EXTERNAL PHARMACISTS' EXAMINATION – JANUARY 2025
MARKING SCHEME

Question 1

A child weighing 15 kg needs to take a 4 mg/kg/dose of medicine X orally twice daily. The maximum daily dose of medicine X is 10 mg/kg/day. Medicine X is only available as a 50 mg/5 mL oral suspension in a 100 mL bottle.

1.1. Calculate the daily dose required for this patient. Show the steps of your calculation. **(08 marks)**

(02 marks) *(02 marks)*
4 mg/kg/dose × 15 kg = 60 mg/dose **(04 marks)**

(02 marks) *(02 marks)*
60 mg/dose × 2 dose = 120 mg **(04 marks)**

1.2. Calculate the number of days the patient can use one bottle of this oral suspension. **(12 marks)**

(03 marks) *(03 marks)*
50 mg/5 mL × 100 mL = 1000 mg **(06 marks)**

(03 marks) *(03 marks)*
1000 mg / 120 mg/day = 8 days **(06 marks)**

Question 2

Answer the following questions according to the National Medicines Regulatory Authority Act No. 05 of 2015, its regulations and guidelines.

2.1. List the certificates that are needed to be displayed in a community pharmacy. **(06 marks)**

1. Licence to sell therapeutic goods by retail
2. Certificate of registration as a pharmacist issued by the Sri Lanka Medical Council (SLMC) of the Responsible Pharmacist
3. Certificate of registration as a pharmacist issued by the Sri Lanka Medical Council (SLMC) of the on-duty pharmacist

(3 × 02 marks = 06 marks)

2 2 2

For complete name of the certificate. incomplete 1 mark each.

2.2. Can a pharmacy operate without a pharmacist? **(14 marks)**

NO

A pharmacy cannot operate without a pharmacist. **(02 marks)**

According to NMRA Act section 120(03), the practice of pharmacy, which includes the dispensing, sale, and distribution of medicines, must always be supervised by a registered pharmacist.

- A pharmacy must function, (selling, dispensing and distribution of medicines)must be under the direct supervision of a qualified and registered pharmacist at all times during operating hours.
- The Pharmacy License granted by the NMRA is issued upon the presence of a registered pharmacist in charge, ensuring that all medicinal products are dispensed correctly and in accordance with legal and professional standards.
- This requirement is critical to ensuring that medicines are dispensed safely and appropriately, with the necessary expertise to manage drug interactions, proper dosages, and other healthcare-related concerns.

For any one of the above points

(legal background 03 marks + discussion 03 marks = 06 marks)

6 6 12

Question 3

3.1. List **four (04)** limitations of the vaginal route of medication administration. **(08 marks)**

- The absorption rate of drugs through the vaginal mucosa can vary depending on factors such as the drug's molecular size, or solubility, or the formulation used. This can result in inconsistent therapeutic effects. Not all drugs are suitable for vaginal administration due to issues related to absorption, stability, or irritation. Only certain types of medications (such as hormonal treatments, antifungals, and some local anesthetics) are commonly formulated for this route.
- Local Irritation: Some medications, especially those in cream, gel, or suppository form, can cause local irritation, discomfort, itching, or allergic reactions in the vaginal area, leading to discomfort for the user.
- The vaginal administration of medication may be less convenient compared to oral or topical forms, as it may require privacy, the ability to insert the medication properly, and regular application.
- Increased Risk of Infection

  Vaginal medications can alter the local pH or disrupt the natural flora, which may increase the risk of infections like bacterial vaginosis or yeast infections.
- Leaking of the medicine: Some vaginal formulations (such as creams or gels) may cause leakage, staining of clothing, or a sensation of wetness, which can be bothersome.
- User Adherence: Vaginal medications often require regular administration, which might be challenging for users to remember or incorporate into their daily routines.
- Cultural or Psychological Barriers: Some individuals may have cultural, psychological, or personal barriers to using vaginal medications due to discomfort with the route of administration or privacy concerns.

