

## **Part 1.**

- **Describe proper labels for Pharmaceutical products as required by the Food and Drug Administration.**

The proper labels required by the Food and Drug Administration are as follows:

1. Product Name
2. Dosage Form and Strength
3. Pharmacologic Category
4. Formulation/Composition
5. Indication(s)
6. Dosage and Mode of Administration
7. Contraindication(s), Precaution(s), Warning(s) (if applicable)
8. Interactions
9. Adverse Drug Reaction(s)
10. Overdose and Treatment
11. Storage Condition(s)
12. Net Content or Pack Size
13. Name and Address of MAH
14. Name and Address of Manufacturer
15. For prescription drug products, Rx Symbol and Caution Statement
16. ADR Reporting Statement
17. Registration Number
18. Batch Number and Lot Number (if any)
19. Expiration Date and Date of Manufacture

Additionally, the FDA also mandated that these required information must be written in English and/or Filipino and readable with normal vision without straining. For products intended to be sold without any product information sheet and box outer carton, the minimum mandatory information enumerated above must be clearly reflected on the primary label. For purposes of ensuring compliance with the FDA Regulations, the FDA requires manufacturers and distributors to submit revised labeling materials upon renewal of their respective Marketing Authorizations (MA) covering the registered drug product.

- **Differentiate between white and red labels**

White and Red Labels are both necessary in pharmacy and drugstore settings because it has a distinct function which serves as a guide for healthcare professionals and customers in different aspects of medication management. White Labels are usually used to label loose capsules and tablets which are intended to be taken orally.

Loose capsules and tablets are those dosage forms which are not individually packed in blister or strip packages. The "white" term means that the drug which is to be labeled is for oral use. Red Labels, on the other hand, are used to label compounded drugs which are externally used. These compounded drugs include ointments, creams, lotion, etc. The labels must have a warning notice "Warning: For External Use Only" to avoid confusion and misuse. The "red" term signifies that the drug which is to be labeled is for external use.

## **Part 2.**

- **Define Patient's Medication Profile**

Patient's Medication Profile is a record of information about a patient's drug therapy like the medicines they take regularly including over-the-counter drugs and complementary drugs. It could be their past treatment that they undergo or treatment that they recently just took.

- **What is the importance of the Patient's Medication Profile?**

Keeping a patient's medication profile is necessary as it helps pharmacists enhance their patient care ability to efficiently perform their professional duties. The patient medication profile can also aid the pharmacist with third-party payments, tax information and finding prescription numbers. More importantly, a patient's medication profile helps patients to better manage their medicines and reduces their chance of experiencing any unexpected side effects from their medicines.

- **List down the pertinent information in the Patient's Medication Profile.**

The pertinent information in the Patient's Medication Profile includes their name, age, sex, weight, height, allergies or drug sensitivities, names of the medications, prescribing physicians, instructions, medicine's route of administration, and chronic disease conditions as well as all prescription and over-the-counter medications being used, lastly, pharmacy information.