27 OCT 2014

PROPOSED HEALTH PRODUCTS (ADVERTISEMENT OF THERAPEUTIC PRODUCTS) REGULATIONS 2015

CONSULTATION PERIOD: 27 October 2014 – 23 November 2014

INTRODUCTION

1. In proposing the framework for advertisement controls under the Health Products Act (HPA), HSA has studied the best international practices, and conducted various focus group discussions with the pharmaceutical industry, local healthcare professionals, professional councils and associations in the month of March – April 2014.

2. The objectives of advertisement control for health products remain the same, that is, to ensure that the health products that are advertised or promoted for sale do not adversely affect public health, mislead consumers or induce unnecessary consumption. However, changes are introduced to ensure that our advertisement controls remain relevant in today's society and operating environment.

SUMMARY OF CHANGES

3. In the transfer of controls for pharmaceutical products to the HPA, the main changes introduced for advertisement control are highlighted below, with the details in the draft regulations attached:

a) Removal of Permit System for Advertisement of Therapeutic products (TP) and prescribe broad principles for compliance by the industry

Under the current regime in the Medicines Act, HSA regulates advertisements and sales promotion of pharmaceutical products, through a pre-publish permit system and post-market surveillance. In

this age of internet and social media, information is easily available to the public and it is therefore no longer effective to rely on a permit system to curtail information flow. In line with international best practices, the regulations moving forward will allow industry to self-regulate based on a set of rules and guiding principles. This will empower the industry to produce health product-related information that enables public to make informed choices, while preserving adequate regulatory oversight by HSA. This will also reduce the regulatory burden and costs on the industry.

HSA will then continue its post-market efforts to conduct surveillance and monitor the TP advertisements published to ensure that the companies comply with the prescribed rules and principles.

b) Control of Promotional Sales Activities Directed to the Public

With the removal of permit system for advertisements of TP, controls for the conduct of sales promotions, such as sales discounts and provision of samples, are stipulated in the regulations for better clarity and transparency. The control mechanisms aim to prevent any inducement of unnecessary consumption by the public.

c) Prohibition of objectionable claims and certain types of advertisements

One key principle applied in the control of TP advertisements focuses on the strict prohibition of objectionable claims and on certain types of advertisements.

The rationale for such prohibition is for consumer protection, aim at minimising likelihood of inappropriate self-medication or delays in seeking professional treatment for serious conditions.

Any reference to the 19 diseases or conditions listed in the Second Schedule to the Regulations is prohibited. This prohibition extends to the

reference of any sign & symptom clinically attributable with any of the specified disease/condition.

Any direct to consumer advertising of Prescription only medicines (POM) is also prohibited. This includes any display of such advertisements in the waiting areas of clinics and hospitals.

d) Pharmacy Only Medicines to carry advisories/ warnings as required by HSA

All direct to consumer advertisements of Pharmacy-only (P-only) medicines are required to feature advisories and warnings as directed by HSA.

e) Regulatory requirements for internet and corporate websites

The advertisement control of advertisements under HPA covers those on internet and social media platforms.

Corporate websites of the registrant or licensee of the TPs will be allowed to carry product-related information including those on POM. However, corporate websites of product registrants and licensees will not be allowed to hold discussion forums which could inadvertently provide anecdotal information about the TPs. However, if online platforms (like microsites), featuring therapeutic products, are set up by companies to specially target consumers, they would be subject to advertisement controls that are set out in the prescribed requirements.

Pure discussion forums set up by consumers will not be subject to the advertisement requirements stipulated.