

# National Pharmacovigilance Programme: Annual Stocktaking meeting

An overview of one year experience

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# Main pharmacovigilance activities

- Assisting the health professionals by providing reliable, evidence based and balanced information on medicines and therapeutics
- Contributing to safe use of medicines
- Promoting the cost effective, rational and safe use of medicines

# Main pharmacovigilance activities

- Promoting ADR reporting, evaluating (root cause analysis), documenting and communicating the outcome of the reported ADRs
- Providing knowledge on medicine & medicine related problems to the Clinicians/public and answer their queries on these issues

# LHMC-Regional center

## Peripheral Centers:

- VPCI, Delhi
- Model pharmacy Apothecaries, N Delhi
- MAMC, N Delhi
- Subharti MC, Meerut
- Era Lucknow MC, Lucknow

# LHMC-Regional center

- One year of Pharmacovigilance
  - Initial Constrains
  - Symposium/conference
  - Poor attendance – Excuses - busy in Patient care
  - Interactive Session with individual departments
  - Manpower / Pharmacologist Appointment
  - Periodic reminder by visits / Telephone / Posters/ Slogans / sensitization / SMS
  - Sharing information with respective deptt.

## Total ADE Reports Received -594

- Repots of LHMC- 108
- Analysed and sent 702
- Quarterly summary

	LHMC	Others
• Dec.-March 06	18	35
• April-June 06	25	124
• July- Sept. 06	35	225
• Oct.-Nov. 06	30	210

# LHMC- Regional Center

- Patients ID (N=108) 22 Not Mentioned (NM)
- Age <12years 21  
>60years 06
- Sex (M/F) 51/57
- Weight 108 (NM)

# LHMC-Regional center

## Outcome attributed to Adverse event

- Death 01
- Life threatening 08
- Hospitalization-initial 17  
or prolonged
- Disability 03
- Congenital anomaly Nil
- Required intervention 10
- Others 62

# LHMC-Regional center

- Date of event starting 23 (NM)
- Date of event 59 (NM)

## Description of event

Complete	+ (20)
Partial	++ (62)
Not present	+++ (26)



# LHMC-Regional center

- Treatment of ADE

No Treatment

65

## Commonly used drugs for treatment

Antihistaminic: CPM, Cetrizine

Steroids: Prednesolone, HC, Mometasone

# LHMC-Regional center

## Suspected medication (#1 & #2)

Name - Brand

Generic	83 (NM)
• Labeled strength	48 (NM)
• Dose	65 (NM)
• Frequency	34 (NM)
• Route	16 (NM)
• Therapy dates	70 (NM)

# LHMC-Regional center

- Two or more suspected drugs 15
- Two or more diagnosis 2
- Polypharmacy 76
  
- Therapy start date 70 (NM)
- Therapy stop date 89 (NM)
- Lot No. 106 (NM)

# LHMC-Regional center

## Concomitant drugs

- Anti microbial agents
- Analgesic
- Acid suppressants
- CNS drugs
- CVS drugs
- Others

# LHMC-Regional center

- Clinician Name & Prof. Address
- Reporter Reported by (Name & Address)

Doctor 105

Nurse Nil

Pharmacist Nil

Patients 3

Others Nil

Health Professional 108 (NM)

# LHMC-Regional center

- Event abated after use stopped or reduced

Yes	41
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No	8
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NA	Nil
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NM	45
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- Event reappeared after reintroduction

Yes	2
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No	2
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NA	5
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NM	99
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# LHMC-Regional center

- Type of drug causing ADE:
  - Anti microbial agents
  - Analgesic
  - Acid suppressants
  - CNS drugs
  - CVS drugs
  - Others

# LHMC-Regional center

## Organ system affected

- Skin 49
- CNS 20
- CVS 10
- Hematology 8
- GIT 10
- OTHERS 11

# LHMC-Regional center

- Causality assessment

Certain	2
Probable	37
Possible	52
Unlikely	12
Unclassified	2
Unclassifiable	3

# LHMC-Regional center

## Suggestions

- Active Involvement of medical/paramedical staff
- Administrative intervention – Managerial level
- Modification of patient case sheet
- Periodic Symposium/workshops
- Scientific incentives to the involved staff
- Integration of NPVP with Pharmaceutical Industry- PMS

# LHMC-Regional center

- Positive overwhelm response
- Short memory of prescribers
  - Improving trends

**Thank you**





