



What Steps Do Consumers Need To Take To Ensure Safety of Medication?

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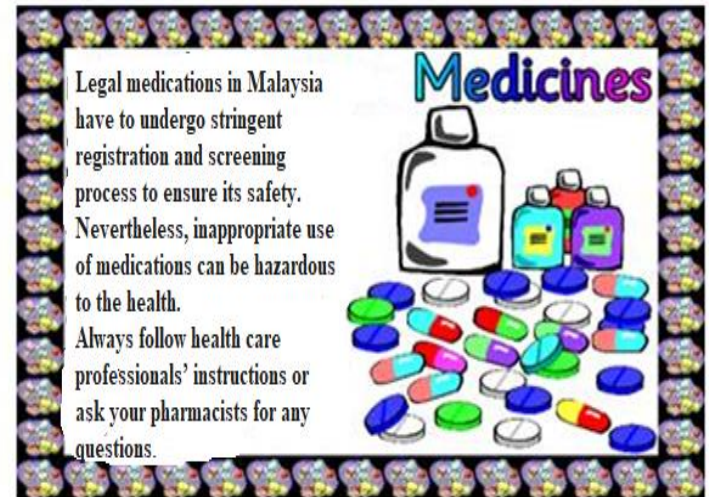
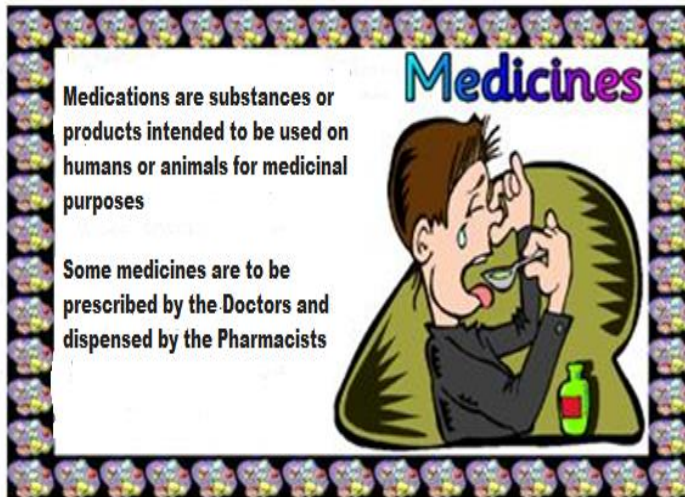
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Introduction

- Drug product safety is an important pharmacopoeia criteria and regulatory requirement to be released into the market.
- The National Pharmaceutical Regulatory Authority (NPRA), Pharmaceutical Services Division defined pharmaceutical testing for registration, licensing and monitoring of drug products for its safety and efficacy¹.
- Drug products must be identified **in good condition as registered and not as degraded, expired or fake**.
- **Degraded, expired or fake drug products** can cause adverse reactions and are considered **unsafe to use**.

Introduction





Drug Products(capsules or tablets)





How to identify whether your drug is a registered product?

- Consumers must ensure that drug products are registered with the Drug Control Authority(DCA).
- DCA is the executive body established under the Control of Drugs and Cosmetics Regulations 1984 and is an integral part of NPRA.
- Products registered with the DCA have **two** main features, the **registration number** and the **genuine hologram meditag**.
- The registration number starts with '**MAL**', followed by **eight numbers**, and ending with the letter **T,A,X** or **N²**.



PRODUCT CODES

Product Codes

A: Scheduled Poisons

X: Non-scheduled Poisons (OTC products)

T: Traditional Medicines

K/KE: Cosmetics

C: Contract Manufactured

E: Export Only

R: Repacked

S: Second source

CONTOH NOMBOR PENDAFTARAN:

MAL20021234 (A, X, T, K)

A	Ubat mengandungi Racun terkawal (cth: Antibiotik)
X	Ubat TIDAK mengandungi Racun Terkawal (cth: vitamin)
T	Ubat tradisional (cth: jamu)
K	Kosmetik atau dinotifikasikan cthnya: NOT12345678K





How to identify FAKE drug products?

