For discussion
On 18 May 2000

LegCo Panel on Trade and Industry
Special meeting on 18 May 2000

Labelling Requirements for Pharmaceutical and Tobacco Products

INTRODUCTION

This paper sets out the existing labelling requirements for pharmaceutical and tobacco products sold in Hong Kong.

PHARMACEUTICAL PRODUCTS

Background

2. Under the Pharmacy and Poisons Ordinance (Cap. 138), no person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product unless it is registered with the Pharmacy and Poisons Board. This ensures that all pharmaceutical products, whether imported or locally manufactured, comply with the safety, efficacy and quality requirements. If a pharmaceutical product is imported into Hong Kong by more than one importer, each of them is required to apply for registration separately and will be assigned different registration numbers.

Existing labelling requirements

3. Statutory labelling requirements for pharmaceutical products are stipulated in the Pharmacy and Poisons Ordinance and its regulations. For safety and efficacy purposes, the Product Registration Committee (the Committee) of the Pharmacy and Poisons Board may also require additional labelling in respect of a particular product.

4. In general, a product should bear the following on its label or on the container :-

(a) Name of the product

(b) Name and quantity of each active ingredient

(c) Name and address of the manufacturer

(d) Hong Kong registration number of the product

(e) Batch Number

(f) Expiry date

(g) Specific storage conditions, if any.

5. For certain types or classes of pharmaceutical products, there are additional labelling requirements relating to safety precautions, warnings on side effects or overdose, proper way of administration, specific information on safety, efficacy and proper use of the medicines. The Committee may also require a registered pharmaceutical product to have its labelling modified if necessary.

6. Failure to comply with the labelling requirements may result in the refusal of registration or deregistration of the product concerned. It is also an offence and the offender is liable to a maximum fine of $100,000 and imprisonment of 2 years.

Adequacy of the existing labelling requirements

7. As far as safety and efficacy of pharmaceutical products are concerned, the Administration considers that the present system of product registration and labelling requirements have enabled that adequate instructions to be displayed on the labels of pharmaceutical products so as to ensure that medicines are taken safely and properly by the consumers.

8. The consumers can identify easily the manufacturer of the pharmaceutical products. The registration number allows the consumers to verify whether a product is registered or not. Although labelling of names and addresses of the importers is not required at present, the systems of import/export control and registration of pharmaceutical products enable the Department of Health to trace the importers of every consignment of pharmaceutical products as and when required.

TOBACCO PRODUCTS

Existing Labelling Requirements

9. According to section 9 of Smoking (Public Health) Ordinance (Cap.371) (the Ordinance), no person shall sell, offer for sale or possess for the purposes of sale any cigar, pipe tobacco or cigarette tobacco unless the

container thereof bears a health warning in the prescribed form and manner, which is stipulated in detail by subsidiary legislation. The maximum penalty for contravening this requirement is a fine at level 4 ($25,000).

The adequacy of the existing labelling requirements

10. It is our established policy to review and, where appropriate, amend the contents of the health warning on tobacco products from time to time, to re-inforce the anti-smoking messages. For the pursuits of this objective, we consider the current requirements adequate.

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Health and Welfare Bureau
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