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		SOP No.	IPC/PvPI/QA/020
Section	All section	Revision No.	00
Effective Date	01/11/2016	Review Date	31/10/2019

Title: SOP for handling of Medication Error, Lack of therapeutic efficacy ICSRs.

1.0 OBJECTIVE

1.1 To lay down a procedures for handling preventable ADRs of Medication error and Lack of therapeutic efficacy.

2.0 SCOPE

2.1 This SOP shall be applicable to NCC and AMC under PvPI.

3.0 RESPONSIBILITY

3.1 All Pharmacovigilance Associates working at NCC and AMCs, Coordinators of respective AMCs shall be responsible for adhering to this SOP.

3.2 All the Officers and Section-In-charge shall ensure that this SOP has been reflected in the section/ departments.

3.3 Quality Manager/Technical Manager, AMC Coordinator shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer In charge – Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 Medication error includes prescribing error, omission error, wrong time error, unauthorized drug error, Improper dose error, wrong dosage form error, wrong drug preparation error, incorrect drug administration- technique error, expired medicine use error, dispensing error, medication administration error and LOE (Annexure-I)

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pv. Associate		05/10/2016
Reviewed by	Dr. Rajesh Sharma	S-A		08/10/2016
Approved by	Dr. Kalaiselvan	D.S.O		08/10/2016

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National Coordination Centre-Pharmacovigilance Programme of India

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- 5.2 The monitoring of the medication errors shall be done by the coordinator of the respective AMC.
- 5.3 ADR reports related to Medication error, LOE shall be reported through safety database with proper coding as per WHOART/MedDRA.
- 5.4 The record of medication error, LOE shall be kept in a separate file that shall be producible to the audit team whenever required.
- 5.5 The outcome of the medication error attribute to its seriousness shall be reported within 14 calendar days.
- 5.6 However, LOE in case of contraceptives, vaccines, anaesthesia or any medication used to treat life threatening conditions then reporting shall be done in expedited manner i.e. within 24 hours.

6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.
- 6.1.1 Do not use adhesive tape or whitener on SOP.
- 6.1.2 Do not share the SOP information outside the organization.

7.0 REFERENCES: In house**8.0 ABBREVIATIONS**

ADR : Adverse Drug Reaction
SOP : Standard Operating Procedure

	Name	Designation	Signature	Date
Prepared by	Rishi Kr	Pr. Associate	[Signature]	05/10/2016
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NCC	:	National Coordination Centre
AMC	:	Adverse Drug Reaction Monitoring Centre
QA	:	Quality Assurance
LOE	:	Lack of Therapeutic Efficacy
ICSRs	:	Individual Case Safety Reports
WHO	:	World Health Organization
WHO-ART	:	WHO Adverse Drug Reaction Terminology
MedDRA	:	Medical Dictionary for Regulatory Activities

9.0 ANNEXURE:

Annexure-I : Definitions of Medication Errors

	Name	Designation	Signature	Date
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Reviewed by	Dr. Pradeep Thota	SA		06/10/2016
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Annexure-I
Definitions of Medication Error

Definition of Medication Error- A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

Levels of Medication Errors

Type	Definition
Prescribing Error	Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy and other factors), dose, dosage form, concentration, route of administration, rate of administration or instructions for use of drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescription or medication orders that lead to errors that reach to the patient.
Omission error	The failure to administer an ordered dose to a patient before the next scheduled dose, if any.
Wrong Time Error	Administration of medication outside a predefined time interval from the scheduled administration time (this interval should be established by each individual healthcare facility).
Unauthorized drug error	Administration of a medication to the patient, not authorized by a legitimate prescriber for the patient.
Improper Dose error	Administration to the patient of a dose that is greater than or less than the amount ordered by prescriber or administration of duplicate dose to the patient, i.e. one or more dosage units in addition to those that were ordered.

	Name	Designation	Signature	Date
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Reviewed by	Dr. P. S. D. Thakur	S-A		06/10/2016
Approved by	Dr. Kalaiselvan	P.S.		07/10/2016



Annexure-I
Definitions of Medication Error

Wrong Dosage – form error	Administration to the patient of a drug product in a different dosage form that ordered by the prescriber.
Wrong drug-preparation error	Drug product incorrectly formulated or manipulated before administration of a drug.
Incorrect Drug Administration-technique error	Inappropriate procedure or improper technique in the administration of a drug.
Expired medicine use error	Administration of drug that has expired or for which the physical or chemical dosage form integrity has been compromised.
Lack of therapeutic efficacy (LOE)	Unable to produce desired therapeutic effect.
Dispensing Error	The wrong dose/ wrong strength dispensed to the patient.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pr. Associate		05/10/2016
Reviewed by	Dr. Anand Mohan	SA		06/10/2016
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