriptions of the method(s) used to estimate the subject/patient exposure should be provided.

5.6.1 Cumulative and interval subject exposure in Clinical Trials.

5.6.2 Cumulative and interval patient exposure from Marketing Experience from India.

5.6.3 Cumulative and interval patient exposure from Marketing Experience from rest of the world.

5.7. Presentation of Individual Case Histories:
This section of PSUR should provide the individual case information potentially available to a organization provide brief case narrative, concomitant medications, medical history indication treated with suspect drug(s), re – challenge & de – challenge, causality assessment. Provide following information:

5.7.1 Reference Prescribing Information for causality assessment.

5.7.2 Individual Cases received from India.

5.7.3 Individual cases received from rest of the world.

5.7.4 Cumulative and Interval Summary Tabulations of Serious Adverse Events from Clinical Trials.

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5.8. Studies:

This section of PSUR should capture the brief summary of clinically important emerging efficacy/effectiveness and safety findings obtained from the organization sponsored clinical trials and published safety studies that became available during the reporting interval of the report which has potential impact on product safety information.

5.8.1 Summaries of Significant Safety Findings from Clinical Trials during the reporting period.

5.8.2 Findings from Non-interventional Studies.

5.8.3 Findings from Non-Clinical Studies.

5.8.4 Findings from Literature.

5.9. Other Information:

This section of PSUR should include the details about signals and Risk Management Plan in place by organization (if any).

5.9.1 Signal and risk evaluation: In this section organization will provide the details of signal and risk identified during the reporting period and evaluation of signals identified during the reporting period.

5.9.2 Risk Management Plan: In this section organization will provide the brief details of safety concern(s) and necessary action taken by him to mitigate these safety concerns.

5.10. Overall Safety Evaluation:

This section of PSUR should capture the overall safety evaluation of the biological product based upon its risk benefit evaluation for approved indication.

5.10.1. Summary of Safety Concerns

5.10.2. Benefit Evaluation & Benefit Risk Analysis Evaluation

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5.11. Conclusion:

This section of PSUR should provide the details on the safety profile of biological product and necessary action taken by the organization in this regards.

6 DOCUMENTATION:

PSUR document controlling detail is maintained in Annexure No. BM/PV/ANX/003.

7 REFERENCES:-

The guideline for industry on Pharmacovigilance requirement for biological product.

8 IMPLEMENTATION:-

7.1. Develop/ modify relevant SOPs if applicable.

7.2. Train the staff if applicable.