

## NONPRESCRIPTION DRUG PROMOTION IN MASS-MEDIA PRINT PUBLICATION IN INDONESIA

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*The objectives of the study were to identify whether nonprescription drug promotion in mass-media print publications in Indonesia complied with the regulations of "Keputusan Menteri Kesehatan No. 386/Men.Kes/SK/TV/1994" on drug promotion and WHO Ethical Criteria for Medicinal Drug Promotion, as well as to identify the type of information given to consumers. The study was conducted by random sampling of 110 advertisements from mass-media print publications from the year 2000 until 2004. The results of the study showed that only 1.8% of nonprescription drug advertisements complied with the regulations. The type of information advertised to consumers was the active ingredient(s) (80.9%), major indications for use (98.2%), major precautions (9.1%), contra-indications (5.4%), side effects (20.9%), the name of the product or the brand name (100%), name of manufacturer or distributor (93.6%), address of manufacturer/distributor (45.5%), dosage (80.9%), and registration number (82.7%). Our findings showed that 27.3% advertisements did not list the active ingredient(s) completely or used no International Nonproprietary Name (INN), and 44.5% advertisements contained claims of product effectiveness that were unsupported by clinical or other scientific evidence.*

**Keywords:** *Nonprescription medicine, Drug promotion, Advertisements*

### INTRODUCTION

Nonprescription or over-the-counter (OTC) drugs products are available to consumers without a prescription. These drugs are effective for their intended use and provide a margin of safety when used as directed. Casual and inappropriate use of nonprescription drugs can lead to serious adverse consequences, both directly (e.g. adverse drug reaction, drug-drug interaction) and indirectly (e.g. delays in seeking appropriate medical attention). Medication errors related to the use of nonprescription drugs can be particularly pronounced when consumers lack information or have limited reading skills (Somnath 2002).

The safety and efficacy of self-medication depends on the knowledge and skills in selecting medicines. Unfortunately, consumers are more exposed to information from commercial sources produced by the pharmaceutical industries, and they are not properly equipped with the required skills to select medicines appropriately. Suryawati and Santosa (1994) found that users' knowledge about OTC drug they most commonly used in their household was insufficient for an appropriate self-medication

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action, i.e.  $5.2 \pm 1.2$ , of the maximum score 10. This situation could lead to inappropriate and excessive usage of OTC-medicines.

Direct-to-consumer advertisings are commonly misleading, inaccurate or loaded with unbalanced information. In New Zealand, a three-months survey of on advertising found that direct-to-consumer advertising did not provide consumers with objective information on risk, benefits and options of treatment, thus posing a serious risk to the sustainability of health system. In the USA, between 1997 and 1999, 52% of direct-to-consumer advertisements were found to be in violation of the Food, Drug and Cosmetics Act (Woloshin *et al.* 2001). A US survey showed that printed direct-to-consumer advertisements commonly failed to provide quantitative description of drug's benefits, but mainly included emotional appeals and tended to promote the medication of normal health and minor illnesses (Vitry 2004).

One of the ways to promote rationality of drug use is through commercial advertisement control. The target is to provide information to consumers which is objective, complete and not misleading. In 1988, the World Health Organization (WHO) released the *Ethical Criteria for Medicinal Drug Promotion* (WHO 1988). To control commercial advertisements, the Indonesian government has introduced a specific decree known as the *Keputusan Menteri Kesehatan No. 386/Men.Kes/SK/IV/1994*, which organizes and regulates drug promotion in the country (Indonesian Ministry of Health 1994). The *Keputusan Menteri Kesehatan No. 386/Men.Kes/SK/IV/1994* monitors the quality of information in advertisements. The aim is not only to monitor compliance of pharmaceutical industry to the regulation, but also to ensure that consumers get objective and complete information that does not mislead, as well as to promote the safe and effective use of drugs.

The objectives of the study are to identify whether nonprescription drug promotion (including natural health product advertisements) in mass-media print publications in Indonesia complies with the regulation *Keputusan Menteri Kesehatan No. 386/Men.Kes/SK/IV/1994* on drug promotion and WHO's *Ethical Criteria for Medicinal Drug Promotion*. In addition, this research aims to identify the types of information given to consumers.

## METHODS

This is an exploratory, descriptive study into OTC's promotion and advertisement in mass-media print publication. Data was obtained retrospectively, and taken from the advertisement of nonprescription drugs

between the year 2000 and 2004. The types of nonprescription drug advertisement in this study were for the OTC-medicines and natural health products. 110 advertisement samples were collected from mass-media print publications (64 magazines, 37 newspapers, and 9 consumer brochures). Advertisement samples were taken by using randomly selected method.

