



Ref : Hmch/06-2/23

Date: 01.04.2023

## PHARMACOVIGILANCE COMMITTEE

### **Pharmacovigilance and the WHO International Drug Monitoring Program**

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of the adverse effects of drugs or any other possible drug-related problems, Recently its scope have been widened to include the following:

- Herbals
- traditional and complementary medicines
- blood products
- biologicals
- medical devices
- vaccines

#### **The specific aims of Pharmacovigilance are to:**

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
- Improve public health and safety in relation to the use of medicines
- Contribute to the assessment of benefit, harm, effectiveness, and rise of medicines, encouraging their safe, rational and more effective (including cost-effective) use (including therapeutic ineffectiveness - considered and adverse drug reaction
- especially for herbal, traditional and complementary medicine, where trial for efficacy is not done).
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

#### **Preamble:**

It is mandatory for every medical college in India to have a Pharmacovigilance committee, as per regulations of Medical Council of India, 2010. Therefore, the Pharmacovigilance committee of Himalaya Medical College and Hospital is constituted.

#### **GOAL:**

The broad goal of the committee will be to generate awareness about the need of identifying and reporting of Adverse Drug Reactions (ADR), amongst all sections of health care providers (doctors, consultants, nurses, pharmacists and undergraduate students, service providers etc) of Himalaya Medical College and Hospital and to pick



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Ref : Hm.C.H./06-223

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up and identify ADR occurring in patients admitted to medical college hospital and reports the same to the appropriate authorities.

## **OBJECTIVES:**

1. To generate awareness about ADRs among health care providers and students, by different activities.
2. To pick up ADRs occurring in the patients admitted to Hospital and report the same to appropriate authorities i.e., National Pharmacovigilance centre.
3. To carryout casulty analysis of ADRs.
4. To undertake scientific and research activities pertaining to ADRs.
5. To make effort to minimize the chances of ADR and thereby make drug therapy safer and rational.

To take up activities to strengthen the ongoing National Pharmacovigilance programme.

## **TENURE OF THE COMMITTEE:**

01-04-2023 to 31-03-2025 (two years)

The committee shall be reconstituted every two years.

## **Scope of the Committee:**

The committee shall meet once in 03 months and whenever required. The committee shall be responsible for planning, implementing and monitoring of various activities of the Pharmacovigilance committee. They will also work as mentors and facilitators.

Roles:

1. Chairman

The chairman will chair and conduct all meeting and will function as administrative head of the committee.

2. Convener:

The convener shall be responsible for arranging meetings and conducting activities with help of member secretary. He/She will also chair the meetings in absence of the chairman.

3. Member Secretary:

The Member secretary will play the pivotal role and shall undertake following activities to help the task of the convener:

- i) Prepare agenda of the meetings and send in advance to the members.
- ii) Arrange the meetings, write minutes, circulate and document the same.
- iii) Organize the awareness generation programmes



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iv) Coordinate the ADR collection and reporting to the appropriate authorities.

v) Carry out casulty assessment.

vi) Coordinate the research activities.

vii) Raise a library for the committee.

viii) Carry out any other task assigned by the committee.

#### 4. Members:

Members will primarily work as subject experts and will also do the mentoring of young faculty/resident doctors/students in the area of ADR. They will give suggestion for better and effective functioning of the committee and shall work as facilitators.

*Gyan Bhushan.*

Superintendent

Superintendent

Himalaya Medical College & Hospital

Chiksi, Paliganj, Patna

#### Preamble:

It is mandatory for every medical institution to have a Pharmacovigilance committee, as per regulations of Ministry of Health, Govt. of India. The Pharmacovigilance committee of Himalaya Medical College and Hospital is constituted.

#### GOAL:

The broad goal of the committee will be to generate awareness about the work of identifying and reporting of Adverse Drug Reactions (ADRs) amongst all workers of health care providers (doctors, pharmacists, nurses, physiotherapists, radiologists, students, service providers etc.) of Himalaya Medical College and Hospital and to put



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Ref: Hmch/06-3/23

Date: 01.04.2023.

## MINUTES OF MEETING OF PHARMACO VIGILANCE COMMITTEE HELD ON 01-04-2023

The Meeting of pharmacovigilance committee is held on 01-04-2023 at the of the **Himalaya Medical College & Hospital**, Chaired by Chairman of the committee.

### AGENDA:

1. Reconstitution of pharmacovigilance committee
2. To plan distribution of Adverse Drug Reaction (ADR) forms to various departments in the hospital for reporting ADRs.
3. Conduct sensitization programme for faculty and other staff involved in ADR reporting.
4. To discuss who should upload the ADRs to pharmacovigilance programme of India.