(any 4 × 02 marks = 08 marks)

3.2. Write the advice given to a patient on how to administer a semisolid vaginal preparation. **(12 marks)**

1. Thoroughly wash your hands with soap and water before handling the medication to prevent contamination.
2. **This medication comes with an applicator. Make sure the applicator is clean and free from contamination.**
3. **Attach the applicator to the tube: Fill the applicator with the prescribed amount.**
4. **You can administer the medication while lying on your back with your knees bent (like when lying down or during rest), or you can stand with one leg elevated, placing your foot on a chair or stool. Choose the position that feels most comfortable for you.**
5. **Hold the applicator and gently insert it into the vagina, aiming toward the back and as far as it comfortably goes.**
6. **Once the applicator is in place, press the plunger to release the prescribed amount of medication. Ensure the full dose is administered.**
7. **After the medication has been delivered, gently remove the applicator from the vagina.**
8. **After administering the medication, wash your hands thoroughly to prevent contamination and to maintain hygiene.**
9. **After applying the medication, lie down or stay in a resting position for a few minutes to allow the medication to stay in place and be absorbed. (This can help prevent leakage)**
10. If you use a disposable applicator, discard it according to the instructions. If the applicator is reusable, clean it thoroughly with soap and warm water.

(12 marks <u>or</u> 0 marks)

all Idea or ~~Re~~ Advices in the bolded sentances should be present in the answer for full marks. Incomplete annswers @ marks

Question 4

4.1. Briefly discuss one ethical issue if apprentice pharmacists are providing fraudulent information to the Ceylon Medical College Council regarding their duration of training during apprenticeship? **(10 marks)**

Principles:

- honesty/dishonesty/trust/accountability
- integrity in professional practice
- professionalism

(05 marks for ethical issue identification and description + 05 marks for discussion of the issue)

4.2. What would be the impact on the Sri Lankan healthcare system when apprentice pharmacists submit fraudulent information about their apprenticeship? **(10 marks)**

1. Compromise in Patient Safety

- Inadequate Training and Skills: Fraudulent claims about the duration or quality of training may allow individuals to bypass necessary learning and supervision. As a result, those pharmacists may not possess the required knowledge or skills to safely dispense medications, counsel patients, or manage drug therapy. This could lead to errors in medication administration, incorrect drug dispensing, and ultimately, harm to patients.
- Increased Risk of Medication Errors: Unqualified or undertrained pharmacists might make mistakes in dosage calculations, drug interactions, or labeling, which can directly threaten patient health and safety.

2. Decreased Trust in the Healthcare System

- Erosion of Public Confidence: If it becomes known that apprentice pharmacists are providing false information about their training, public trust in the entire healthcare system could diminish. Patients rely on healthcare professionals to make informed decisions, and the public may begin to question the integrity of other healthcare professionals or institutions, including the regulatory bodies.

- Undermining Professional Integrity: Such fraudulent actions set a poor precedent for future generations of pharmacists and could contribute to an overall decline in professional ethics, impacting the behavior of others in the field.

3. Regulatory and Legal Consequences

- Damage to Regulatory Bodies: The Ceylon Medical College Council and other regulatory authorities would face challenges in maintaining the integrity of their training and certification processes. Fraudulent submissions could undermine the credibility of these bodies, making it harder for them to enforce standards and ensure the competence of healthcare professionals.
- Legal Repercussions: Apprentice pharmacists caught submitting fraudulent information could face legal actions, including revocation of certification or employment. This may also lead to fines or penalties for institutions that failed to monitor and verify training durations properly.

4. Impact on Professional Development and Workforce Quality

- Reduced Standards in the Profession: If fraudulent submissions are not detected or addressed, the overall standard of the pharmacist workforce could deteriorate. This leads to a situation where the public and healthcare providers may unknowingly rely on inadequately trained professionals, which could compromise the overall quality of pharmaceutical services.
- Increased Burden on Other Healthcare Professionals: If undertrained pharmacists are allowed to practice, other healthcare professionals (such as doctors and nurses) may have to compensate for their shortcomings, leading to an increased workload and strain on the healthcare system.