## RESULTS AND DISCUSSION

The result of the study showed that only 1.8% of advertisements for nonprescription drug complied with the regulation *Keputusan Menteri Kesehatan No. 386/Men.Kes/SK/IV/1994* on drug promotion and WHO's *Ethical Criteria for Medicinal Drug Promotion*. Lack of compliance by the pharmaceutical industries is probably due to poor enforcement of the regulations by the government (i.e. National Agency on Drug and Food Control). Another reason of poor compliance may be due to lack of publicity of the regulations on advertisement of nonprescription drug, either to the pharmaceutical industries or advertising agents. As a result, the quality of drug information in drug advertisements is still far from expected. In addition, Indonesian consumers have been found to have poor knowledge about drug use. Therefore, this situation is considered inappropriate to support safe and effective self-medication (Suryawati and Santosa 1994).

From this study, we found that the types of information given to consumers were active ingredient(s), major indication(s) for usage, major precaution, contra-indications, side effects, the name of the product or the brand name, name of manufacturer or distributor, address of manufacturer or distributor, dosage, and registration number (Table 1).

As depicted in Table 1, a small number of advertisements of nonprescription drug provided information on contra-indication, side effect and precaution in usage of drug. The type of information on side effect most commonly mentioned in these advertisements was "This drug may cause drowsiness". Information related to organ damage (e.g. hepatic damage, irritant to the stomach, renal impairment) was never included in the advertisements. Information related to contra-indications which was most commonly mentioned in the advertisements was "Use with caution in children, pregnant women or in breastfeeding mothers". Information on contra-indications relating to organ damage (e.g. renal failure, or hepatic failure) was never included in the advertisements. Statements regarding side effects, contra-indications, precaution, and dosage were usually written in very small size, making it difficult to read by consumers. This lack of

information on side effects and contra-indications in these advertisements can lead to irrational drug use by consumers.

**Table 1:** Information provided to consumer.

| Type of information                    | N   | Percentage(%) |
|--|-----|---------------|
| Name of product or brand name          | 110 | 100.0         |
| Major indication(s) for use            | 108 | 98.2          |
| Name of manufacturer or distributor    | 103 | 93.6          |
| Registration number                    | 91  | 82.7          |
| Active ingredient(s)                   | 89  | 80.9          |
| Dosage                                 | 89  | 80.9          |
| Address of manufacturer or distributor | 50  | 45.5          |
| Side effects                           | 23  | 20.9          |
| Major precautions                      | 10  | 9.1           |
| Contra-indications                     | 6   | 5.4           |

In this study, we found that there were many irregularities and non-compliance issues in these nonprescription drug advertisements. 27.3% of advertisements did not disclose the active ingredient(s) completely and did not use the INN to identify the name of the active ingredient. Examples of this kind of advertisement would be like (i) Product X consists of multivitamin and minerals, (ii) Product X contains high dose of vitamin C, and (iii) Product X contains vitamin B complex (vitamin B complex is a combination of vitamins B1, B6 and B12).

An advertisement must clearly communicate the intended use of the product. When describing product efficacy, they must be consistent with the terms of market authorization (TMA). In our study, 44.5% of advertisements contained claims of product effectiveness that are unsupported by clinical or other scientific evidences. Examples of this type of unsubstantiated claims would include (i) Product X increases stamina against stress, (ii) Product X relieves fatigue, (iii) Product X prevents severe influenza, and (iv) Product X increases stamina. The sentences are usually found in vitamin product advertisements. These advertisements did not convey specific clinical outcomes, but mainly included emotional appeals and tended to promote the medication of normal health.

An advertisement must not be misleading as to the duration of use of the advertised product. We found that 10% of advertisements targeting the general public seemed to support the continuous use of drug, which can lead to overdose problems. Examples of such statements include (i) Use product X early to improve health, (ii) Product X should be used earlier to achieve a certain outcome, and (iii) Product X can be consumed daily without any side

effect. In one advertisement on diarrhoea, there was a statement that said "Remember, in case you have diarrhoea take product X". Obviously, such statement would not help people to make a rational decision on usage of drug.

Some of these drug advertisements (4.5%) were found to be directed to children. Drug advertising must be overtly directed to adults, so it is misleading to suggest that a child is capable of making a rational decision regarding the use of the advertised product (Bellam 2005). We found that 6.4% of advertisements promote the use of natural health products for certain serious conditions that should be treated only by qualified health practitioner. These included treatment for cancer, hypertension, hyperuricemia and hyperlipidemia.

Although this study shows a number of irregularities and non-compliance to the drug advertisement regulations, there were 1.8% advertisements that seemed to support rational drug use. This type of advertisement is usually found in medical magazines. To promote the rationality on the usage of drugs in self-medication, consumers must get objective, unbiased and complete information. The National Agency for Drug and Food Control must regulate commercial advertisements by monitoring the quality of information in the advertisement routinely.

## CONCLUSION

The study shows that there are still many irregularities and non-compliance within advertisement of nonprescription drug. The direct-to-consumer advertising is likely to be uninformative and promotional rather than educational. The government has the responsibility to ensure compliance with the regulations controlling advertisements in order to improve drug usage among the population.

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