STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Handling of Medical Inquiries	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedures for Medical Inquiries for……...

2.0 SCOPE:

This SOP is applicable to all the manufacturing sites of ……..

3.0 RESPONSIBILITY:

3.1 Pharmacovigilance Department:

Receiving, Processing, follow up, response and documentation of Medical Inquiries, receipt and drafting of standard response. Preparation, distribution, retrieval and destruction of this SOP.

3.2 Pharmacovigilance Officer In-charge(PvOI):

Responding to Medical Inquiries and approval on draft response, notifying the respective department of any/all Medical Inquiries, product complaints received. Review, Training and effective implementation of this SOP.

4.0 ACCOUNTABILITY:

PvOI

5.0 PROCEDURES:

5.1. Receipt of Inquiries

……./subsidiary's employee, who receives a communication about any …… /subsidiary product which are approved/ marketed anywhere in the world, concerning a medical inquiry, shall inform the CPV personnel immediately via phone/fax/email.

All communications related to ADR/AE and PQC from any reporter will be handled as per SOP's "Handling of Adverse Events & Safety Information" and "Market Complaint".

Communication that is medical in nature like query related to its posology, contraindication, warning or precautions etc. related to any …….. /subsidiary product (s) are handled as follows:

5.1.1. Phone call communication

- The PV department also has a dedicated telephone number service. During office hours, if the inquiry is

medical in nature; calls shall be put through to the responsible PV representative/designee on duty.

- In circumstances when the call cannot be placed to a PV representative/designee, the person receiving the call shall note the caller's details, time and date of inquiry and arrange for the on- duty PV representative/designee to call the inquirer back once he/she is available (hand-written notes shall be passed to the PV representative/designee).
- All the information received about any ……/subsidiary product(s) must be filled in Medical Inquiry Form as per Annexure - I, if a Medical inquiry is also associated with an ADR/AE, shall be handled as per SOP "Handling of Adverse Events &Safety Information" and a separate ADR/AE Reporting Form will be filled.

5.1.2 Written Inquiries

All Inquiries from letters, faxes and emails received regarding medical Inquiries shall be passed to the PV representative/designee on duty on the day of receipt for triaging and processing. All letters and faxes shall be stamped with the date received. Any communication received by e-mail will be printed and stored in the respective source.

5.1.3 Queries via portal

- Any type of communication/query medical/non-medical in nature can be directly mailed to PV department at email id available at ……. website.
- In case a query is not medical in nature, then it shall be forwarded to concerned department for appropriate response.

5.1.4. Media and Legal

If the caller identifies as a representative of a media, legal or insurance company, the caller's details shall be requested and informed that no comment can be given and a response will be provided by a designated representative from concerned department of …….. /subsidiary.

5.2. Customer Group

5.2.1. Healthcare Professionals

All inquiries from healthcare professionals shall be answered by considering approved SPCs/PIs/PILs or other information sources as reference. The response issued may include both verbal and written communication.

5.2.2. Consumers

- Requests for advice on personal medical matters will be refused, and the consumer would be advised to consult with his or her own doctor or local pharmacist.
- Factual information about a medicine may be provided to consumers as long as this does not interfere with the doctor/patient relationship. All requests of this nature shall be handled with care and judgment and a decision taken as to whether the company can responsibly answer the inquiry.

5.3. Responding to inquiries

5.3.1. Initial processing

- The PV representative/designee shall review the form.
- All medical inquiries should be numbered as follows:
- The type of case, sequential number of complaints received in total by the company and prefixed by the four digit of the current year.
- Numbering System of Medical Inquiry (MI):

  Medical Inquiry shall be assigned as MI/YY/NNNN,

  Where,

  MI: Denotes Medical Inquiry

  /: Separator

  YY: Last two digits of the calendar Year

  NNNN: Serial Number of Medical inquiry

  Example: MI/24/0001: Denotes first Inquiry received in year 2024
- The PV representative/designee shall attempt to provide an immediate response to the inquiry.
- If further details are required to provide a full response, or an answer in writing is required, then a response time shall be agreed with the enquirer. When a deadline is not provided by the enquirer, the initial response shall be provided within 15 business days.
- The response shall be finalized in consultation with the PvOI.

5.3.2. Response materials

- If an inquiry is answered over the phone, the same should be documented and details of the response shall be recorded in medical inquiry form.
- If written response is provided, a copy of the materials shall be attached to the inquiry form and filed.

5.3.3. Other Response Materials

Other sources of information for giving response, as mentioned below, may be used

- SPC/PI/PIL
- External databases (e.g. Pub Med)
- On-line journals
- Other published documentation.
- This list is not exhaustive and other sources of information can also be used, with the agreement of the PvOI or designee.

5.4. ICSR and PQC

If an inquiry also concerns an ICSR or PQC, the person handling the inquiry shall make every effort to collect the minimum essential information.

Further handling of inquiry shall be as follows:

5.4.1. If the inquiry is just a product complaint, PV shall follow the SOP.

5.4.2. If the inquiry is just an AE, PV shall follow the SOP.

5.4.3. If the inquiry is a product complaint and AE (including lack of effect etc.), PV shall follow the SOP.

5.5. Quality Review

5.5.1. On a monthly basis all the medical inquiry forms shall be reviewed by Pharmacovigilance personnel to ensure that all queries have been handled appropriately.

5.5.2. The inquiry form is signed and dated by the Pharmacovigilance personnel performing the review.

6.0 DISTRIBUTION:

Not Applicable

7.0 REFERENCES:

Not Applicable

8.0 ABBREVIATIONS:

ADR	Adverse Drug Reaction
AE	Adverse Event

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PV	Pharmacovigilance
ICSR	Individual Case Safety Report
MI	Medical Inquiries
NA	Not Applicable
PI	Prescribing Information
PIL	Patient Information Leaflet
PQC	Product Quality Complaints
SOP	Standard Operating Procedure
SPC	Summary of product Characteristic

9.0 ANNEXURE:

S.No.	Title	Annexure No.	No.
1.	Medical Inquiry Form		
2.	Medical Query Log Book		

10.0 REVISION HISTORY:

Revision No.	Effective Date	Reason for change	CC No.
1.		New SOP	NA