5. Negative Impact on Healthcare Delivery

- Inefficiency in Pharmaceutical Services: Pharmacists play a vital role in the healthcare system by ensuring proper medication distribution, providing patient education, and contributing to therapeutic decision-making. When unqualified individuals are placed in these positions due to fraudulent claims, it could lead to inefficiencies and gaps in service delivery.
- Undermining Collaborative Healthcare: Pharmacists are key members of healthcare teams. A reduction in their professional competency due to fraudulent

apprenticeship claims can disrupt collaboration between healthcare professionals, diminishing the effectiveness of multidisciplinary care.

6. Ethical and Moral Implications

- Violation of Professional Ethics: Fraudulent practices directly violate the ethical guidelines that govern healthcare professionals. Pharmacists are expected to uphold principles such as honesty, integrity, and accountability. Any compromise in these principles could have a ripple effect on the overall ethical standards in the healthcare sector.
- Impact on Future Pharmacists: Allowing fraudulent claims can set a dangerous precedent for upcoming generations of pharmacists, teaching them that dishonesty may be acceptable to further their career. This can have long-term negative consequences on the overall culture of professionalism and ethics within the sector.

In summary, fraudulent submissions by apprentice pharmacists can lead to significant consequences for the Sri Lankan healthcare system, ranging from compromised patient safety to a loss of public trust, and it could contribute to a weakening of the healthcare infrastructure. Proper checks and balances must be in place to ensure that such fraudulent activities are prevented and that the quality of healthcare services is maintained.

(2 marks each for any of the 2 consequences mentioned above – 2 marks × 2 = 4 marks)

(3 marks each for describing the mentioned consequences – 3 marks × 2 = 6 marks)

Question 5

5.1. List **four (04)** reasons for storing medicines in amber colour glass containers?

(08 marks)

1. Protection from UV Light:

- Amber glass provides protection from ultraviolet (UV) light, which can degrade especially light-sensitive drugs.
- UV exposure can cause chemical changes of medicine structure, reducing their potency or making them ineffective.
- Amber glass helps to shield medications from harmful light exposure, thus maintaining their stability and effectiveness.

2. Prevention of Degradation as glass dosent interact with many chemicals

3. Increased Shelf Life or maintain potency during the shelf life

- By reducing the amount of light that reaches the drug and reduction of the drug and container interaction, helps to preserve the potency of the medication over a longer period/ ensures they remain effective throughout their shelf life.

4. Protection Against Chemical Reactions producing harmful by products

- Light exposure can cause photochemical reactions in some medications, or drug/container interaction can lead to the formation of harmful byproducts the likelihood of these reactions, maintain safety of the medicines

5. Aesthetic and Brand Perception

- Make product them more recognizable to consumers. While not as critical as the protective qualities, the color of the container may influence consumer perception and trust in the product.

7. Barrier to Contaminants

- Amber glass containers often come with tightly sealed lids, which help prevent exposure to dust, moisture, and other environmental contaminants. This can further ensure the safety and effectiveness of the medication.

(any 4 × 02 marks = 08 marks)

5.2. Can amber colour glass containers with medicines be stored under direct sunlight? Briefly explain your answer. **(12 marks)**

No, they should not be stored under direct sunlight **(02 marks)**

- **Exposure to visible light** - Amber glass primarily protects against only UV light, but visible light, especially high-intensity light in direct sunlight, can still harm some medications, leading to chemical changes or reduced efficacy.

- **Heat Exposure** - Storing medicines in direct sunlight can also cause temperature fluctuations, and excessive heat can accelerate degradation/ cause other reactions like oxidation reactions in the container and reduce the shelf life of medications.

- **Regulatory requirement:** Because direct sunlight exposure degrades medicines the NMRA do not recommend storage of any medicine in direct sunlight

(Mentioning any 2 reasons in bold: 2 marks x 2= 4 marks
Explanation of any 2 reasons : 3 marks x 2 = 6 marks)