SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES

Osudu, Agaram Village, Koodapakkam post, Puducherry - 605502

Date: 2-8-2021

From
Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

Sub: Permission to conduct value-added course: PHARMACOVIGILAIANCE

Dear Sir,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled: PHARMACOVIGILAIANCE on **September 2021 – January 2022** We solicit your kind permission for the same.

Kind Regards

Dr.G.Somasundaram

FOR THE USE OF DEANS OFFICE

Names of Committee members for evaluating the course:

Dean: Dr. Jayalakshmi HOD: Dr. G.Somasundaram Expert: Dr. Jaikumar

The committee has discussed about the course and is approved.

Dean **Subject Expert** **HOD**

G.G. JAYALAKSHMI, M.Sc., MBBS., DHCD., M.D.,
DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
Osudu, Agaram, Koodapakkam Post,
Puducherry - 605502

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute of Medical Sciences
PONDICHERRY - 605 502

OFFICE OF THE DEAN

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.
[Recognised by Medical Council of India, Ministry of Health letter No. U/12012/249/2005-ME (P -II) dt. 11/07/2011]
[Affliated to Bharath University, Chennai - TN]

Circular **Date :** 9-8-2021

Sub: Organizing Value-added Course: **Pharmacovigilance** in enhancing performance skill in Second year students in **Pharmacovigilance** reg.

With reference to the above-mentioned subject, it is to bring to your notice that a Sri Lakshmi Narayana Institute of Medical science is organizing "**PHARMACOVIGILAIANCE**". **September 2021 – January 2022**.The course content is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before **27-8-2021.**

Applications received after the mentioned date shall not be entertained under any circumstances.

Dr.G.JAYALAKSHMI, BSC., MBBS., DTCD., M.D.,
DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
Osudu, Agaram, Kudapakkam Post,
Villianur Commune, Puducherry - 605502.

Dean

Encl: Copy of Course content

Course Proposal

Course Title: Pharmacovigilance

Course Objective:

1.Introduction to Pharmacovigilance

2. Need for Pharmacovigilance

3.Preclinical research phases

4.Post marketing surveillance

5. ADR Forms

6.Reporting ADR Forms

7.What need to be collected from ADR from

8.How to collect data from ADR

9. Significance of reporting ADR

10.ADR reporting procedure

11.VIGI FLOW

12.Pharmacovigilance in India

13.Uppsala monitoring center

Course Outcome: On successful completion of the course the students will have skill in reporting ADR

Course Audience: 2nd Year MBBS Students

Course Coordinator: Dr.G.Somasundaram,

Course Faculties with Qualification and Designation:

Dr.S.Jaikumar, Asst Prof Dept of Pharmacology

Course Curriculum/Topics with schedule (Min of 30 hours)

SlNo	Date	Topic	Time	Hours
1	27/9/2021	Introduction to Pharmacovigilance	4-7 PM	3
2	4/10/2021	Need for Pharmacovigilance	4-7 PM	3
3	18/10/2021	Preclinical research phases	4-7 PM	3
4	25/10/2021	Post marketing surveillance	4-7 PM	3
5	8/11/2021	ADR Forms	4-7 PM	3
6	15/11/2021	Reporting ADR Forms	4-6 PM	2
7	22/11/2021	What need to be collected from ADR from	4-6 PM	2
8	29/11/2021	How to collect data from ADR	4-6 PM	2
9	6/12/2021	Significance of reporting ADR	4-6 PM	2
10	20/12/2021	ADR reporting procedure	4-6 PM	2
11	28/1/2022	VIGI FLOW	4-6 PM	2
12	4/1/2022	Pharmacovigilance in India	4-5 PM	1
13	10/1/2022	Uppsala monitoring centre	4-5 PM	1
			Total Hours	30

REFERENCE BOOKS: (Minimum 2)

1. "Stephens' detection and evaluation of adverse drug reactions: principles and practice 6th ed.: Chichester, West Sussex, UK: John Wiley & Sons, 2012".