### MINUTES OF MEETING:

1. Pharmacovigilance committee was reconstituted as follows:

#### **Committee Members:**

##### **Chairman**

Dr. Binod Prasad

##### **Co-ordinator**

Dr. R.N. Seth, Professor Department of Pharmacology

##### **Member Secretary**

Dr. Archana Kumari, Assistant Professor of Pharmacology



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Date: 01.04.2023

## Members

Dr. Ashok Kumar, Professor of General Medicine

Ashok Kumar

Dr. Vipin Kumar, Assistant Professor of Psychiatry

Vipin Kumar

Dr. Sanu Priya, Tutor, Department of Pharmacology

Sanu Priya.

Ms. Kumari Sindhu - Pharmacist

Kumari Sindhu

## Causality Assessment

Dr. Kartik Prasad Singh, Associate Professor of Pharmacology

Kartik Prasad Singh

Dr. A.K Mahto, Associate Professor of General Medicine

A.K. Mahto

Dr. Choudhary Laxmi Narayan, Associate Professor of Psychiatry

Laxmi Narayan

2. To distribute ADR forms in the OPDs and inpatient wards for reporting ADRs from 01-04-2023.
3. To conduct sensitization programme of pharmacovigilance for the faculty of the hospital on 01-04-2023
4. Dr. Archana Kumari, Assistant Professor, Department of Pharmacology to upload the ADRs collected to National Co-ordination centre i.e. pharmacovigilance programme of India under the supervision of Dr. R.N. Seth, Professor, Department of Pharmacology.

Meeting attended by :

| Name   | Designation  | Signature         |
|--|--------------|-------------------|
| Dr. Binod Prasad                                       | Chairperson  | Binod Prasad      |
| Dr. R.N. Seth,<br>Professor Department of Pharmacology | Co-ordinator | Raj Narayan Seth. |



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Date: 01.04.2023

Dr. Archana Kumari  
Assistant Professor of Pharmacology

Member Secretary

*Archana Kumari*

Dr. Ashok Kumar  
Professor of General Medicine

Member

*Ashok Kumar*

Dr. Vipin Kumar  
Assistant Professor of Psychiatry

Member

*Vipin Kumar*

Dr. Sanu Priya  
Tutor, Department of Pharmacology

Member

*Sanu Priya.*

Ms. Kumari Sindhu- Pharmacist

Member

*Kumari Sindhu*

## Causality Assessment

Dr. Kartik Prasad Singh, Associate Professor of Pharmacology

*Kartik Prasad Singh*

Dr. A.K Mahto, Associate Professor of General Medicine

*A.K. Mahto*

Dr. Choudhary Laxmi Narayan, Associate Professor of Psychiatry

*Laxmi Narayan*



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Ref : Hmch/14-1/23

Date: 15/07/2023

## MINUTES OF MEETING OF PHARMACO VIGILANCE COMMITTEE HELD ON 15-07-2023

The Meeting of pharmacovigilance committee is held on 15-07-2023 at the **Himalaya Medical College & Hospital**, Chaired by Chairman of the committee.

The Following were aims of the meeting:

1. Monitoring of Adverse Drug Reactions due to Drug Administered.
2. Overseeing the safety of Drugs.
3. Analyzing the Medical errors, such as overdose, misuse / abuse of Drugs which may also result in ADR.

The Doctors/ Nurse shall report any ADR in the prescribed format to the quality department of the hospital and also to the pharmacovigilance committee. The cases of ADR will be investigated and the followed upon by the various department (The quality control department, pharmacy and clinical pharmacology department). The mild and moderate ADR are managed by the doctors whom will have to be reported. The severe ADR shall be investigated by the committee and reported to the higher authorities.

The committee also sensitized the doctors and nurses periodically about the safety and ADR of the drugs.

the Pharmacovigilance committee will meet once in three monts and whenever required.

The following members have attended the meeting.



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Ref: Hmch/14-1/23

Date: 15/07/2023

Meeting attended by :


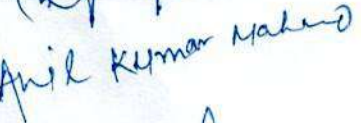

| Name  | Designation      | Signature   |
|---|------------------|---|
| Dr. Binod Prasad  | Chairperson      |  |
| Dr. R.N. Seth,<br>Professor Department of Pharmacology    | Co-ordinator     | Raj Narayan Seth.   |
| Dr. Archana Kumari<br>Assistant Professor of Pharmacology | Member Secretary | Archana Kumari  |
| Dr. Ashok Kumar<br>Professor of General Medicine          | Member           | Ashok Kumar   |
| Dr. Vipin Kumar<br>Assistant P-rofessor of Psychiatry     | Member           | Vipin Kumar   |
| Dr. Sanu Priya<br>Tutor, Department of Pharmacology       | Member           | Sanu Priya  |
| Ms. Kumari Sindhu- Pharmacist                             | Member           | Kumari Sindhu   |

## Causality Assessment

Dr. Kartik Prasad Singh, Associate Professor of Pharmacology

Dr. A.K Mahto, Associate Professor of General Medicine

Dr. Choudhary Laxmi Narayan, Associate Professor of Psychiatry





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Ref: Hmch/29-4/23

Date: 20.11.2023

## MINUTES OF MEETING OF PHARMACO VIGILANCE COMMITTEE HELD ON 20-11-2023

The Meeting of pharmacovigilance committee is held on 20-11-2023 at college Council **Himalaya Medical College & Hospital**, Chaired by Chairman of the committee.

