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UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

SECOND BPHARM PART II EXAMINATION – JANUARY 2014

PH 2223: PHARMACY LAW AND ETHICS (SEQ)

03 HOURS

INSTRUCTIONS

- Answer **all** questions.
- No paper should be removed from the examination hall.
- Marks will be penalized for illegible handwriting.
- Do not use any correction fluid.

1. With reference to Cosmetics, Devices and Drugs Act (CDDA) No.27 of 1980 and Regulations No.38 of 1984 and its amendments, answer the following.

   1.1 Define the term "Device." ***(10 marks)***

   1.2 State the information required for registration of a device. ***(30 marks)***

   1.3 Describe briefly the following;

   1.3.1 Medical Device Evaluation Sub Committee ***(20 marks)***

   1.3.2 Advertising a device ***(20 marks)***

   1.3.3 Borderline devices ***(20 marks)***

2. Mr. Amal is planning to initiate manufacturing pharmaceutical products starting from the formulation of Paracetamol liquid. He chooses the brand name as '**Parakid**'.

   2.1 Indicate the legal documents that he required to obtained from Cosmetics, Devices & Drugs Regulatory Authority. ***(15 marks)***

   2.2

   2.2.1 State the drug schedule of *Parakid.* ***(10 marks)***

   2.2.2 Describe briefly the drug schedule specified under 2.2.1. ***(25 marks)***

   2.3 Is this brand name acceptable? Explain your answer briefly with the reasons. ***(20 marks)***

   2.4 Indicate the labeling requirements of the above mentioned drug. ***(30 marks)***

3. Briefly describe the following;

   3.1 Approved analyst ***(15 marks)***

   3.2 Ethical drug promotion ***(20 marks)***

   3.3 Cosmetics, Devices & Drugs Regulatory Authority ***(30 marks)***

   3.4 Community Pharmacist ***(35 marks)***

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4. The following questions are based on Poison, Opium and Dangerous Drugs Ordinance.

4.1 Briefly describe the following;

4.1.1 Poison and poisonous substances ***(20 marks)***

4.1.2 Sale of poison book ***(25 marks)***

4.1.3 Disposal of poisons ***(20 marks)***

4.2

4.2.1 Define the term 'Prepared opium.' ***(10 marks)***

4.2.2 State the restrictions on import and export of raw and prepared opium. ***(25 marks)***

5.

5.1 Name the **three** acts that were repealed by the Consumer Affairs Authority Act No. 09 of 2003. ***(10 marks)***

5.2 With respect to Consumer Affairs Authority Act No. 09 of 2003, define the following terms.

5.2.1 Consumer

5.2.2 Manufacturer

5.2.3 Trader

5.2.4 Goods and services ***(20 marks)***

5.3 State the **four** objectives of the consumer affairs authority. ***(20 marks)***

5.4 State briefly **five** functions of the consumer affairs authority. ***(20 marks)***

5.5 Explain the rights of a consumer. ***(30 marks)***

6.

6.1 Define the following terms;

6.1.1 Compulsory licensing ***(10 marks)***

6.1.2 Parallel importing ***(10 marks)***

6.1.3 Brand and generic drugs ***(10 marks)***

6.2 Explain briefly the patent and its importance. ***(20 marks)***

6.3 Name **three** non-patentable items. ***(10 marks)***

6.4 With respect to the Food Act No. 26 of 1980,

6.4.1 State briefly **five** prohibitions with respect to food. ***(20 marks)***

6.4.2 List out the members of the food advisory committee. ***(20 marks)***