2. Mann's Pharmacovigilance, 3rd Edition ISBN: 978-0-470-67104-7 May 2014 Wiley-Blackwell 866 Pages

VALUE ADDED COURSE

1. Name of the programme& Code

PHARMACOVIGILAIANCE PH 03

2. Duration& Period

30 hrs &- **September 2021 – January 2022**

3. Information Brochure and Course Content of Value-Added Courses

Enclosed as Annexure- I

4. List of students enrolled

Enclosed as Annexure- II

5. Assessment procedures:

Multiple choice questions- *Enclosed as Annexure- III*

6. Certificate model

Enclosed as Annexure- IV

7.No. of times offered during the same year:

September 2021 – January 2022

8. Year of discontinuation: 2022

9. Summary report of each program year-wise **September 2021 – January 2022**

Value Added Course- September 2021 – January 2022					
Sl. No	Course Code	Course Name	Resource Persons	Target Students	Strength& Year
1	PH 03	PHARMACOVIGILAIANCE	Dr.S.Jai kumar	II MBBS	20 September 2021 – January 2022

10. Course Feed Back

Enclosed as Annexure- V

RESOURCE PERSON **COORDINATOR**

Dr.S.Jai kumar

Dr. G.Somasundaram

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY.
Sri Lakshmi Narayana Institute Of Medical Sciences,
PONDICHERRY - 605 502.

PHARMACOVIGILAIANCE

PARTICIPANT HAND BOOK

BIHER

SLIMS

COURSE DETAILS

Particulars	Description
Course Title	**PHARMACOVIGILAIANCE**
Course Code	PHARM 03
TOPIC and contents of the course in the hand book.	**1.Introduction to Pharmacovigilance** **2.Need for Pharmacovigilance** **3.Preclinical research phases** **4.Post marketing surveillance** **5.ADR Forms** **6.Reporting ADR Forms** **7.What need to be collected from ADR from** **8.How to collect data from ADR** **9.Significance of reporting ADR** **10.ADR reporting procedure** **11.VIGI FLOW** **12.Pharmacovigilance in India** **13.Uppsala monitoring centre**
Key Competencies	On successful completion of the course the students will have skill in reporting ADR
Target Student	II MBBS Students
Duration	30hrs
Theory Session	10hrs
Practical Session	20hrs
Assessment Procedure	Multiple choice questions

INTTRODUCTION

What is Pharmacovigilance? Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health. What is an Adverse Drug Reaction (ADR)? The {Drug Regulatory Authority} defines an Adverse Drug Reactions (ADR) or adverse reaction as a response to a medicine used in humans or animals, which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine. Why is Pharmacovigilance important? When a medicine is released onto the market there is still a great deal that is unknown about the safety of the product. Once marketed the medicines are used by patients who have many different diseases, who are using several other drugs and who have different traditions and diets which may affect the way in which they react to a medicine. Different brands of medicines may differ in the manner in which they are produced and the ingredients that are used. The adverse drug reactions and poisonings associated with traditional and herbal remedies also need to be monitored in each country. The information we receive on the adverse effects of drugs in other countries may not be relevant or applicable to {Country}'s citizens. In some cases, adverse effects to certain drugs may only occur in {Country}'s citizens. In order to prevent unnecessary suffering by patients and to decrease the financial loss sustained by the patient due to the inappropriate or unsafe use of medicines, it is essential that a monitoring system for the safety of medicines in {Country} is supported by doctors, pharmacists, nurses and other health professionals in the country. The {Drug Regulatory Authority} and the Department of Health's Essential Drug Programme are committed to improving drug safety through adverse drug reaction monitoring in {Country}. Through the {Drug Regulatory Authority}'s national pharmacovigilance programme, adverse reactions should be reported on a daily basis. What is the Size or Severity of the ADR Problem in {Country}? While no studies have comprehensively assessed the burden of adverse drug reactions on health care, it is likely that the problem is considerable in {Country}. Studies conducted in developed countries have consistently shown that approximately 5% of hospitalised patients are admitted into hospital as a result of an ADR and 6-10% of in-patients will experience a serious ADR during hospitalisation. Even these startling figures don't represent the whole picture. These studies generally excluded ADRs caused by overdose, drug

