(1) Index No:.....

UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

SECOND BPHARM PART II EXAMINATION – NOVEMBER/DECEMBER 2021

PH 2223 PHARMACY LAW & ETHICS – SEQ

TIME: THREE HOURS

INSTRUCTIONS

- There are **two** parts in this paper **(Part A** and **Part B)**.
- 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. Name the main legislation that regulates pharmaceutical products in Sri Lanka. ***(10 marks)***

1.2. Briefly explain the functions of *medicines regulatory division* establised under the legislation stated in 1.1. ***(20 marks)***

1.3. There are several regulations published by the Sri Lankan government to make medicines affordable. Briefly explain one such regulation. ***(20 marks)***

1.4. Read the following incidences carefully. Name the respective legislation(s) that govern each of the incident. ***(50 marks)***

a) Maximum selling price of metformin 500 mg tablets
b) Maximum selling price of bread
c) Prevention of monopolization of product supplies
d) Marketing electronic cigarettes
e) Labeling of Schedule I pharmaceutical product
f) Sale of sunscreen lotion
g) Registration of Animal Feed
h) Selling Arsenic containing medical preparations
i) Breeder's rights
j) Annual leaves for office workers

02. Describe the purpose(s)/objective(s) of below mentioned legislations.

2.1. Consumer Affairs Authority Act, no 09 of 2003 ***(20 marks)***
2.2. Homoeopathy Act, no. 07 of 1970 ***(20 marks)***
2.3. National Authority on Tobacco and Alcohol Act, no. 27 of 2006 ***(20 marks)***
2.4. Intellectual Property Act, no. 36 of 2003 ***(20 marks)***
2.5. Transplantation of Human Tissues Act, no. 48 of 1987 ***(20 marks)***

03.

3.1. Interpret the term "food" according to the Food Act, no 26 of 1980. ***(10 marks)***
3.2. State the objectives of the Food Act. ***(20 marks)***
3.3. Briefly explain three prohibitions with respect to manufacturing and trading of food items. ***(30 marks)***
3.4. "*Food authority should work in collaboration with Sri Lanka Customs, Excise Department, and National Medicines Regulatory Authority.*" Justify the above statement. ***(40 marks)***

04.

4.1. List three main legislations authorized for the prevention and control of drug abuse in Sri Lanka. (***20 marks***)

4.2. Briefly describe the objectives and functions of one of the authorities established under the Acts mentioned in 4.1. (***25 marks***)

4.3. Briefly explain the duties of precursor control authority. (***25 marks***)

4.4. Do you agree with the following statement *"Preventive measures are better than the rehabilitation of illegal drug addicts"?* Explain the reasons for your answer. (***30 marks***)

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

No.	Sentence	T/F
A.	Prices of all medicines are controlled by the Sri Lankan government.	
B.	The shop and office employees act is applicable to employees work in shops, offices, and factories.	
C.	A newly discovered insect from *Sinharaja* forest can be patented.	
D.	Medicined can be freely advertised.	
E.	Amoxicillin is a part 1 poison according to the poisons, opium, and dangerous drugs ordinance.	
F.	Establishment of the national authority on tobacco and alcohol is for the purpose of identifying and regulating drug abuse in Sri Lanka.	
G.	When a pharmacist terminates his practice, the remaining poisons cloud be sold to another pharmacy.	
H.	The world intellectual property organization (WIPO) has mandated to promote the protection of intellectual property rights in all the member states.	
I.	Atropine, its salts & their preparations are part 1 poisons according to poisons opium and dangerous drugs ordinance.	
J.	Unlike for drugs, food does not need to conform to prescribed standards.	
K.	Containers for poison & poisonous substances should not be different from ordinary containers.	
L.	The name and address of the person who dispensed the medicines should be marked on the prescription.	
M.	Nutraceuticals and functional foods are regulated under the food act.	
N.	Labels of poisons must be labeled "NOT TO BE TAKEN" in three languages.	
O.	No trader is allowed to eliminate or substantially damage a competitor in that market.	
P.	Promotion of safe and rational use of products by health care professionals and consumers is one of the objectives of the NMRA Act.	
Q.	The customs ordinance has nothing to do with the provisions in the food act.	
R.	Medical practitioners shall report all cases of food poisoning to the superintendent of health services or to the medical officer of health in the relevant area.	
S.	Every vendor of food shall if so required by an authorized officer, disclose the name, address and other details required of the person from whom that vendor purchased that food.	
T.	Dentists cannot dispense or sell poisons for the treatment of their patients.	

PART B

06.

6.1. Principles of ethics guide researchers to conduct research without harm for the study participants. Separate ethical principles have been developed for human and animal research. Discuss how ethical principles can be applied in animal research. (***50 marks***)

6.2. Write a short note on the following.

6.2.1. Council of the Ceylon Medical College (***25 marks***)

6.2.2. National Medicinal Drug Policy (***25 marks***)

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