



OFFICE OF THE DEAN AND CEO
GOVERNMENT AUTONOMOUS MEDICAL COLLEGE, RATLAM
Sailana Road, Village- Banjali, Ratlam -457001 (Madhya Pradesh)

No. 4563 /Estb./Ratlam/GMC

Date- 21/05/2021

OFFICE ORDER

It is essential to recognise ADR and to establish a causal relationship between the drug and the adverse event. It is desirable that ADR should be objectively assessed and presented based on an acceptable "Probability Scale." Many causality methods have been proposed to assess the relationship between a drug and an adverse event in a given patient, ranging from short questionnaires to comprehensive algorithms.

The causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO-UMC), and the Naranjo Probability Scale are the generally accepted and most widely used methods for causality assessment in clinical practice as they offer a simple methodology. The WHO-UMC causality system takes into account the clinical-pharmacologic aspects, whereas previous knowledge of the ADR plays a less prominent role. The "Naranjo ADR Probability Scale," which has gained popularity among clinicians because of its simplicity. The above scales are structured, transparent, consistent, and easy to apply assessment methods.

As per the recommendation of 2nd Quality Review Panel of Pharmacovigilance Programme of India (PvPI), it is mandatory to establish CAC in every ADR Monitoring Centre (AMC) to detect the causal relationship between the adverse event(s) and the suspected drug(s) of the reported case using WHO Causality Assessment scale.

Sanction is hereby accorded to the constitution of the CAC of GMC Ratlam of following members (& invited members if required):-

CAUSALITY ASSESSMENT COMMITTEE (CAC)

S.No.	Name of Member	Designation in medical college	Designation in PC
1	Dr Neeraj Kumar Agrawal Chairperson	Associate Professor, Dept of Pharmacology	Coordinator & Member Secretary
2	Dr Sudhanshu Sharma Vice-Chairperson	Professor & Head , Department of Dermatology	Deputy coordinator
3	Dr Sanjib Das Member & Pharmacologist	Professor & Head , Department of Pharmacology	Chairperson
3	Dr Mohit Kulmi Member & Pharmacologist	Assistant Professor, Dept of Pharmacology	Member
4	Dr Ritesh Churihar Member & Pharmacologist	Assistant Professor, Dept of Pharmacology	Member
5	Dr Anurag Jain Member & Clinician	Associate Professor, Dept of Surgery	None


Government Medical College
Ratlam (M.P.)

PAGE 192




OFFICE OF THE DEAN AND CEO
GOVERNMENT AUTONOMOUS MEDICAL COLLEGE, RATLAM
Sailana Road, Village- Banjali, Ratlam -457001 (Madhya Pradesh)

6	Dr Tarunendra Mishra Member & Clinician	Assistant Professor, Dept of Medicine	None
7	Dr Anand Shukla Member	Demonstrator, Dept of Pharmacology	Member

After the CAC meeting, the Patient Safety Pharmacovigilance Associate will enter the ICSRs in VIGIFLOW to NCC-PvPI (Serious adverse events- not later than 15 days)

Terms of Reference for CAC:

- The committee shall be responsible for causality assessment of each Adverse Event/Case reported from their respective AMC / Peripheral Hospitals.
- The CAC shall meet at least once in a month to do causality of each Adverse Event/Case reported from their respective AMC / Peripheral Hospitals.
- After the causality assessment, Coordinator and Technical Associate shall be responsible to submit the reports to NCC-PvPI and in case of serious Adverse Events (SAE) not later than 15 days.
- Tenure of the CAC shall be for the period of three years.


21/05/2021
Dr. Jitendra Gupta
Government Medical College
Dean & CEO
Ratlam (M.P.)

Government Autonomous Medical College, Ratlam

No. /Estb./Ratlam/GMC

Date- 21/05/21

Copy to: 4564 - 65

1. Medical Superintendent, GMC Ratlam
2. Members, CACcommittee

PAGE 292