abuse, or therapeutic failures. The cost to most countries for managing adverse drug reactions is considerable. Who should report Adverse Drug Reactions? All health care workers, including doctors, dentists, pharmacists, nurses and other health professionals are requested to report all suspected adverse reactions to drugs 2 (including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is unusual, potentially serious or clinically significant. It is vital to report an adverse drug reaction to the {Drug Regulatory Authority}'s Pharmacovigilance programme even if you do not have all the facts or are uncertain that the medicine is definitely responsible for causing the reaction. What will happen to my Adverse Drug Reaction or Product Quality Report? (Insert your draft flow diagram here and explain it briefly) The information obtained from your reported reactions promotes the safe use of medicines on a local and national level. Your reported case will be entered into the national adverse drug reaction database and analysed by expert reviewers. A wellcompleted adverse drug reaction/product quality form submitted by you could result in any of the following: • additional investigations into the use of the medication in {Country} • educational initiatives to improve the safe use of the medication. • appropriate package insert changes to include the potential for the reaction reported by you • changes in the scheduling or manufacture of the medicine to make the medicine safer Therefore, the purpose of ADR reporting is to reduce the risks associated with drug prescribing and administration and to ultimately improve patient care and safety. What are the benefits of these reports for me and for my patients? {Insert your response here} Will reporting have any negative consequences on the health worker or the patient? This adverse drug reaction report does not constitute an admission that you or any other health professional contributed to the event in any way. The outcome of the report, together with any important or relevant information relating to the reaction you have reported, will be sent back to you as appropriate. The details of your report will be stored in a confidential database. The names of the reporter or any other health professionals named on a report and the patient will be removed before any details about a specific adverse drug reaction are used or communicated to others. The information obtained from your report will not be used for commercial purposes. The information is only meant to improve our understanding of the medicines we use in the country. How do I know if a patient's condition is an ADR? 1. Take a Proper History and do a proper examination • A full drug and medical history should be done • Can this adverse be explained by other causes e.g. patient's underlying disease, other drug/s, over-the-counter medicines or traditional medicines; toxins or foods 3 • It is essential that the patient is thoroughly investigated to decide what the actual cause of any new medical problem is. A drug-related cause should be considered, especially

when other causes do not explain the patient's condition 2. Establish time relationships • some reactions occur immediately after being given a medicine while other reactions take time to develop) • The time from the start of therapy to the time of onset of the suspected reaction must be logical. 3. Do a thorough physical examination with appropriate laboratory investigations • Few drug produce distinctive physical signs • Exceptions include fixed drug eruptions, steroid-induced dermal atrophy, acute extrapyramidal reactions • Lab tests are especially important if the drug is considered essential in improving patient care or of the lab test results will improve management of the patient • try to describe the reaction as clearly as possible and where possible provide an accurate diagnosis 4. Effect of Dechallenge and Rechallenge should be determined. (when necessary) 4 Dechallenge = withdraw of drug • resolution of suspected ADR when the drug is withdrawn is a strong, although not conclusive indication of drug-induced disease. • In cases where a withdrawal reaction is experienced, a dechallenge is when the drug is again given to the patient. • "Positive" dechallenge = improvement of reaction when dechallenge occurs Rechallenge = reintroducing the drug after a dechallenge. • this is only justifiable when the benefit of re-introducing the drug to the patient outweighs the risk of recurrence of the reaction. This is rare. In some cases the reaction may be more severe on repeat exposure. 5. Check the known pharmacology of the Medicine. • Is the reaction known to occur with the particular drug as stated in the package insert or other reference? • If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.) Causality Classification In order to assess the likelihood that the suspected adverse reaction is actually due to the medicine, the WHO has provided a list of causality assessment criteria for deciding on the contribution of the medicine towards the adverse event. These criteria are defined as follows: WHO Definitions for Causality Assessment Certain: • Clinical event, lab test abnormality with plausible time relationship to drug intake • Cannot be explained by concurrent disease or other drugs /chemicals • Response to dechallenge- plausible • Event must be definitive pharmacologically / immunologically • Positive rechallenges (if performed). Probable/ Likely: • Clinical event, lab test abnormality with reasonable time relationship to drug intake • Unlikely to be to concurrent disease, drugs / chemicals • Clinically reasonable response to withdrawal (dechallenge) • Rechallenge not required Possible: • Clinical event lab test abnormality with reasonable time relationship to drug intake • Could also be explained by concurrent disease or other drugs or chemicals • Information on drug withdrawal may be lacking or unclear Unlikely: 5 • Clinical event , lab test with improbable time relationship to drug intake • Other drugs , chemicals or underlying disease provide plausible explanations Inaccessible /unclassifiable: • Insufficient

