Exam Date & Time: 25-May-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmacovigilance [PPR-BP805ET]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Definition of pharmacovigilance by WHO include all, EXCEPT, (1)

1)	Assessment		2)	Detection		3)	Patient safety		4)	Understanding	

2) USFDA maintains a voluntary ADR reporting system through its ---------- programme (1)

1)	MedWatch		2)	MHRA		3)	Vigibase		4)	Vigiflow	

3) In Eudravigilance, the reaction monitoring report is used for ---------- (1)

1)	Clinical Trail reports		2)	Multi-Axial terminology		3)	Regulatory reports		4)	Signal Detection	

4) The main use of ATC system is for (1)

1)	Better marketing decisions		2)	Drug utilization studies		3)	Identifying counterfeit drug		4)	Regulatory approval of drugs	

5) INN was not normally intended for (1)

1)	Pharmacopoeia		2)	Brand naming		3)	Product information		4)	Drug regulation	

6) ATC system is NOT suitable for (1)

1)	Decision about reimbursement		2)	Drug consumption statistics globally		3)	Drug utilization studies		4)	Tool for drug quality use	

7) Assumed average maintenance dose per day for a drug used for its main indication in adults (1)

1)	Average prescribed daily dose		2)	Consumed daily dose		3)	Defined daily dose		4)	Prescribed daily dose	

8) Pharmacovigilance program of India following ---------- reporting system (1)

1)	Active		2)	Cohort		3)	Spontaneous		4)	None of	

	surveillance reporting			event reporting			reporting			the above	

9) ---------- is usually the only agency with the mandate to ensure the safety, efficacy and quality of vaccines.

												(1)
1)	Drug controller		2)	National drug committee		3)	The National Regulatory Authority		4)	US-FDA		

10) The basic crisis management process include all, except,

												(1)
1)	Assess the risk		2)	Identify the risk		3)	Initiate preventive measures		4)	Loss of resources		

11) Use of Case reports is

												(1)
1)	Describe a new pathogen		2)	Describe presentation of disease		3)	Recognize common manifestation of a known disease		4)	Recognize known adverse reaction of a drug		

12) Case-control studies are generally,

1)	Prospective		2)	Retrospective		3)	Can be both		4)	Monitor one time		(1)

13) Sentinel sites are

												(1)
1)	Cost effective		2)	For Passive reporting		3)	Part of spontaneous reporting system		4)	Supported by electronic methods		

14) ICH has produced a comprehensive set of safety guidelines to uncover potential risks like,

												(1)
1)	Carcinogenicity		2)	Genotoxicity		3)	Reprotoxicity		4)	All of the above		

15) In general, polypharmacy has been defined as ----------

												(1)
1)	a single patient taking more than five drugs daily		2)	multiple medications prescribed to manage the same disease		3)	multiple medications taken to manage comorbid conditions		4)	the prescription of two drugs that may interact to result in adverse effects		

16) Reports of Serious Adverse Events including deaths incorporated in the following section of Schedule Y ----------

(1)

1)	122-A		2)	122-B		3)	122-DAB		4)	122-E	

17) Local toxicity test will be done by ----------

1)	Dermal Toxicity		2)	Rectal Toxicity		3)	Vaginal Toxicity		4)	All of the above	

(1)

18) As per schedule Y time line for Investigator(s) to report all serious and unexpected adverse events to the sponsor is ----------

(1)

1)	24 hours		2)	48 hours		3)	7 days		4)	15 days	

19) Genetic polymorphism of ---------- gene predicts severe skin rashes with Abacavir

(1)

1)	CYP2C9		2)	CYP2D6		3)	HLA-B		4)	SLCO1B1	

20) Which one of the drug is an example for pregnancy category X?

(1)

1)	Gentamicin		2)	Losartan		3)	Metformin		4)	Methotrexate	

II Long Answers

Answer all the questions.

1) Define adverse drug reactions (ADRs). Explain various causality assessment scales of ADRs (10)

2) Enlist Passive surveillance methods and explain them in detail. (10)

III Short Answers

Answer all the questions.

1) Describe breifly on Pharmacovigilance Program of India (PvPI). (5)

2) What is defined daily dose (DDD)? Write its application in drug utilization research. (5)

3) Write a note on MedRA coding. (5)

4) Discuss ICH standards for post approval expidited reporting. (5)

5) Describe safety data generation in various phases of drug development. (5)

6) Discuss single dose toxicity studies in schedule Y. (5)

7) Define genetic polymorphism and its impact on adverse drug reactions. (5)

-----End-----