

22 September 2004

<p>DIRECTIVE ON THE USE OF THE HOLOGRAM SECURITY DEVICE (MEDITAG™) FREQUENTLY ASKED QUESTIONS ON IMPLEMENTATION REQUIREMENTS</p>

1. **Background:**

- 1.1. Due to the concerns of the Government in respect of counterfeit, imitation and unregistered products being manufactured or imported and sold, and in an effort to streamline the manufacture, import and sale of genuine products, the Ministry of Health has issued a directive on the use of a hologram security device to authenticate and verify that products sold have been duly registered with the Drug Control Authority (DCA). The directive can be referred under the Circular Section of the website (www.bpfk.gov.my).
- 1.2. The security label is only one of the many means that will be employed by the Ministry of Health to complement its enforcement activities to ensure public safety.
- 1.3. The requirement for the affixation of this security device (called the Meditag™) to product labels, is only applicable to pharmaceuticals, including OTC external personal care products, traditional products and health supplements. Cosmetics are currently excluded from the exercise. Implementation on the use of the hologram label will be carried out in 2 phases.
 - 1.3.1 Phase 1 beginning **1st January 2005** for products which are **non-parenterals**, i.e. not in the form of injections ; &
 - 1.3.2 Phase 2 from **1st July 2005** for **parenterals/injectables**
- 1.4. Products like vaccines and biologicals which are temperature sensitive and require cold chain maintenance are exempted from the requirement of security labelling.
- 1.5. The **local manufacturer** (meaning also the repacker for products which are imported in bulk and packed locally) or the **importer** shall be **responsible** for affixing the security device onto the individual unit packs.
- 1.6. With the affixation of the hologram security device onto the product label, **the requirement to label OTC products with “diluluskan oleh KKM” does not remain and may be considered optional.**

2. Frequently Asked Questions (FAQ):

- 2.1 Queries have been received by both the Ministry of Health and the hologram supplier (Mediharta Sdn Bhd) regarding details on how, where and when to apply the labels and the following **FAQ and Answer Panels** will try to address the various issues that have been raised regarding implementation requirements.
- 2.2 A public awareness programme will be coordinated in stages to disseminate information on the implementation and purpose of the security device.

No.	Question	Answer
1.	What is the size and shape of the hologram label?	The size of Meditag™ is 8mm x 16mm . It is rectangular in shape.
2.	What is the price of Meditag™ ?	Each label costs RM0.056 . The price is not inclusive of delivery charges, nor insurance charges, tax and sales duties. The minimum order is 1 roll or 2 sheets. Each roll consists of 15,000 labels and is usually used with labelling machines. The sheets each contains 100 labels and is suitable for manual labelling.
3.	What is the size of the roll form?	Each roll is 220mm in diameter. Roll width is 10mm. Core diameter is 76mm. Space in between each Meditag™ is 4mm. The backing of the Meditag™ is glassine.
4.	Where is the hologram label to be applied?	The hologram shall be affixed onto the outer packaging of the product on the front panel of the product label . Where there is no outer packaging, the label shall be applied to the immediate packaging, i.e. the bottle label. The hologram label cannot be applied onto the outer shrink wrap . The customer purchasing a product should be able to locate the presence of the hologram without having to open the packaging. None of the product particulars on the label shall be covered over by the security device.
5.	Where should the security label be affixed for promotional packs containing 2 or more items?	Each individual item that is a product registered with the DCA will have to bear the security label.

6.	If manufacturers and importers packed and sold their products in a box of one dozen to their dealers must they apply the hologram label onto the box of one dozen or on each individual pack/bottle?	<p>The hologram label is to be applied to each individual unit of sale to the level of the end customer.</p> <p>It is not however required that each blister strip be affixed with a hologram label. The unit of sale for blister/strip packed products would be the box or sachet of 4's, 8's, 10's or 20's that they are packed in.</p> <p>A similar situation applies for injectables. The box unit pack for sale is to be labelled and not the individual ampoules in each box.</p>
7.	Are registered importers allowed to send the hologram labels to their manufacturers who are located outside Malaysia?	Yes, the labels can be sent to the overseas manufacturer and the product is then imported fully labelled. The importer to whom the labels have been sold will remain the responsible party.
8.	Who is supposed to buy and apply the security label if both principals and distributors are companies in Malaysia as well as registered with BPFK?	<p>The company that is on record with the DCA as the importer for a particular product will be the party responsible for the security labels on the product in question.</p> <p>Even if the registered importer outsources the actual process of stickering the labels onto the physical stock to another agent, the importer will still be accountable.</p> <p>SOP's for the labelling procedure, including documentation and reconciliation records should be maintained.</p>
9.	How detailed should the security label reconciliation record be?	Reconciliation records should be as required under GMP requirements as for any other type of product label.
10.	When will DCA begin inspection or enforcement on the use of the labels?	<p>Enforcement will be at the point of sale, and can begin any time after implementation.</p> <p>The implementation will be in 2 phases, with the 1st phase for all non-injectable products starting 1st January 2005. All non-injectables which are imported or manufactured on or after 1st January 2005 should carry the security label.</p> <p>The 2nd phase of implementation for</p>

		parenteral preparations will begin 1st July 2005.
11.	What happens to those products already available for sale or on the shelves? Will a recall need to be done?	<p>A recall need not be instituted for products already on the market. Companies are advised to project and plan realistically to ensure that there is no overstocking of products without the security label.</p> <p>Products placed on shelves after the implementation dates should preferably bear the hologram labels. It is possible that consumers may exercise their choice immediately after implementation and purchase only those products that have the hologram label.</p>
12.	Would food supplements and plaster products require security label?	All products registered with the DCA , with the exception of cosmetic products, will need to be affixed with the security label. Please refer back to Q8 on the implementation phases.
13.	Are registered importers and manufacturers of cosmetic products allowed to purchase and apply Meditag™ onto their products?	Currently the requirement for security label does not apply to cosmetics. It is NOT recommended that cosmetic products carry the Meditag™ label as it may lead to confusion.
14.	If manufacturers and importers are unable to get sufficient stocks, can they be allowed to sell their products without the label?	<p>No, all products manufactured and imported after the stated implementation date(s) will need to bear the label.</p> <p>Forecast of orders for the security labels are needed by the supplier to understand requirement needs. As demand is dynamic, the information supplied is vital to ensure adequate stocks are kept to fulfil customer orders.</p>
15.	Will registered manufacturers and importers be liable if their assigned Meditag™ (serial number) is found in counterfeit products?	<p>There are security features, both overt (visible) and covert (hidden) that can be used for verification of label authenticity.</p> <p>The Meditag™ labels supplied to registered importers and manufactureres will carry unique serialised numbers. As such each label can be traced to its “owner”. If genuine Meditag™ labels are found on counterfeit products, the owner would definitely have some explanations to do.</p>

16.	Who can buy the Meditag™ labels?	Only licensed manufacturers and importers of pharmaceutical, traditional medicine and health supplement products can purchase the labels.
17.	How do I ensure an authentic purchase of Meditag™ labels?	<p>The only agent authorized by the Government to supply the hologram security device is Mediharta Sdn Bhd.</p> <p>Should more information be required on the technical and supply aspects , please contact Mediharta. Tel: +6(03) 2093 3075 Fax: +6(03) 2093 9763 Website: www.mediharta.com.my Email: enquiries@mediharta.com.my</p>