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UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

SECOND BPHARM PART II EXAMINATION – DECEMBER 2016

PH 2223 PHARMACY LAW AND ETHICS (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- Answer **all** questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

1.

1.1 Read through the products/services or incidences given in the table below carefully. Name the respective legislation or legislations governing each of them in the next column. **Only for this part of the question negative marks will be calculated for each wrong answer.** ***(40 marks)***

Hint: - Examine the first entry

No.	PRODUCT/SERVICE/INCIDENT	LEGISLATION OR LEGISLATIONS
	Importation of Vancomycin dry powder for injection *(given)*	National Medicines Regulatory Act (Answer)
1.	Vaping in public places	
2.	Arsenic	
3.	Barbiturates	
4.	The current Intellectual Property system in Sir Lanka	
5.	Establishment and operations of department of Ayurveda	
6.	Maximum retail price of essential goods	
7.	Importation of a bio technological product to be use in animal treatment	
8.	Trading Paracetamol Syrup for childern	
9.	Lancet	

10.	Animal feed	
11.	BCG vaccine	
12.	Mosquito repellant cream	
13.	Breeder's rights	
14.	Weedicides	
15.	Donation of body upon death	
16.	E-cigarette	
17.	Beverages containing Alcohol more than 1% by volume	
18.	Canned Fresh milk	
19.	the maximum quantity of any article to be sold on any day	
20.	Coca leaf extract	

1.2. What is meant by "Intellectual Property (IP)"? ***(20 marks)***

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1.3. What are the benefits that can be expected from promoting and protecting "Intellectual Property"? ***(20 marks)***

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1.4. What rights does a "Patent" provide? ***(20 marks)***

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2.

2.1. What is the main objective of Food Act No 26 of 1980? ***(10 marks)***

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2.2. What are the duties of the Food Advisory Committee? ***(20 marks)***

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2.3. Who is the Chief Food Authority? ***(10 marks)***

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2.4. Name the officers that can be appointed as Authorized Officers for the purpose of Food Act.

(60 marks)

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3.

3.1. What is National Advisory committee (National Medicines Regulatory Authority Act)?

(20 marks)

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3.2. List the main divisions proposed in the National Medicines Regulatory Authority Act?

(20 marks)

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3.3. What are the main objectives of National Medicines Regulatory Authority? ***(60 marks)***

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4.1. What is a Borderline Product? ***(20 marks)***

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4.2. What are the initiatives that have been taken by the Government to regulate these products?

(20 marks)

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4.3. What is the purpose of National Authority on Tobacco and Alcohol Act (No. 27 of 2006)

(30 marks)

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4.4. Who are the officers that can be appointed as Authorized officers according to National Authority on Tobacco and Alcohol Act ?

(30 marks)

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5.

5.1 Read the following sentences carefully and mark True sentences with T (True) and False sentences with F (False) ***(50 marks)***

No.	Sentence	T/F
(a)	National Medicinal Drug Policy aim to promote local manufacture of Essential Medicines	
(b)	Registered Pharmacist may entitle to dispense & sell poisons during the course of his practice as a pharmacist	
(c)	National Medicinal Drug Policy will not safeguard the rights of the patients/consumers	
(d)	Intellectual Property rights share the characteristics of other property rights – they can be owned, alienated and licensed	
(e)	Atropine, its salts & their preparations are part 1 poisons according to Poisons opium and dangerous drugs ordinance	
(f)	Containers for poison & poisonous substances should not be different from ordinary containers	
(g)	Licence are not required to collect the seeds, pods, leaves and flowers of poppy plant, coca plant or hemp plant.	
(h)	Provision of services for the treatment of disease, preservation and promotion of the health, according to Ayurveda is one of the key objectives of Department of Ayurveda	
(i)	Exhibiting the maximum retail or wholesale price, of every article available for sale is not mandatory for traders	
(j)	The Licensing of Traders Act, No. 62 of 1961, is responsible for consumer protenction	
(k)	Every vendor of food shall if so required by an Authorized Officer, disclose the name, address and such other particulars required of the person from whom that vendor purchased that food.	
(l)	Homoeopathic Council was not established under the provisions of Homoeopathy Act (No. 7 of 1970)	
(m)	NATA recommend measures in consultation with the National Dangerous Drugs Control Board, for the elimination or minimization of illicit drug use	
(n)	Any person above the age of Eighteen years, may consent to the donation, to take effect upon his death, of his body or any part thereof	
(o)	Dietary supplements, nutraceuticals or Functional foods are regulated under the provisions of Food Act	
(p)	No trader is allowed to eliminate or substantially damage a competitor in that market	
(q)	No trader who has in his possession or custody or under his control any article for the purposes of trade shall refuse to sell such article	

(r)	The Ayurvedic College and Hospital Board do not have the power to determine the courses of instruction to be given to students admitted to the College of Ayurvedic Medicine	
(s)	The Customs Ordinance has nothing to do with provisions in the Food Act	
(t)	An Ayurvedic Research Committee was established under the Ayurveda Act	
(u)	Maintenance of a "Sale of poison book" is not mandatory for a whole sale druggist, in his ordinary whole sale dealing to a pharmacist	
(v)	Listed seller may sell specified poisons indicated in his licence	
(w)	Veterinary surgeons may dispense or sell poisons for the treatment of animals as well as humans, depending on the condition	
(x)	The selection of an Essential Medicines List prioritizes the medicines that are important	
(y)	Prof. Seneka Bibile played the leading role in developing such a pharmaceutical policy aimed at ensuring that impoverished people would get reasonable drugs at a low price	

5.2. What are the items for which "Three language policy" is mandatorily implemented? ***(25 marks)***

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5.3. What is the difference between Raw and Prepared Opium? ***(25 marks)***

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