/contradictory evidence which cannot be supplemented or verified Conditional / unclassified • More data is essential for proper assessment or additional data are under examination In most cases there is some level of uncertainty as to whether the drug is directly responsible for the reaction. Many of the questions above may remain unanswered or may be contradictory, however this should not dissuade you, from reporting the reaction to the {National Pharmacovigilance Programme}. A well-documented report which includes information about all the above-mentioned questions can provide us with the first signal of a previously unknown problem. What types of reactions should be reported to the {Drug Regulatory Authority}'s Pharmacoviglance Programme? Report adverse drug reactions such as: • all ADRs to newly marketed drugs or new drugs added to the Essential Drugs List • all serious reactions and interactions • ADRs which are not clearly stated in the package insert. • unusual or interesting adverse drug reactions • all adverse reactions or poisonings to traditional or herbal remedies What Product Quality Problems should I report? Report Product Quality Problems such as: • suspected contamination • questionable stability • defective components • poor packaging or labelling • therapeutic failures What should I know about the {Drug Regulatory Authority}'s Pharmacovigilance Programme? The {Drug Regulatory Authority} has a responsibility to ensure the safety, efficacy and quality of all medicines used by the {Country} public. Therefore it is the responsibility of the MCC to monitor the performance of these medicines once they are marketed. Essential drugs are particularly important as they are used by a large percentage of the population. The MCC's national pharmacovigilance programme, which is co-ordinated by the {Drug Regulatory Authority} offices, presently has one national pharmacovigilance centre in {place of institution}. The {Country Pharmacovigilance Programme} housed within {Institution Name} is responsible for monitoring the safety of all registered medicines in {Country}. These units are responsible for collecting, evaluating and communicating the findings of ADR reports to the {National Pharmacovigilance Committee}. This committee advises the Council on how to prevent or minimise the risk of these adverse 6 reactions in {Country}. The {Drug Regulatory Authority} may communicate their findings and recommendations to the appropriate organisations or individuals. These include but are not limited to health professionals, pharmaceutical manufacturers, the Essential Drugs Programme or other directorates within the Department of Health, other public health institutions, the media and the public. How can I prevent ADRs from occurring in my patients? Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines that are described as follows: Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following

the basic principles of rational use of medicines as follows: 1. Use few drugs, whenever possible 2. Use drug that you know well 3. Do not change therapy from known drugs to unfamiliar one without good reasons. 4. Use text books and other reference material providing information on drug reactions and interactions. 5. Take extra care when you prescribe drugs known to exhibit a large variety of interactions and adverse reactions (anticoagulants, hypoglycemic, and drug affecting the CNS) with careful monitoring of patients with such reactions. 6. Beware of the interaction of drugs with certain food stuffs, alcohol and even with house hold chemicals. 7. Review all the drug used by your patients regularly, taking special notice with those bought without prescription .(Over the counter, herbal preparations). 8. Be particularly careful when prescribing to children, the elderly, the pregnant and nursing women, the seriously ill and patients with hepatic and renal diseases. Careful ongoing monitoring is also essential in these patients is essential. 9. If your patients show signs or symptoms not clearly explained by the course of their illness, think of adverse drug reaction. 10. If you suspect an adverse reaction, consider stopping the drug or reduce the dosage as soon possible and please notify the adverse drug reaction to {Pharmacoviglance Programme Co-ordinator} at the {drug regulatory authority}.

