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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY
SECOND BPHARM PART II EXAMINATION – JUNE/JULY 2023
PH 2223 PHARMACY LAW AND ETHICS – SEQ PAPER

TIME: THREE HOURS

INSTRUCTIONS

- There are **six** questions in part **A** and **B** of this paper.
- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

PART A

01.

1.1. State eight functions of the National Medicines Regulatory Authority (NMRA). (***20 marks***)

1.2. List ten divisions established at NMRA under the National Medicines Regulatory Authority Act No. 05 of 2015. (***25 marks***)

1.3. Briefly describe the functions of National Medicines Quality Assurance Laboratory. (***25 marks***)

1.4. Justify the reasons for using bioequivalence test reports in registering generic medicines. (***30 marks***)

02.

2.1. According to labelling regulations and guidelines make a list of information that should be presented on a commercial medicinal product label. (***25 marks***)

2.2. Explain the term 'medicinal drug promotion'. (***15 marks***)

2.3. Briefly explain the expected role of medical representatives. (***30 marks***)

2.4. '*Pharmaceutical marketing is different from general marketing*' Justify the above statement. (***30 marks***)

03. Read the following sentences carefully and mark True (T) or False (F). (***100 marks***)

No.	Sentence	T/F
A	A pharmacist who fails to disclose the generic medicines with or without brand names available in the pharmacy and their prices to the customer at the time of sale, commits an offence.	
B	More than one pharmacy outlet can be operated with one retail pharmacy license.	

C	Therapeutic claims stated on the cosmetic product labeling and advertising is not a major concern in cosmetic product registration in Sri Lanka.	
D	Counterfeit medicine is a medicine which is labeled or packaged fraudulently with regard to identification and includes any product with proper ingredients with inferior quality or containing different or inactive ingredients.	
E	No person shall distribute any medicine, medical device or borderline product marked as physician's sample to the general public.	
F	Pictorials must be used in the patient information leaflet to demonstrate the correct usage of dosage forms.	
G	Any recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the defect.	
H	Every person who holds a license to operate a pharmacy shall comply to good pharmacy practices.	
I	Writing generic name of a medicine on the prescription is not a compulsory requirement.	
J	Where the brand name of the medicines, which is in the prescription is not available or affordable to the customer, the pharmacist may dispense any other generic medicine with the consent of the customer.	
K	Over the counter medicines can be freely advertised.	
L	It shall be the responsibility of the importer to ensure quality, safety and efficacy of every medicine, medical device or borderline product imported by him.	
M	The Pharmacist shall inform the customer the range of generic medicines with or without brand names available in the pharmacy and their prices enabling the customer to buy the medicine according to his choice.	
N	In the event of a licensed manufacturer, importer, wholesaler or retailer having a stock of therapeutic goods to be disposed of, such manufacturer, importer, wholesaler or retailer could destroy such items without prior approval from the authority.	
O	The medicine evaluation committee shall take into consideration the efficacy, safety, quality, need and cost of each medicine, in the process of evaluation and may consider pharmacoeconomic analysis where necessary.	
P	Any registered pharmacist may sell medicines bearing the state logo or any mark indicating state property without the prior approval of the Authority.	

PART B

04.

4.1.

4.1.1. List the four principles of biomedical ethics. (***10 marks***)

4.1.2. Define one of the principles that you listed in 4.1.1. (***10 marks***)

4.2

4.2.1. Briefly explain Brambell's five freedoms in animal studies. (***25 marks***)

4.2.2. List three alternatives (3Rs) which are encouraged to reduce the impact of research on animals. (***15 marks***)

4.2.3. Briefly describe one of the alternatives listed in 4.2.2. (***25 marks***)

4.3. Justify the term "ethical conduct" according to the guidelines of WHO good clinical practices. (***15 marks***)

05.

5.1. List one function and one impact of each "Shop and office act" and "Homeopathic drug act" on a pharmacist/healthcare professional. (***20 marks***)

5.2. Briefly discuss the procedure of receiving a patent according to the Intellectual Property Act No. 36 of 2003. (***30 marks***)

5.3. Write short notes on followings.

5.3.1. Difference between "ordinance" and "act" (***15 marks***)

5.3.2. "Qualifications for registration as a pharmacist" according to Medical ordinance (***20 marks***)

5.3.3. "Affordability and equitable access" according to National Medicinal Drug Policy (***15 marks***)

06.

6.1. Answer the following questions based on Poisons, Opium and Dangerous Drugs Ordinance (PODDO).

6.1.1. A patient has been prescribed a forged (fake) prescription for morphine, and a pharmacist has been filling this prescription. As a result, the patient took an overdose of morphine and unfortunately lost his life. Mention five requirements that should be fulfilled in a prescription for morphine to avoid this professional malpractice. (***25 marks***)

6.1.2. Briefly explain the analysis of poisonous samples which are carried out for the purpose of tests, examinations, and legal proceedings for poisonous substances.

(***25 marks***)

6.2. In accordance with "Control of Pesticides Act No. 33 of 1980," state five particulars that should be there in an application for licensing of pesticides which should be forwarded to the registrar of pesticides. (***25 marks***)

6.3. Briefly discuss the importance of National Dangerous Drugs Control Board (NDDCB) to Sri Lanka. (***25 marks***)

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