The following aims of the meeting:

1. To make a plan of action and to implement the collection of data regarding ADR occurring in **Himalaya Medical College & Hospital**.
2. The department of Pharmacology will be in-charge of ADR reporting.
3. Doctors and other para medical staff will be sensitized about ADR.
4. The ADR will be captured in CSDCO ADR reporting form and will be preserved in the pharmacovigilance cell in the department of pharmacology.

The following member have attended the meeting.

Meeting attended by :

| Name  | Designation      | Signature |
|---|------------------|-----------|
| Dr. Binod Prasad  | Chairperson      |           |
| Dr. R.N. Seth,<br>Professor Department of Pharmacology    | Co-ordinator     |           |
| Dr. Archana Kumari<br>Assistant Professor of Pharmacology | Member Secretary |           |
| Dr. Ashok Kumar<br>Professor of General Medicine          | Member           |           |
| Dr. Vipin Kumar<br>Assistant P-rofessor of Psychiatry     | Member           |           |



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Ref: Hmch/29-4/23

Date: 20.11.2023

## MINUTES OF MEETING OF PHARMACO-VIGILANCE COMMITTEE

Dr. Sanu Priya  
Tutor, Department of Pharmacology

Member

*Sanu Priya.*

Ms. Kumari Sindhu- Pharmacist

Member

*Kumari Sindhu*

### Causality Assessment

Dr. Kartik Prasad Singh, Associate Professor of Pharmacology

*Kartik Prasad Singh*

Dr. A.K Mahto, Associate Professor of General Medicine

*A.K. Mahto*

Dr. Choudhary Laxmi Narayan, Associate Professor of Psychiatry

*Laxmi Narayan*

Meeting attended by:

Name

Designation

Signature

Dr. Binod Prasad

Chairman

*Binod Prasad*

Dr. R.N. Seth,

Professor Department of Pharmacology

Chairman

*R.N. Seth*

Dr. Anshu Kishor

Assistant Professor of Pharmacology

Member Secretary

*Anshu Kishor*

Dr. Anshu Kumar

Professor of General Medicine

Member

*Anshu Kumar*

Dr. Anshu Kumar

Associate Professor of Psychiatry

Member

*Anshu Kumar*



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Ref: AmCH/10-1/24

Date: 26/02/2024

## MINUTES OF MEETING OF PHARMACO VIGILANCE COMMITTEE HELD ON 26-02-2024


The Meeting of pharmacovigilance committee is held on 26-02-2024 at college Council **Himalaya Medical College & Hospital**, Chaired by Chairman of the committee.

The following aims of the meeting:

1. To make a plan of action and to implement the collection of data regarding ADR occurring in **Himalaya Medical College & Hospital**.
2. The department of Pharmacology will be in-charge of ADR reporting.
3. Doctors and other para medical staff will be sensitized about ADR.
4. The ADR will be captured in CSDCO ADR reporting form and will be preserved in the pharmacovigilance cell in the department of pharmacology.

The following member have attended the meeting.

Meeting attended by :

| Name  | Designation      | Signature   |
|---|------------------|---|
| Dr. Binod Prasad  | Chairperson      |  |
| Dr. R.N. Seth,<br>Professor Department of Pharmacology    | Co-ordinator     | Raj Narayan Seth.   |
| Dr. Archana Kumari<br>Assistant Professor of Pharmacology | Member Secretary | Archana Kumari  |
| Dr. Ashok Kumar<br>Professor of General Medicine          | Member           | Ashok Kumar   |



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Ref : Hmch/10-1/24

Date: 26/02/2024

Dr. Vipin Kumar Member  
Assistant P-rofessor of Psychiatry

Vipin Kumar

Dr. Sanu Priya Member  
Tutor, Department of Pharmacology

Sanu Priya.

Ms. Kumari Sindhu- Pharmacist Member

Kumari Sindhu

## Causality Assessment

Dr. Kartik Prasad Singh, Associate Professor of Pharmacology

Kartik Prasad Singh

Dr. A.K Mahto, Associate Professor of General Medicine

Anil Kumar Mahto.

Dr. Choudhary Laxmi Narayan, Associate Professor of Psychiatry

Laxmi Narayan