Annexure II

SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES

Participant list of Value-added courses: **Pharmacovigilance**

September 2021 – January 2022

Sl.No	Name of the Student	Register No	Student signature
1	POOJA KUMARI	U16MB351	
2	PRADEEP .T	U16MB352	
3	PRASHANT.S	U16MB353	
4	PRIYADARSHINI .K	U16MB354	
5	PRIYADARSHINI .S	U16MB355	
6	PRIYADARSHINI .U	U16MB357	
7	PRIYADHARSHINI .V	U16MB358	
8	PRIYADHARSHINI.S	U16MB356	
9	PRIYANK VATS	U16MB359	
10	RADHIKA .C	U16MB360	
11	RAJASHREE .M	U16MB361	
12	RAJAT TYAGI	U16MB362	
13	RAJEEV RANJAN SINGH	U16MB363	
14	RAMAPRIYA .M	U16MB364	
15	RIYAS AHAMED .M	U16MB365	
16	RUCHI YADAV	U16MB366	
17	RUPESH RANJAN	U16MB367	
18	SAI PAVAN KUMAR .B	U16MB368	
19	SAJUTI DEY	U16MB369	
20	SAKTHIMALAR .R	U16MB370	

RESOURCE PERSON

COORDINATOR

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502.

SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATON AND RESEARCH

Annexure - I

PHARMACOVIGILAIANCE

MULTIPLE CHOICE QUESTIONS

Course Code: PHA03

1) What is Pharmacovigilance?

a) Adverse drug reaction (ADR) monitoring

b) Therapeutic drug monitoring

c) Vigilance over the pharma company for drug production

d) All

2) Pharmacovigilance includes

a) Drug related problems

b) Herbal products

c) Medical devices and vaccines

d) All

3) Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?

a) Meta analysis

b) Post Marketing Surveillance (PMS) studies.

c) Population studies

d) Regression analysis

4. The incidence ADR is highest in _____.

a) Children b) Elderly c) Women d) Men

5) National Pharmacovigilance programme (NPP) was officially inaugurated at New Delhi in the year

a) 2002 b) 2004 c) 2006 d) 2008

6) The international center for adverse drug reaction monitoring is located in

a) USA b) Australia c) France d) Sweden

7. According to the principles of ICH GCP what should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification?

A. Data entered into the case report form

B. Source information

C. All clinical trial information

D. Essential documents

8. Science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications is known as

a) Pharmacovigilance.

b) Clinical Trails.

c) Observational study.

d) Qualitative study.

9) Which one of the following is the 'WHO online database' for reporting ADRs?

a) ADR advisory committtee b) Medsafe c) Vigibase d) Med watch

10) National pharmacovigilance programme co-ordinating center located in

a) Ghaziabad,UP

b) JIPMER, Pondicherry

c) AIIMS, Delhi.

d) CMC, Vellore

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research
(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that Radhika.c has actively participated in the Value Added Course on "**Pharmacovigilance**" held 2021 to 2022 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

Dr. S. Jaikumar
RESOURCE PERSON

Dr. G.Somasundaram
COORDINATOR

Student Feedback Form

Course Name: Pharmacovigilance

Subject Code: **PH 03**

Name of Student: Radhika. C. Roll No.: U6MB360

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
2	Course contents met with your expectations				✓	
3	Lecturer sequence was well planned				✓	
4	Lectures were clear and easy to understand					✓
5	Teaching aids were effective				✓	
6	Instructors encourage interaction and were helpful				✓	
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

Date; 27-1-2021

From
Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry.

Sub: Completion of value-added course: Pharmacovigilance

Dear Sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled**: Pharmacovigilance on September 2021 – January 2022**. We solicit your kind action to send certificates for the participants that is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards

Dr.G.Somasundaram

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY.
Sri Lakshmi Narayana Institute Of Medical Sciences,
PONDICHERRY - 605 502.