- Visual inspection of the packaging of the drug product
- Imitation of appearance of drug products (e.g. tablets, capsules)
- Unexpected side effects (due to incorrect substances, improper dosage and hazardous substances, etc.)
- **Fake registration number and Fake hologram sticker or No registration number and No hologram sticker.**

Hologram Meditag or Medication Hologram

Introduced in 2005



Hologram Meditag or Medication Hologram

Introduced in 2005



UBAT ANDA TULEN?

GUNAKAN DEKODER MEDI TAG™
PASTIKAN KETULENAN LABEL DAN PRODUK.

LABEL HOLOGRAM MEDITAG™
A386436217

A. TOLAK KE ATAS:
TIDAK NAMPAK 'KKM'
A386436217

B. TOLAK KE BAWAH:
NAMPAK 'KKM'
A386436217

Dekod Meditag™ di sini
Kenali Ubat Anda

Jika kedua-dua ciri A dan B dapat dikesan, maka label hologram produk adalah TULEN. Sekiranya dekoder tidak memberi sebarang kesan pada label hologram, ketulenan produk diragui.

The image is a composite graphic designed to look like a poster or brochure. On the left, there's a vertical strip showing various pills and a blister pack. The main area features a large title in green, followed by a subtitle in black. Below this, a large, bold title 'UBAT ANDA TULEN?' is set against a yellow background. Underneath, instructions in bold black and red text tell users to use a 'MEDI TAG' decoder to verify the authenticity of their medication labels and products. The guide includes three visual examples of how to use the decoder: a top view showing the decoder being held over a label, and two side views (A and B) showing the decoder being pushed against the label from different angles. Each example is accompanied by a small image of the decoder and a unique alphanumeric code (A386436217). To the right of these instructions is a photograph of a smiling female pharmacist in a white lab coat and purple hijab, working at a counter. In the bottom right corner, there's a paragraph in Malay explaining that if both features A and B are visible, the product is authentic ('TULEN'), while the absence of a reaction from the decoder suggests the product's authenticity is doubtful. The entire graphic is framed by a decorative border.



Which one is counterfeit ???





Genuine PRISTIN™
Meditag holograms
that start without any
“A” in front





How to Recognise degraded drug products?

- Degradation products are unwanted chemicals that can develop during:
 - Manufacturing process
 - Transportation,
 - Improper storage of drug products
- It can be recognised through physiochemicals and other laboratory examinations of drug products



How to identify expired drug products?

- Expired drug products can be less effective or risky due to a change in chemical composition or a decrease in strength.
- Certain expired medications are at risk of bacterial growth.
- Visual examination of drug products indicates spoiled medicine change in terms of physical appearance.
- Once the expiration date has passed, there is no guarantee that the medicine will be safe and effective.
- If your medicine has expired, do not use it.



Physical appearance and color coating of drugs products

- Mostly, drugs are white crystalline powders or white-yellowish crystalline powders³.
- The colour of drug products (tablets or granules in capsules) is masked with coating materials with natural food colours for the following TWO reasons:
- To be attractive and palatable to mask its bitter taste.
- To mask or protect from bad effects of drug product in certain areas of the stomach.

HOW DO YOU STORE YOUR MEDICATIONS

Consumers have to ensure the storage conditions as per label specified on the packaging of drug product and appropriately store above specified upon regular use.



Temperature

➤ 3 types of storage temperatures

1. room temperature
2. cold temperature
3. Freeze storage

1. Room temperature:

➤ Upto 30/25° c

2. Cold temperature/Refrigerator storage:

➤ Upto 2-8° c

3. Freeze storage:

➤ Storage between -20 to -10° c



CONCLUSION

Consumers can detect and report the unregistered, degraded, fake or expired drug products to NPRA Malaysia.

More awareness is needed to create an educated public while using drug products in terms of identifying quality drug products

In view of this, it is important to emphasise the role of consumers to accomplish the long-term safety of drug products

Consumers complaints can be sent to NPRA



Official Portal

**NATIONAL PHARMACEUTICAL
REGULATORY AGENCY**
MINISTRY OF HEALTH MALAYSIA

1. <https://www.npra.gov.my/index.php/en/consumers.html>
2. <https://www.pharmacy.gov.my/v2/en/faq/how-identify-registered-drugs-or-pharmaceutical-products.html>
(Pharmaceutical Services Division, Ministry of Health, Malaysia)



3. UNITED STATES PHARMACOPOEIA- NF (2017) (GENERAL CHAPTER)

Reference



Thank You

