



UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

SECOND BPHARM PART II EXAMINATION – J UNE/JULY 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 following incidences carefully. Name the respective legislation or legislations governing each of them. **Only for this part of the question negative marks will be calculated for each wrong answer.** (40 marks)

EXAMPLE: Importation of Amoxicillin capsules (*given*) - National Medicines Regulatory Act (Answer)

(a) Maximum retail price of bread –

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(b) Trading beverages containing Alcohol more than 1% by volume to persons under 21 years of age

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(c) Distribution of a product which is not a tobacco product but having the appearance of a tobacco product

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(d) Preservation of umbilical code (Code blood banking)

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(e) Storing of poisons

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(f) Importation of a bio technological product to be used in animal treatment

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- (g) Donation of Cornea
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- (h) Selling poisons to be used in horticulture
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- (i) Labelling of an schedule I pharmaceutical product
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- (j) Cultivation, conservation and propagation of medicinal plants
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- (k) Authorization to use the title "Vaidyacarya"
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- (l) Display tar and nicotine content in each product
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- (m) Breeder's rights
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- (n) Protection of inventions
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- (o) Labelling of milk products
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- (p) Refusal to sell articles in the store/shop
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- (g) Donation of Cornea
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- (h) Selling poisons to be used in horticulture
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- (i) Labelling of an schedule I pharmaceutical product
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- (j) Cultivation, conservation and propagation of medicinal plants
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- (k) Authorization to use the title " *Vaidyacarya* "
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- (l) Display tar and nicotine content in each product
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- (m) Breeder's rights
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- (n) Protection of inventions
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- (o) Labelling of milk products
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- (p) Refusal to sell articles in the store/shop
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(q) Prevention of monopolisation of product supplies

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(r) Sale of sunscreen lotion

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(s) Promotion of paracetamol tablets

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(t) Retail sale of drugs

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1.2 What are the main differences that can be identified with respect to the provisions of Cosmetics, Devices and Drugs Act and National Medicines Regulatory Act? **(40 marks)**

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1.3 List four (04) designated persons who can be appointed as authorized officers according to the Food Act. **(20 marks)**

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2.1 What is an approved pesticide? (10 marks)

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2.2 Name the licensing authority for pesticides. (10 marks)

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2.3 What are the main types of substances regulate under the Control of Pesticides Act? (10 marks)

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2.4 List five (05) key details that should be given on a pesticide label in all three languages. (60 marks)

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3.1 List four main institutions and committees established under the Ayurveda Act. (20 marks)

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3.2 What are the main objectives of the Department of Ayurveda? (25 marks)

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3.3 What is the Ayurvedic Code? (15 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)	Every trader who sells any article shall on demand, issue to the purchaser a receipt with date, quantity, price and nature of the transaction	
(b)	Establishment of the National Authority on Tobacco and Alcohol for the purpose of identifying and regulating drug abuse in Sri Lanka	
(c)	National Authority on Tobacco and Alcohol encourages and assist health promotion through the media sponsorships and community based projects	
(d)	Intellectual Property rights share the characteristics of other property rights – they can be owned, alienated and licensed	
(e)	Arsenic is a part 1 poison according to Poisons opium and dangerous drugs ordinance	
(f)	The main purpose of Homoeopathy Act is establishment of a Homoeopathic Council	
(g)	A newly discovered butterfly from <i>Sinharaja</i> forest can be patented	
(h)	There are no Authorized officers defined in the National Authority on Tobacco and Alcohol Act	
(i)	Amoxicillin is a Part 1 poison according to Poisons opium and dangerous drugs ordinance	
(j)	The current Intellectual Property system in Sri Lanka is governed by the Intellectual Property Act No 36 of 2003	
(k)	Any trader can sell poisons which are registered with respective authority	
(l)	The Minister may make regulations in respect of identifying the tobacco products that are harmful or injurious to human health	
(m)	No person shall obtain or have in his possession any dangerous drug unless having a permission or provision of director	
(n)	The Sri Lanka Veterinary Council established under the Veterinary Surgeons and Practitioners Act No:46 of 1956. Regulates the practice of veterinary medicine and surgery in Sri Lanka	
(o)	National Dangerous Drugs Control Board Conduct and undertake research studies into the pre-valances, aetiology and legal, medical, social, cultural and economic implications of the abuse	
(p)	The Minister may make regulations in respect of specifying the types or categories of tobacco products which do not generate smoke	
(q)	No person shall label, package, treat, process, sell or advertise any food in a manner that is misleading	
(r)	Unlike for drugs, food does not need to conform to prescribed standards	

(s)	The Customs Ordinance has nothing to do with provisions in the Food Act	
(t)	A person shall not publish a tobacco advertisement or an alcohol advertisement	
(u)	Nutraceuticals and Functional foods are regulated under Food act	
(v)	Promotion of safe and rational use of products by health care professionals and consumers is one of the objectives of NMRA Act	
(w)	Once the food processing establishment is registered, ownership can be transferred	
(x)	The World Intellectual property organization (WIPO), a specialized agency in the United Nation's System, is mandated to promote the protection of Intellectual Property rights in all the member states	
(y)	Automatic vending machine can be used to dispense beers only	

5.2 You are appointed as a member of a committee to compose a Code of Ethics for pharmacy professionals in the county X.

5.2.1 State basic **aspects** you should consider in preparing of such code of ethics in relation to pharmacy. (10 marks)

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5.2.2 Briefly describe an important **principle**, you are planning to include into the code. (15 marks)

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5.2.3 Discuss briefly the possible difficulties faced by a pharmacist in practicing such a code of ethics. (25 marks)

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6. A medical professional Dr. David and the team, working in a research institute in USA had planned to carry out a clinical trial on the safety and efficacy of a recently discovered antihypertensive drug.

6.1

6.1.1 State three different ways of recruiting human subjects to Dr. David's study. (10 marks)

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6.1.2 Describe briefly five different principles of ethics that should be considered in selecting subjects. (25 marks)

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6.1.3 A subject (P) in the above study refused to participate the study, 6 months after commencing clinical trial and requested the permission from Dr.David to leave the study. Dr. David accepted the request and P left the study. Consequently, Dr.David had to stop his study, due to lack of participants. According to the principles of ethics, state whether Dr. David's act (allowing P to leave the study) is acceptable/ unacceptable? (05 marks)

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6.1.4 State two possible reasons for leaving subjects from a clinical trial. (10 marks)

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